

By the Committee on Health Regulation; and Senator Peaden

588-06443-08

20082756c1

1 A bill to be entitled

2 An act relating to drugs, devices, and cosmetics; amending
3 and reorganizing provisions in part I of ch. 499, F.S.;
4 amending s. 499.002, F.S.; expanding the provisions of the
5 section to include administration and enforcement of,
6 exemptions from, and purpose of the part; amending and
7 redesignating ss. 499.004, 499.0053, 499.07, 499.071, and
8 499.081, F.S., as provisions in that section relating to
9 such functions to conform; amending s. 499.003, F.S.;
10 revising and providing definitions; amending and
11 redesignating provisions in ss. 499.012, 499.029, and
12 499.0661, F.S., relating to definitions, as provisions of
13 that section; amending s. 499.005, F.S.; conforming
14 provisions to changes made by the act, including the
15 substitution of the term "prescription drug" for the term
16 "legend drug"; amending s. 499.0051, F.S.; substituting
17 the term "prescription drug" for the term "legend drug"
18 with regard to criminal acts; consolidating criminal act
19 provisions of part I of ch. 499, F.S.; amending and
20 redesignating ss. 499.0052, 499.00535, 499.00545, 499.069,
21 and 499.0691, F.S., as criminal offense provisions in that
22 section; providing penalties; conforming provisions to
23 changes made by the act; amending s. 499.0054, F.S.,
24 relating to advertising and labeling of drugs, devices,
25 and cosmetics to include certain exemptions; amending and
26 redesignating ss. 499.0055 and 499.0057, F.S., as
27 provisions relating to those functions in that section;
28 amending s. 499.006, F.S.; conforming provisions to
29 changes made by the act; amending s. 499.007, F.S.;

588-06443-08

20082756c1

30 conforming provisions to changes made by the act;
31 providing that a drug or device is misbranded if it is an
32 active pharmaceutical ingredient in bulk form and does not
33 bear a label containing certain information; amending ss.
34 499.008 and 499.009, F.S.; conforming provisions to
35 changes made by the act; amending s. 499.01, F.S.;
36 providing that the section relates only to permits;
37 providing requirements for obtaining a permit to operate
38 in certain capacities; deleting certain permit
39 requirements; amending and redesignating provisions of ss.
40 499.012, 499.013, and 499.014, F.S., relating to such
41 functions as provisions of that section; conforming
42 provisions and cross-references to changes made by the
43 act; amending s. 499.012, F.S.; providing that the section
44 relates to permit application requirements; amending the
45 provisions to conform; amending and redesignating
46 provisions of s. 499.01, F.S., relating to such functions
47 as provisions of that section; conforming provisions and
48 cross-references to changes made by the act; amending s.
49 499.01201, F.S.; conforming provisions to changes made by
50 the act; amending s. 499.0121, F.S., relating to storage
51 and handling of prescription drugs and recordkeeping;
52 directing the department to adopt rules requiring a
53 wholesale distributor to maintain pedigree papers separate
54 and distinct from other required records; deleting a
55 requirement that a person who is engaged in the wholesale
56 distribution of a prescription drug and who is not the
57 manufacturer of that drug provide a pedigree paper to the
58 person who receives the drug; deleting the department's

588-06443-08

20082756c1

59 requirement to adopt rules with regard to recordkeeping by
60 affiliated groups; conforming provisions and cross-
61 references to changes made by the act; amending and
62 redesignating a provision of s. 499.013, F.S., relating to
63 such functions as a provision of that section; amending s.
64 499.01211, F.S.; conforming provisions and cross-
65 references to changes made by the act; creating s.
66 499.01212, F.S.; requiring a person who is engaged in the
67 wholesale distribution of a prescription drug to provide a
68 pedigree paper to the person who receives the drug;
69 requiring certain information in a pedigree paper;
70 requiring a wholesale distributor to maintain and make
71 available to the department certain information; providing
72 exceptions to the requirement of a pedigree paper;
73 repealing s. 499.0122, F.S., relating to medical oxygen
74 and veterinary legend drug retail establishments;
75 repealing s. 499.013, F.S., relating to manufacturers and
76 repackagers of drugs, devices, and cosmetics; amending ss.
77 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;
78 conforming provisions and cross-references to changes made
79 by the act; amending ss. 499.032 and 499.033, F.S.;
80 conforming terminology to changes made by the act;
81 amending s. 499.039, F.S.; conforming a provision and
82 cross-reference; amending ss. 499.04 and 499.041, F.S.;
83 conforming provisions to changes made by the act; amending
84 s. 499.05, F.S.; conforming provisions to changes made by
85 the act; requiring the department to adopt rules with
86 regard to procedures and forms relating to pedigree paper
87 requirements, alternatives to compliance with the

588-06443-08

20082756c1

88 requirement of certain pedigree papers, and the return of
89 prescription drugs purchased before a specified date;
90 amending and redesignating provisions of ss. 499.013 and
91 499.0122, F.S., as provisions relating to rulemaking
92 functions of that section; amending ss. 499.051, 499.052,
93 499.055, and 499.06, F.S.; conforming provisions to
94 changes made by the act; amending s. 499.062, F.S.;

95 providing that the section relates to seizure and
96 condemnation of drugs, devices, or cosmetics; conforming a
97 provision to changes made by the act; amending and
98 redesignating ss. 499.063 and 499.064, F.S., as provisions
99 relating to such functions in that section; amending ss.
100 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming
101 provisions and cross-references to changes made by the
102 act; amending ss. 409.9201, 460.403, 465.0265, 794.075,
103 895.02, and 921.0022, F.S.; conforming cross-references to
104 changes made by the act; providing an effective date.

105
106 Be It Enacted by the Legislature of the State of Florida:

107
108 Section 1. Section 499.002, Florida Statutes, is amended;
109 section 499.004, Florida Statutes, is redesignated as subsection
110 (2) of that section and amended; section 499.0053, Florida
111 Statutes, is redesignated as subsection (3) of that section and
112 amended; section 499.07, Florida Statutes, is redesignated as
113 subsection (4) of that section and amended; section 499.071,
114 Florida Statutes, is redesignated as subsection (5) of that
115 section and amended; and section 499.081, Florida Statutes, is
116 redesignated as subsection (6) of that section and amended, to

588-06443-08

20082756c1

117 read:

118 499.002 Purpose, administration, and enforcement of and
119 exemption from this part ss. ~~499.001-499.081~~.--

120 (1) This part is Sections ~~499.001-499.081~~ are intended to:

121 (a)~~(1)~~ Safeguard the public health and promote the public
122 welfare by protecting the public from injury by product use and
123 by merchandising deceit involving drugs, devices, and cosmetics.

124 (b)~~(2)~~ Provide uniform legislation to be administered so
125 far as practicable in conformity with the provisions of, and
126 regulations issued under the authority of, the Federal Food,
127 Drug, and Cosmetic Act and that portion of the Federal Trade
128 Commission Act which expressly prohibits the false advertisement
129 of drugs, devices, and cosmetics.

130 (c)~~(3)~~ Promote thereby uniformity of such state and federal
131 laws, and their administration and enforcement, throughout the
132 United States.

133 (2) ~~499.004 Administration and enforcement by~~
134 ~~department.~~The department of Health shall administer and
135 enforce this part ss. ~~499.001-499.081~~ to prevent fraud,
136 adulteration, misbranding, or false advertising in the
137 preparation, manufacture, repackaging, or distribution of drugs,
138 devices, and cosmetics.

139 (3) ~~499.0053 Power to administer oaths, take depositions,~~
140 ~~and issue and serve subpoenas.~~For the purpose of any
141 investigation or proceeding conducted by the department under
142 this part ss. ~~499.001-499.081~~, the department may administer
143 oaths, take depositions, issue and serve subpoenas, and compel
144 the attendance of witnesses and the production of books, papers,
145 documents, or other evidence. The department shall exercise this

588-06443-08

20082756c1

146 power on its own initiative. Challenges to, and enforcement of,
147 the subpoenas and orders shall be handled as provided in s.
148 120.569.

149 (4) ~~499.07 Duty of prosecuting officer.~~ Each state
150 attorney, county attorney, or municipal attorney to whom the
151 department or its designated agent reports any violation of this
152 part ss. 499.001-499.081 shall cause appropriate proceedings to
153 be instituted in the proper courts without delay and to be
154 prosecuted in the manner required by law.

155 (5) ~~499.071 Issuance of warnings for minor~~
156 ~~violations.~~ This part does Sections 499.001-499.081 do not
157 require the department to report, for the institution of
158 proceedings under this part ss. 499.001-499.081, minor violations
159 of this part ss. 499.001-499.081 when it believes that the public
160 interest will be adequately served in the circumstances by a
161 suitable written notice or warning.

162 (6) ~~499.081 Carriers in interstate commerce exempted from~~
163 ~~ss. 499.001-499.081.~~ Carriers engaged in interstate commerce are
164 not subject to this part ss. 499.001-499.081 if they are engaged
165 in the usual course of business as carriers.

166 Section 2. Section 499.003, Florida Statutes, is amended;
167 paragraphs (a) through (f) of subsection (1) of section 499.012,
168 Florida Statutes, are redesignated as subsections (55), (56),
169 (52), and (48), paragraph (c) of subsection (48), and subsection
170 (53), respectively, of that section and amended; paragraphs (f)
171 through (j) and (l) through (n) of subsection (3) of section
172 499.029, Florida Statutes, are redesignated as subsections (25),
173 (23), (26), (27), (35), (40), (41), and (43), respectively, of
174 that section and amended; and subsection (1) of section 499.0661,

588-06443-08

20082756c1

175 Florida Statutes, is redesignated as subsection (38) of that
176 section and amended, to read:

177 499.003 Definitions of terms used in this part ~~ss. 499.001-~~
178 ~~499.081.~~--As used in this part ~~ss. 499.001-499.081~~, the term:

179 (1) "Advertisement" means any representation disseminated
180 in any manner or by any means, other than by labeling, for the
181 purpose of inducing, or which is likely to induce, directly or
182 indirectly, the purchase of drugs, devices, or cosmetics.

183 (2) "Affiliated group" means an affiliated group as defined
184 by s. 1504 of the Internal Revenue Code of 1986, as amended,
185 which is composed of chain drug entities, including at least 50
186 retail pharmacies, warehouses, or repackagers, which are members
187 of the same affiliated group. The affiliated group must disclose
188 the names of all its members to the department.

189 (3)(2) "Affiliated party" means:

190 (a) A director, officer, trustee, partner, or committee
191 member of a permittee or applicant or a subsidiary or service
192 corporation of the permittee or applicant;

193 (b) A person who, directly or indirectly, manages,
194 controls, or oversees the operation of a permittee or applicant,
195 regardless of whether such person is a partner, shareholder,
196 manager, member, officer, director, independent contractor, or
197 employee of the permittee or applicant;

198 (c) A person who has filed or is required to file a
199 personal information statement pursuant to s. 499.012(9) ~~s.~~
200 ~~499.012(4)~~ or is required to be identified in an application for
201 a permit or to renew a permit pursuant to s. 499.012(8) ~~s.~~
202 ~~499.012(3)~~; or

203 (d) The five largest natural shareholders that own at least

588-06443-08

20082756c1

204 5 percent of the permittee or applicant.

205 ~~(4)(3)~~ "Applicant" means a person applying for a permit or
206 certification under this part ~~ss. 499.001-499.081~~.

207 ~~(5)(4)~~ "Authenticate" means to affirmatively verify upon
208 receipt ~~before any distribution~~ of a prescription legend drug
209 ~~occurs~~ that each transaction listed on the pedigree paper
210 described in s. 499.01212(2)(b) has occurred. A wholesale
211 distributor is not required to open a sealed, medical convenience
212 kit to authenticate a pedigree paper for a prescription drug
213 contained within the kit.

214 ~~(6)(5)~~ "Certificate of free sale" means a document prepared
215 by the department which certifies a drug, device, or cosmetic,
216 that is registered with the department, as one that can be
217 legally sold in the state.

218 ~~(7)~~ "Chain pharmacy warehouse" means a wholesale
219 distributor permitted pursuant to s. 499.01 that maintains a
220 physical location for prescription drugs that functions solely as
221 a central warehouse to perform intracompany transfers of such
222 drugs to a member of its affiliated group.

223 ~~(8)(6)~~ "Closed pharmacy" means a pharmacy that is licensed
224 under chapter 465 and purchases prescription drugs for use by a
225 limited patient population and not for wholesale distribution or
226 sale to the public. The term does not include retail pharmacies.

227 ~~(9)(7)~~ "Color" includes black, white, and intermediate
228 grays.

229 ~~(10)(8)~~ "Color additive" means, with the exception of any
230 material that has been or hereafter is exempt under the federal
231 act, a material that:

232 (a) Is a dye pigment, or other substance, made by a process

588-06443-08

20082756c1

233 of synthesis or similar artifice, or extracted, isolated, or
234 otherwise derived, with or without intermediate or final change
235 of identity from a vegetable, animal, mineral, or other source;
236 or

237 (b) When added or applied to a drug or cosmetic or to the
238 human body, or any part thereof, is capable alone, or through
239 reaction with other substances, of imparting color thereto;

240
241 ~~except that the term does not include any material which has been~~
242 ~~or hereafter is exempt under the federal act.~~

243 (11)~~(9)~~ "Compressed medical gas" means any liquefied or
244 vaporized gas that is a prescription drug, whether it is alone or
245 in combination with other gases.

246 (12)~~(10)~~ "Contraband prescription ~~legend~~ drug" means any
247 adulterated drug, as defined in s. 499.006, any counterfeit drug,
248 as defined in this section, and also means any prescription
249 ~~legend~~ drug for which a pedigree paper does not exist, or for
250 which the pedigree paper in existence has been forged,
251 counterfeited, falsely created, or contains any altered, false,
252 or misrepresented matter.

253 (13)~~(11)~~ "Cosmetic" means an article, with the exception of
254 soap, that is:

255 (a) Intended to be rubbed, poured, sprinkled, or sprayed
256 on; introduced into; or otherwise applied to the human body or
257 any part thereof for cleansing, beautifying, promoting
258 attractiveness, or altering the appearance; or

259 (b) Intended for use as a component of any such article;

260
261 except that the term does not include soap.

588-06443-08

20082756c1

262 (14)~~(12)~~ "Counterfeit drug," "counterfeit device," or
263 "counterfeit drug, counterfeit device, or counterfeit cosmetic"
264 means a drug, device, or cosmetic which, or the container, seal,
265 or labeling of which, without authorization, bears the trademark,
266 trade name, or other identifying mark, imprint, or device, or any
267 likeness thereof, of a drug, device, or cosmetic manufacturer,
268 processor, packer, or distributor other than the person that in
269 fact manufactured, processed, packed, or distributed that drug,
270 device, or cosmetic and which thereby falsely purports or is
271 represented to be the product of, or to have been packed or
272 distributed by, that other drug, device, or cosmetic
273 manufacturer, processor, packer, or distributor.

274 (15)~~(13)~~ "Department" means the Department of Health.

275 (16)~~(14)~~ "Device" means any instrument, apparatus,
276 implement, machine, contrivance, implant, in vitro reagent, or
277 other similar or related article, including its components,
278 parts, or accessories, which is:

279 (a) Recognized in the current edition of the United States
280 Pharmacopoeia and National Formulary, or any supplement thereof,

281 (b) Intended for use in the diagnosis, cure, mitigation,
282 treatment, therapy, or prevention of disease in humans or other
283 animals, or

284 (c) Intended to affect the structure or any function of the
285 body of humans or other animals,

286
287 and that ~~which~~ does not achieve any of its principal intended
288 purposes through chemical action within or on the body of humans
289 or other animals and which is not dependent upon being
290 metabolized for the achievement of any of its principal intended

588-06443-08

20082756c1

291 purposes.

292 ~~(17)-(15)~~ "Distribute or distribution" or "distribution"
293 means to sell; offer to sell; give away; transfer, whether by
294 passage of title, physical movement, or both; deliver; or offer
295 to deliver. The term does not mean to administer or dispense.

296 (18) "Drop shipment" means the sale of a prescription drug
297 from a manufacturer to a wholesale distributor, where the
298 wholesale distributor takes title to, but not possession of, the
299 prescription drug and the manufacturer of the prescription drug
300 ships the prescription drug directly to a chain pharmacy
301 warehouse or a person authorized by law to purchase prescription
302 drugs for the purpose of administering or dispensing the drug, as
303 defined in s. 465.003.

304 ~~(16) "Diverted from the legal channels of distribution for~~
305 ~~prescription drugs" means an adulterated drug pursuant to s.~~
306 ~~499.006(10).~~

307 ~~(19)-(17)~~ "Drug" means an article that is:

308 (a) Recognized in the current edition of the United States
309 Pharmacopoeia and National Formulary, official Homeopathic
310 Pharmacopoeia of the United States, or any supplement to any of
311 those publications;

312 (b) Intended for use in the diagnosis, cure, mitigation,
313 treatment, therapy, or prevention of disease in humans or other
314 animals;

315 (c) Intended to affect the structure or any function of the
316 body of humans or other animals; or

317 (d) Intended for use as a component of any article
318 specified in paragraph (a), paragraph (b), or paragraph (c), but
319 does not include devices or their components, parts, or

588-06443-08

20082756c1

320 accessories.

321 (20)~~(18)~~ "Establishment" means a place of business at one
322 general physical location.

323 (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and
324 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

325 (22)~~(20)~~ "Freight forwarder" means a person who receives
326 prescription legend ~~legend~~ drugs which are owned by another person and
327 designated by that person for export, and exports those
328 prescription legend ~~legend~~ drugs.

329 (23)~~(9)~~ "Health care clinic" means a health care clinic
330 licensed under part X of chapter 400.

331 (24)~~(21)~~ "Health care entity" means a closed pharmacy or
332 any person, organization, or business entity that provides
333 diagnostic, medical, surgical, or dental treatment or care, or
334 chronic or rehabilitative care, but does not include any
335 wholesale distributor or retail pharmacy licensed under state law
336 to deal in prescription drugs.

337 (25)~~(f)~~ "Health care facility" means a health care facility
338 licensed under chapter 395.

339 (26)~~(h)~~ "Hospice" means a corporation licensed under part
340 IV of chapter 400.

341 (27)~~(i)~~ "Hospital" means a facility as defined in s.
342 395.002 and licensed under chapter 395.

343 (28)~~(22)~~ "Immediate container" does not include package
344 liners.

345 (29)~~(23)~~ "Label" means a display of written, printed, or
346 graphic matter upon the immediate container of any drug, device,
347 or cosmetic. A requirement made by or under authority of this
348 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~those~~

588-06443-08

20082756c1

349 sections that any word, statement, or other information appear on
350 the label is not complied with unless such word, statement, or
351 other information also appears on the outside container or
352 wrapper, if any, of the retail package of such drug, device, or
353 cosmetic or is easily legible through the outside container or
354 wrapper.

355 (30)~~(24)~~ "Labeling" means all labels and other written,
356 printed, or graphic matters:

357 (a) Upon a drug, device, or cosmetic, or any of its
358 containers or wrappers; or

359 (b) Accompanying or related to such drug, device, or
360 cosmetic.

361 ~~(25) "Legend drug," "prescription drug," or "medicinal
362 drug" means any drug, including, but not limited to, finished
363 dosage forms, or active ingredients subject to, defined by, or
364 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
365 Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or
366 (c).~~

367 ~~(26) "Legend drug label" means any display of written,
368 printed, or graphic matter upon the immediate container of any
369 legend drug prior to its dispensing to an individual patient
370 pursuant to a prescription of a practitioner authorized by law to
371 prescribe.~~

372 (31)~~(27)~~ "Manufacture" means the preparation, deriving,
373 compounding, propagation, processing, producing, or fabrication
374 of any drug, device, or cosmetic.

375 (32)~~(28)~~ "Manufacturer" means a person who prepares,
376 derives, manufactures, or produces a drug, device, or cosmetic.
377 "Manufacturer" also means the holder or holders of a New Drug

588-06443-08

20082756c1

378 Application (NDA), an Abbreviated New Drug Application (ANDA), a
379 Biologics License Application (BLA), or a New Animal Drug
380 Application (NADA), provided that such application has become
381 effective or is otherwise approved consistent with s. 499.023; a
382 private label distributor for whom the private label
383 distributor's prescription drugs are originally manufactured and
384 labeled for the distributor and have not been repackaged; or the
385 distribution point for the manufacturer, contract manufacturer or
386 private label distributor whether the establishment is a member
387 of the manufacturer's affiliated group or is a contract
388 distribution site.

389
390 The term excludes pharmacies that are operating in compliance
391 with pharmacy practice standards as defined in chapter 465 and
392 rules adopted under that chapter.

393 (33)~~(29)~~ "New drug" means:

394 (a) Any drug the composition of which is such that the drug
395 is not generally recognized, among experts qualified by
396 scientific training and experience to evaluate the safety and
397 effectiveness of drugs, as safe and effective for use under the
398 conditions prescribed, recommended, or suggested in the labeling
399 of that drug; or

400 (b) Any drug the composition of which is such that the
401 drug, as a result of investigations to determine its safety and
402 effectiveness for use under certain conditions, has been
403 recognized for use under such conditions, but which drug has not,
404 other than in those investigations, been used to a material
405 extent or for a material time under such conditions.

406 (34) "Normal distribution chain" means a wholesale

588-06443-08

20082756c1

407 distribution of a prescription drug where the wholesale
408 distributor or its wholly owned subsidiary purchases and receives
409 the specific unit of the prescription drug directly from the
410 manufacturer and distributes the prescription drug directly, or
411 through up to two intracompany transfers, to a chain pharmacy
412 warehouse or a person authorized by law to purchase prescription
413 drugs for the purpose of administering or dispensing the drug, as
414 defined in s. 465.003. For purposes of this subsection,
415 "intracompany transfer" means any transaction or transfer between
416 any parent, division, or subsidiary wholly owned by a corporate
417 entity.

418 ~~(35)(j)~~ "Nursing home" means a facility licensed under part
419 II of chapter 400.

420 ~~(36)(30)~~ "Official compendium" means the current edition of
421 the official United States Pharmacopoeia and National Formulary,
422 or any supplement thereto.

423 ~~(37)(31)~~ "Pedigree paper" means:

424 ~~(a)~~ ~~Effective July 1, 2006,~~ a document in written or
425 electronic form approved by the department that contains ~~of~~
426 ~~Health and containing~~ information required by s. 499.01212
427 regarding the sale and that records each distribution of any
428 given prescription legend drug, ~~from sale by a pharmaceutical~~
429 ~~manufacturer, through acquisition and sale by any wholesaler or~~
430 ~~repackager, until final sale to a pharmacy or other person~~
431 ~~administering or dispensing the drug. The information required to~~
432 ~~be included on the form approved by the department pursuant to~~
433 ~~this paragraph must at least detail the amount of the legend~~
434 ~~drug; its dosage form and strength; its lot numbers; the name and~~
435 ~~address of each owner of the legend drug and his or her~~

588-06443-08

20082756c1

436 ~~signature; its shipping information, including the name and~~
437 ~~address of each person certifying delivery or receipt of the~~
438 ~~legend drug; an invoice number, a shipping document number, or~~
439 ~~another number uniquely identifying the transaction; and a~~
440 ~~certification that the recipient wholesaler has authenticated the~~
441 ~~pedigree papers. If the manufacturer or repackager has uniquely~~
442 ~~serialized the individual legend drug unit, that identifier must~~
443 ~~also be included on the form approved pursuant to this paragraph.~~
444 ~~It must also include the name, address, telephone number and, if~~
445 ~~available, e-mail contact information of each wholesaler involved~~
446 ~~in the chain of the legend drug's custody; or~~

447 ~~(b) A statement, under oath, in written or electronic form,~~
448 ~~confirming that a wholesale distributor purchases and receives~~
449 ~~the specific unit of the prescription drug directly from the~~
450 ~~manufacturer of the prescription drug and distributes the~~
451 ~~prescription drug directly, or through an intracompany transfer,~~
452 ~~to a chain pharmacy warehouse or a person authorized by law to~~
453 ~~purchase prescription drugs for the purpose of administering or~~
454 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
455 ~~this subsection, the term "chain pharmacy warehouse" means a~~
456 ~~wholesale distributor permitted pursuant to s. 499.01 that~~
457 ~~maintains a physical location for prescription drugs that~~
458 ~~functions solely as a central warehouse to perform intracompany~~
459 ~~transfers of such drugs to a member of its affiliated group as~~
460 ~~described in s. 499.0121(6)(f)1.~~

461 ~~1. The information required to be included pursuant to this~~
462 ~~paragraph must include:~~

463 ~~a. The following statement: "This wholesale distributor~~
464 ~~purchased the specific unit of the prescription drug directly~~

588-06443-08

20082756c1

465 ~~from the manufacturer."~~

466 ~~b. The manufacturer's national drug code identifier and the~~
467 ~~name and address of the wholesaler and the purchaser of the~~
468 ~~prescription drug.~~

469 ~~e. The name of the prescription drug as it appears on the~~
470 ~~label.~~

471 ~~d. The quantity, dosage form, and strength of the~~
472 ~~prescription drug.~~

473 ~~2. The wholesale distributor must also maintain and make~~
474 ~~available to the department, upon request, the point of origin of~~
475 ~~the prescription drugs, including intracompany transfers; the~~
476 ~~date of the shipment from the manufacturer to the wholesale~~
477 ~~distributor; the lot numbers of such drugs; and the invoice~~
478 ~~numbers from the manufacturer.~~

479
480 ~~The department may adopt rules and forms relating to the~~
481 ~~requirements of this subsection.~~

482 ~~(38)(1) DEFINITION. As used in this section, the term~~
483 ~~"Permittee" means any person holding a permit issued pursuant to~~
484 ~~s. 499.012.~~

485 ~~(39)(32)~~ "Person" means any individual, child, joint
486 venture, syndicate, fiduciary, partnership, corporation, division
487 of a corporation, firm, trust, business trust, company, estate,
488 public or private institution, association, organization, group,
489 city, county, city and county, political subdivision of this
490 state, other governmental agency within this state, and any
491 representative, agent, or agency of any of the foregoing, or any
492 other group or combination of the foregoing.

493 (40) "Person authorized by law" to "purchase," "posses,"

588-06443-08

20082756c1

494 "administer" or "receive" prescription or legend drugs means:

495 (a) A person authorized by law to administer the drug, as
496 defined in s. 465.003; and

497 (b) An entity of which a person authorized by law to
498 administer the drug, as defined in s. 465.003, is a member,
499 officer, employee or agent, including but not limited to, a
500 professional corporation or a professional limited liability
501 company described in chapter 621 of the Business Organizations
502 Code, provided that:

503 1. The entity provides to the seller of the drug with a
504 copy of the license under which the person authorized to
505 administer the drug may purchase the drug;

506 2. The entity designates, to the seller of the drug, a
507 person employed by the entity who will be responsible for
508 complying with all legal and regulatory requirements with respect
509 to the purchase, storage and handling of the drug; and

510 3. If the entity fails to designate the person described in
511 subparagraph 2., the person whose license was provided to the
512 seller under subparagraph 1. is deemed the person responsible for
513 complying with all legal and regulatory requirements with respect
514 to the purchase, storage and handling of the drug.

515 (41)-(1) "Pharmacist" means a person licensed under chapter
516 465.

517 (42)-(m) "Pharmacy" means an entity licensed under chapter
518 465.

519 (43)-(33) "Prepackaged drug product" means a drug that
520 originally was in finished packaged form sealed by a manufacturer
521 and that is placed in a properly labeled container by a pharmacy
522 or practitioner authorized to dispense pursuant to chapter 465

588-06443-08

20082756c1

523 for the purpose of dispensing in the establishment in which the
524 prepackaging occurred.

525 ~~(44)(n)~~ "Prescribing practitioner" means a physician
526 licensed under chapter 458 or chapter 459 or any other medical
527 professional with authority under state law to prescribe cancer
528 medication.

529 (45) "Prescription drug" means a prescription, medicinal,
530 or legend drug, including, but not limited to, finished dosage
531 forms or active ingredients subject to, defined by, or described
532 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s.
533 465.003(8), s. 499.007(13), or subsection (11), subsection (48),
534 or subsection (55).

535 (46) "Prescription drug label" means any display of
536 written, printed, or graphic matter upon the immediate container
537 of any prescription drug prior to its dispensing to an individual
538 patient pursuant to a prescription of a practitioner authorized
539 by law to prescribe.

540 ~~(47)(34)~~ "Prescription label" means any display of written,
541 printed, or graphic matter upon the immediate container of any
542 prescription legend drug dispensed pursuant to a prescription of
543 a practitioner authorized by law to prescribe.

544 ~~(48)(35)~~ "Prescription medical oxygen" means oxygen USP
545 which is a drug that can only be sold on the order or
546 prescription of a practitioner authorized by law to prescribe.
547 The label of prescription medical oxygen must comply with current
548 labeling requirements for oxygen under the Federal Food, Drug,
549 and Cosmetic Act.

550 ~~(49)(d)~~ "Primary wholesale distributor ~~wholesaler~~" means
551 any wholesale distributor that:

588-06443-08

20082756c1

552 (a)1. Purchased 90 percent or more of the total dollar
553 volume of its purchases of prescription drugs directly from
554 manufacturers in the previous year; and

555 (b)1.2.a. Directly purchased prescription drugs from not
556 fewer than 50 different prescription drug manufacturers in the
557 previous year; or

558 2.b. Has, or the affiliated group, as defined in s. 1504 of
559 the Internal Revenue Code, of which the wholesale distributor is
560 a member has, not fewer than 250 employees.

561 (c)(e) For purposes of this subsection, "directly from
562 manufacturers a manufacturer" means:

563 1. Purchases made by the wholesale distributor directly
564 from the manufacturer of prescription drugs; and

565 2. Transfers from a member of an affiliated group, as
566 defined in s. 1504 of the Internal Revenue Code, of which the
567 wholesale distributor is a member, if:

568 a. The affiliated group purchases 90 percent or more of the
569 total dollar volume of its purchases of prescription drugs from
570 the manufacturer in the previous year; and

571 b. The wholesale distributor discloses to the department
572 the names of all members of the affiliated group of which the
573 wholesale distributor is a member and the affiliated group agrees
574 in writing to provide records on prescription drug purchases by
575 the members of the affiliated group not later than 48 hours after
576 the department requests access to such records, regardless of the
577 location where the records are stored.

578 (50)(36) "Proprietary drug," or "OTC drug," means a patent
579 or over-the-counter drug in its unbroken, original package, which
580 drug is sold to the public by, or under the authority of, the

588-06443-08

20082756c1

581 manufacturer or primary distributor thereof, is not misbranded
582 under the provisions of this part ~~ss. 499.001-499.081~~, and can be
583 purchased without a prescription.

584 ~~(51)-(37)~~ "Repackage" includes repacking or otherwise
585 changing the container, wrapper, or labeling to further the
586 distribution of the drug, device, or cosmetic.

587 ~~(52)-(38)~~ "Repackager" means a person who repackages. The
588 term excludes pharmacies that are operating in compliance with
589 pharmacy practice standards as defined in chapter 465 and rules
590 adopted under that chapter.

591 ~~(53)-(e)~~ "Retail pharmacy" means a community pharmacy
592 licensed under chapter 465 that purchases prescription drugs at
593 fair market prices and provides prescription services to the
594 public.

595 ~~(54)-(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means
596 a wholesale distributor that is not a primary wholesale
597 distributor ~~wholesaler~~.

598 ~~(55)-(39)~~ "Veterinary prescription drug" means a
599 prescription ~~legend~~ drug intended solely for veterinary use. The
600 label of the drug must bear the statement, "Caution: Federal law
601 restricts this drug to sale by or on the order of a licensed
602 veterinarian."

603 ~~(40)~~ ~~"Veterinary prescription drug wholesaler" means any~~
604 ~~person engaged in wholesale distribution of veterinary~~
605 ~~prescription drugs in or into this state.~~

606 ~~(56)-(a)~~ "Wholesale distribution" means distribution of
607 prescription drugs to persons other than a consumer or patient,
608 but does not include:

609 ~~(a)1.~~ Any of the following activities, which is not a

588-06443-08

20082756c1

610 violation of s. 499.005(21) if such activity is conducted in
611 accordance with s. 499.01(2)(g) ~~s. 499.014~~:

612 ~~1.a.~~ The purchase or other acquisition by a hospital or
613 other health care entity that is a member of a group purchasing
614 organization of a prescription drug for its own use from the
615 group purchasing organization or from other hospitals or health
616 care entities that are members of that organization.

617 ~~2.b.~~ The sale, purchase, or trade of a prescription drug or
618 an offer to sell, purchase, or trade a prescription drug by a
619 charitable organization described in s. 501(c)(3) of the Internal
620 Revenue Code of 1986, as amended and revised, to a nonprofit
621 affiliate of the organization to the extent otherwise permitted
622 by law.

623 ~~3.e.~~ The sale, purchase, or trade of a prescription drug or
624 an offer to sell, purchase, or trade a prescription drug among
625 hospitals or other health care entities that are under common
626 control. For purposes of this subparagraph ~~section~~, "common
627 control" means the power to direct or cause the direction of the
628 management and policies of a person or an organization, whether
629 by ownership of stock, by voting rights, by contract, or
630 otherwise.

631 ~~4.d.~~ The sale, purchase, trade, or other transfer of a
632 prescription drug from or for any federal, state, or local
633 government agency or any entity eligible to purchase prescription
634 drugs at public health services prices pursuant to Pub. L. No.
635 102-585, s. 602 to a contract provider or its subcontractor for
636 eligible patients of the agency or entity under the following
637 conditions:

638 ~~a.(I)~~ The agency or entity must obtain written

588-06443-08

20082756c1

639 authorization for the sale, purchase, trade, or other transfer of
640 a prescription drug under this subparagraph ~~sub-subparagraph~~ from
641 the State Surgeon General or his or her designee.

642 b.~~(II)~~ The contract provider or subcontractor must be
643 authorized by law to administer or dispense prescription drugs.

644 c.~~(III)~~ In the case of a subcontractor, the agency or
645 entity must be a party to and execute the subcontract.

646 d.~~(IV)~~ A contract provider or subcontractor must maintain
647 separate and apart from other prescription drug inventory any
648 prescription drugs of the agency or entity in its possession.

649 e.~~(V)~~ The contract provider and subcontractor must maintain
650 and produce immediately for inspection all records of movement or
651 transfer of all the prescription drugs belonging to the agency or
652 entity, including, but not limited to, the records of receipt and
653 disposition of prescription drugs. Each contractor and
654 subcontractor dispensing or administering these drugs must
655 maintain and produce records documenting the dispensing or
656 administration. Records that are required to be maintained
657 include, but are not limited to, a perpetual inventory itemizing
658 drugs received and drugs dispensed by prescription number or
659 administered by patient identifier, which must be submitted to
660 the agency or entity quarterly.

661 f.~~(VI)~~ The contract provider or subcontractor may
662 administer or dispense the prescription drugs only to the
663 eligible patients of the agency or entity or must return the
664 prescription drugs for or to the agency or entity. The contract
665 provider or subcontractor must require proof from each person
666 seeking to fill a prescription or obtain treatment that the
667 person is an eligible patient of the agency or entity and must,

588-06443-08

20082756c1

668 | at a minimum, maintain a copy of this proof as part of the
669 | records of the contractor or subcontractor required under sub-
670 | subparagraph e. ~~sub-sub-subparagraph (V).~~

671 | g.~~(VII)~~ In addition to the departmental inspection
672 | authority set forth in s. 499.051, the establishment of the
673 | contract provider and subcontractor and all records pertaining to
674 | prescription drugs subject to this subparagraph ~~sub-subparagraph~~
675 | shall be subject to inspection by the agency or entity. All
676 | records relating to prescription drugs of a manufacturer under
677 | this subparagraph ~~sub-subparagraph~~ shall be subject to audit by
678 | the manufacturer of those drugs, without identifying individual
679 | patient information.

680 | (b)2. Any of the following activities, which is not a
681 | violation of s. 499.005(21) if such activity is conducted in
682 | accordance with rules established by the department:

683 | 1.a. The sale, purchase, or trade of a prescription drug
684 | among federal, state, or local government health care entities
685 | that are under common control and are authorized to purchase such
686 | prescription drug.

687 | 2.b. The sale, purchase, or trade of a prescription drug or
688 | an offer to sell, purchase, or trade a prescription drug for
689 | emergency medical reasons. For purposes of this subparagraph ~~sub-~~
690 | ~~subparagraph~~, the term "emergency medical reasons" includes
691 | transfers of prescription drugs by a retail pharmacy to another
692 | retail pharmacy to alleviate a temporary shortage.

693 | 3.e. The transfer of a prescription drug acquired by a
694 | medical director on behalf of a licensed emergency medical
695 | services provider to that emergency medical services provider and
696 | its transport vehicles for use in accordance with the provider's

588-06443-08

20082756c1

697 license under chapter 401.

698 ~~4.d.~~ The revocation of a sale or the return of a
699 prescription drug to the person's prescription drug wholesale
700 supplier.

701 ~~5.e.~~ The donation of a prescription drug by a health care
702 entity to a charitable organization that has been granted an
703 exemption under s. 501(c)(3) of the Internal Revenue Code of
704 1986, as amended, and that is authorized to possess prescription
705 drugs.

706 ~~6.f.~~ The transfer of a prescription drug by a person
707 authorized to purchase or receive prescription drugs to a person
708 licensed or permitted to handle reverse distributions or
709 destruction under the laws of the jurisdiction in which the
710 person handling the reverse distribution or destruction receives
711 the drug.

712 ~~7.g.~~ The transfer of a prescription drug by a hospital or
713 other health care entity to a person licensed under this part
714 ~~chapter~~ to repackage prescription drugs for the purpose of
715 repackaging the prescription drug for use by that hospital, or
716 other health care entity and other health care entities that are
717 under common control, if ownership of the prescription drugs
718 remains with the hospital or other health care entity at all
719 times. In addition to the recordkeeping requirements of s.
720 499.0121(6), the hospital or health care entity that transfers
721 prescription drugs pursuant to this subparagraph ~~sub-subparagraph~~
722 must reconcile all drugs transferred and returned and resolve any
723 discrepancies in a timely manner.

724 ~~(c)3.~~ The distribution of prescription drug samples by
725 manufacturers' representatives or distributors' representatives

588-06443-08

20082756c1

726 conducted in accordance with s. 499.028.

727 (d)4. The sale, purchase, or trade of blood and blood
728 components intended for transfusion. As used in this paragraph
729 ~~subparagraph~~, the term "blood" means whole blood collected from a
730 single donor and processed either for transfusion or further
731 manufacturing, and the term "blood components" means that part of
732 the blood separated by physical or mechanical means.

733 (e)5. The lawful dispensing of a prescription drug in
734 accordance with chapter 465.

735 (f)6. The sale, purchase, or trade of a prescription drug
736 between pharmacies as a result of a sale, transfer, merger, or
737 consolidation of all or part of the business of the pharmacies
738 from or with another pharmacy, whether accomplished as a purchase
739 and sale of stock or of business assets.

740 (57)(b) "Wholesale distributor" means any person engaged in
741 wholesale distribution of prescription drugs in or into this
742 state, including, but not limited to, manufacturers; repackagers;
743 own-label distributors; jobbers; private-label distributors;
744 brokers; warehouses, including manufacturers' and distributors'
745 warehouses, chain drug warehouses, and wholesale drug warehouses;
746 independent wholesale drug traders; exporters; retail pharmacies;
747 and the agents thereof that conduct wholesale distributions.

748 Section 3. Subsections (4), (10), (11), (12), (14), (15),
749 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,
750 Florida Statutes, are amended to read:

751 499.005 Prohibited acts.--It is unlawful for a person to
752 perform or cause the performance of any of the following acts in
753 this state:

754 (4) The sale, distribution, purchase, trade, holding, or

588-06443-08

20082756c1

755 offering of any drug, device, or cosmetic in violation of this
756 part ~~ss. 499.001-499.081~~.

757 (10) Forging; counterfeiting; simulating; falsely
758 representing any drug, device, or cosmetic; or, without the
759 authority of the manufacturer, using any mark, stamp, tag, label,
760 or other identification device authorized or required by rules
761 adopted under this part ~~ss. 499.001-499.081~~.

762 (11) The use, on the labeling of any drug or in any
763 advertisement relating to such drug, of any representation or
764 suggestion that an application of the drug is effective when it
765 is not or that the drug complies with this part ~~ss. 499.001-~~
766 ~~499.081~~ when it does not.

767 (12) The possession of any drug in violation of this part
768 ~~ss. 499.001-499.081~~.

769 (14) The purchase or receipt of a prescription ~~legend~~ drug
770 from a person that is not authorized under this chapter to
771 distribute prescription ~~legend~~ drugs to that purchaser or
772 recipient.

773 (15) The sale or transfer of a prescription ~~legend~~ drug to
774 a person that is not authorized under the law of the jurisdiction
775 in which the person receives the drug to purchase or possess
776 prescription ~~legend~~ drugs from the person selling or transferring
777 the prescription ~~legend~~ drug.

778 (18) Failure to maintain records as required by this part
779 ~~ss. 499.001-499.081~~ and rules adopted under this part ~~these~~
780 ~~sections~~.

781 (19) Providing the department with false or fraudulent
782 records, or making false or fraudulent statements, regarding any
783 matter within the provisions of this part ~~chapter~~.

588-06443-08

20082756c1

784 (20) The importation of a prescription ~~legend~~ drug except
785 as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic
786 Act.

787 (22) Failure to obtain a permit or registration, or
788 operating without a valid permit when a permit or registration is
789 required by this part ~~ss. 499.001-499.081~~ for that activity.

790 (24) The distribution of a prescription ~~legend~~ device to
791 the patient or ultimate consumer without a prescription or order
792 from a practitioner licensed by law to use or prescribe the
793 device.

794 (28) Failure to acquire ~~obtain~~ or deliver ~~pass on~~ a
795 pedigree paper as required under this part.

796 (29) The receipt of a prescription drug pursuant to a
797 wholesale distribution without having previously received or
798 simultaneously ~~either first~~ receiving a pedigree paper that was
799 attested to as accurate and complete by the wholesale distributor
800 as required under this part ~~or complying with the provisions of~~
801 ~~s. 499.0121(6)(d)5.~~

802 Section 4. Section 499.0051, Florida Statutes, is amended;
803 section 499.0052, Florida Statutes, is redesignated as subsection
804 (7) of that section and amended; section 499.00535, Florida
805 Statutes, is redesignated as subsection (9) of that section and
806 amended; section 499.00545, Florida Statutes, is redesignated as
807 subsection (10) of that section and amended; section 499.069,
808 Florida Statutes, is redesignated as subsection (11) of that
809 section and amended; and section 499.0691, Florida Statutes, is
810 redesignated as subsections (12) through (15) of that section and
811 amended, to read:

812 499.0051 Criminal acts ~~involving contraband or adulterated~~

588-06443-08

20082756c1

813 | ~~drugs.--~~

814 | (1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.--

815 | (a) A person, other than a manufacturer, engaged in the
816 | wholesale distribution of prescription ~~legend~~ drugs who fails to
817 | deliver to another person complete and accurate pedigree papers
818 | concerning a prescription ~~legend~~ drug or contraband prescription
819 | ~~legend~~ drug prior to, or simultaneous with, the transfer of
820 | ~~transferring~~ the prescription ~~legend~~ drug or contraband
821 | prescription ~~legend~~ drug to another person commits a felony of
822 | the third degree, punishable as provided in s. 775.082, s.
823 | 775.083, or s. 775.084.

824 | (b) A person engaged in the wholesale distribution of
825 | prescription ~~legend~~ drugs who fails to acquire complete and
826 | accurate pedigree papers concerning a prescription ~~legend~~ drug or
827 | contraband prescription ~~legend~~ drug prior to, or simultaneous
828 | with, the receipt of ~~obtaining~~ the prescription ~~legend~~ drug or
829 | contraband prescription ~~legend~~ drug from another person commits a
830 | felony of the third degree, punishable as provided in s. 775.082,
831 | s. 775.083, or s. 775.084.

832 | (c) Any person who knowingly destroys, alters, conceals, or
833 | fails to maintain complete and accurate pedigree papers
834 | concerning any prescription ~~legend~~ drug or contraband
835 | prescription ~~legend~~ drug in his or her possession commits a
836 | felony of the third degree, punishable as provided in s. 775.082,
837 | s. 775.083, or s. 775.084.

838 | (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--Effective
839 | July 1, 2006:

840 | (a) A person engaged in the wholesale distribution of
841 | prescription ~~legend~~ drugs who is in possession of pedigree papers

588-06443-08

20082756c1

842 concerning prescription ~~legend~~ drugs or contraband prescription
843 ~~legend~~ drugs and who fails to authenticate the matters contained
844 in the pedigree papers and who nevertheless attempts to further
845 distribute prescription ~~legend~~ drugs or contraband prescription
846 ~~legend~~ drugs commits a felony of the third degree, punishable as
847 provided in s. 775.082, s. 775.083, or s. 775.084.

848 (b) A person in possession of pedigree papers concerning
849 prescription ~~legend~~ drugs or contraband prescription ~~legend~~ drugs
850 who falsely swears or certifies that he or she has authenticated
851 the matters contained in the pedigree papers commits a felony of
852 the third degree, punishable as provided in s. 775.082, s.
853 775.083, or s. 775.084.

854 (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who
855 knowingly forges, counterfeits, or falsely creates any pedigree
856 paper; who falsely represents any factual matter contained on any
857 pedigree paper; or who knowingly omits to record material
858 information required to be recorded in a pedigree paper, commits
859 a felony of the second degree, punishable as provided in s.
860 775.082, s. 775.083, or s. 775.084.

861 (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~ DRUG
862 FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or
863 receives from a person not authorized to distribute prescription
864 ~~legend~~ drugs under this chapter a prescription ~~legend~~ drug in a
865 wholesale distribution transaction commits a felony of the second
866 degree, punishable as provided in s. 775.082, s. 775.083, or s.
867 775.084.

868 (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG TO
869 UNAUTHORIZED PERSON.--A person who knowingly sells or transfers
870 to a person not authorized to purchase or possess prescription

588-06443-08

20082756c1

871 ~~legend~~ drugs, under the law of the jurisdiction in which the
872 person receives the drug, a prescription ~~legend~~ drug in a
873 wholesale distribution transaction commits a felony of the second
874 degree, punishable as provided in s. 775.082, s. 775.083, or s.
875 775.084.

876 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO
877 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is
878 knowingly in actual or constructive possession of any amount of
879 contraband prescription ~~legend~~ drugs, who knowingly sells or
880 delivers, or who possesses with intent to sell or deliver any
881 amount of contraband prescription ~~legend~~ drugs, commits a felony
882 of the second degree, punishable as provided in s. 775.082, s.
883 775.083, or s. 775.084.

884 (7) ~~499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION
885 ~~LEGEND~~ DRUGS.--A person who knowingly sells, purchases,
886 manufactures, delivers, or brings into this state, or who is
887 knowingly in actual or constructive possession of any amount of
888 contraband prescription ~~legend~~ drugs valued at \$25,000 or more
889 commits a felony of the first degree, punishable as provided in
890 s. 775.082, s. 775.083, or s. 775.084.

891 (a) Upon conviction, each defendant shall be ordered to pay
892 a mandatory fine according to the following schedule:

893 1.~~(1)~~ If the value of contraband prescription ~~legend~~ drugs
894 involved is \$25,000 or more, but less than \$100,000, the
895 defendant shall pay a mandatory fine of \$25,000. If the defendant
896 is a corporation or other person that is not a natural person, it
897 shall pay a mandatory fine of \$75,000.

898 2.~~(2)~~ If the value of contraband prescription ~~legend~~ drugs
899 involved is \$100,000 or more, but less than \$250,000, the

588-06443-08

20082756c1

900 defendant shall pay a mandatory fine of \$100,000. If the
901 defendant is a corporation or other person that is not a natural
902 person, it shall pay a mandatory fine of \$300,000.

903 3.~~(3)~~ If the value of contraband prescription ~~legend~~ drugs
904 involved is \$250,000 or more, the defendant shall pay a mandatory
905 fine of \$200,000. If the defendant is a corporation or other
906 person that is not a natural person, it shall pay a mandatory
907 fine of \$600,000.

908 (b) As used in this subsection ~~section~~, the term "value"
909 means the market value of the property at the time and place of
910 the offense or, if such cannot be satisfactorily ascertained, the
911 cost of replacement of the property within a reasonable time
912 after the offense. Amounts of value of separate contraband
913 prescription ~~legend~~ drugs involved in distinct transactions for
914 the distribution of the contraband prescription ~~legend~~ drugs
915 committed pursuant to one scheme or course of conduct, whether
916 involving the same person or several persons, may be aggregated
917 in determining the punishment of the offense.

918 (8)~~(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION
919 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,
920 or falsely creates any prescription label or prescription ~~legend~~
921 drug label, or who falsely represents any factual matter
922 contained on any prescription label or prescription ~~legend~~ drug
923 label, commits a felony of the first degree, punishable as
924 provided in s. 775.082, s. 775.083, or s. 775.084.

925 (9)~~499.00535~~ KNOWING Sale or purchase of contraband
926 prescription ~~legend~~ drugs resulting in great bodily harm.--A
927 person who knowingly sells, purchases, manufactures, delivers, or
928 brings into this state, or who is knowingly in actual or

588-06443-08

20082756c1

929 constructive possession of any amount of contraband prescription
930 ~~legend~~ drugs, and whose acts in violation of this subsection
931 ~~section~~ result in great bodily harm to a person, commits a felony
932 of the first degree, as provided in s. 775.082, s. 775.083, or s.
933 775.084.

934 (10)499.00545 Knowing Sale or purchase of contraband
935 prescription ~~legend~~ drugs resulting in death.--A person who
936 knowingly manufactures, sells, purchases, delivers, or brings
937 into this state, or who is knowingly in actual or constructive
938 possession of any amount of contraband prescription ~~legend~~ drugs,
939 and whose acts in violation of this subsection ~~section~~ result in
940 the death of a person, commits a felony of the first degree,
941 punishable by a term of years not exceeding life, as provided in
942 s. 775.082, s. 775.083, or s. 775.084.

943 (11)499.069 ~~Criminal punishment for~~ VIOLATIONS OF S.
944 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE
945 ADVERTISEMENT.--

946 (a)(1) Any person who violates any of the provisions of s.
947 499.005 with respect to a device or cosmetic commits a
948 misdemeanor of the second degree, punishable as provided in s.
949 775.082 or s. 775.083; but, if the violation is committed after a
950 conviction of such person under this subsection ~~section~~ has
951 become final, such person is guilty of a misdemeanor of the first
952 degree, punishable as provided in s. 775.082 or s. 775.083 or as
953 otherwise provided in this part ~~ss. 499.001-499.081~~, except that
954 any person who violates s. 499.005(8) or (10) ~~subsection (8) or~~
955 ~~subsection (10) of s. 499.005~~ with respect to a device or
956 cosmetic commits a felony of the third degree, punishable as
957 provided in s. 775.082, s. 775.083, or s. 775.084, or as

588-06443-08

20082756c1

958 otherwise provided in this part ~~ss. 499.001-499.081~~.

959 ~~(b)(2)~~ A publisher, radio broadcast licensee, or agency or
960 medium for the dissemination of an advertisement, except the
961 manufacturer, wholesaler, or seller of the article to which a
962 false advertisement relates, is not liable under this subsection
963 ~~section~~ by reason of the dissemination by him or her of such
964 false advertisement, unless he or she has refused, on the request
965 of the department, to furnish to the department the name and post
966 office address of the manufacturer, wholesaler, seller, or
967 advertising agency that asked him or her to disseminate such
968 advertisement.

969 ~~(12) 499.0691~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
970 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS

971 ~~Criminal punishment for violations related to drugs;~~
972 ~~dissemination of false advertisement.--(1)~~ Any person who
973 violates any of the following provisions commits a misdemeanor of
974 the second degree, punishable as provided in s. 775.082 or s.
975 775.083; but, if the violation is committed after a conviction of
976 such person under this subsection ~~section~~ has become final, such
977 person commits a misdemeanor of the first degree, punishable as
978 provided in s. 775.082 or s. 775.083, or as otherwise provided in
979 this part ~~ss. 499.001-499.081~~:

980 (a) The manufacture, repackaging, sale, delivery, or
981 holding or offering for sale of any drug that is adulterated or
982 misbranded or has otherwise been rendered unfit for human or
983 animal use.

984 (b) The adulteration or misbranding of any drug intended
985 for further distribution.

986 (c) The receipt of any drug that is adulterated or

588-06443-08

20082756c1

987 misbranded, and the delivery or proffered delivery of such drug,
988 for pay or otherwise.

989 (d) The dissemination of any false or misleading
990 advertisement of a drug.

991 (e) The use, on the labeling of any drug or in any
992 advertisement relating to such drug, of any representation or
993 suggestion that an application of the drug is effective when it
994 is not or that the drug complies with this part ~~ss. 499.001-~~
995 ~~499.081~~ when it does not.

996 (f) The purchase or receipt of a compressed medical gas
997 from a person that is not authorized under this chapter to
998 distribute compressed medical gases.

999 (g) Charging a dispensing fee for dispensing,
1000 administering, or distributing a prescription drug sample.

1001 (h) The failure to maintain records related to a drug as
1002 required by this part ~~ss. 499.001-499.081~~ and rules adopted under
1003 this part ~~those sections~~, except for pedigree papers, invoices,
1004 or shipping documents related to prescription ~~legend~~ drugs.

1005 (i) The possession of any drug in violation of this part
1006 ~~ss. 499.001-499.081~~, except if the violation relates to a
1007 deficiency in pedigree papers.

1008 (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
1009 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
1010 PRESCRIPTION DRUGS.--(2) Any person who violates any of the
1011 following provisions commits a felony of the third degree,
1012 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
1013 or as otherwise provided in this part: ~~ss. 499.001-499.081~~.

1014 (a) The refusal or constructive refusal to allow:

1015 1. The department to enter or inspect an establishment in

588-06443-08

20082756c1

1016 which drugs are manufactured, processed, repackaged, sold,
1017 brokered, or held;

1018 2. Inspection of any record of that establishment;

1019 3. The department to enter and inspect any vehicle that is
1020 being used to transport drugs; or

1021 4. The department to take samples of any drug.

1022 (b) The sale, purchase, or trade, or the offer to sell,
1023 purchase, or trade, a drug sample as defined in s. 499.028; the
1024 distribution of a drug sample in violation of s. 499.028; or the
1025 failure to otherwise comply with s. 499.028.

1026 (c) Providing the department with false or fraudulent
1027 records, or making false or fraudulent statements, regarding any
1028 matter within the provisions of this part ~~chapter~~ related to a
1029 drug.

1030 (d) The failure to receive, maintain, or provide invoices
1031 and shipping documents, other than pedigree papers, if
1032 applicable, related to the distribution of a prescription legend
1033 drug.

1034 (e) The importation of a prescription legend drug for
1035 wholesale distribution, except as provided by s. 801(d) of the
1036 Federal Food, Drug, and Cosmetic Act.

1037 (f) The wholesale distribution of a ~~any~~ prescription drug
1038 that was:

1039 1. Purchased by a public or private hospital or other
1040 health care entity; or

1041 2. Donated or supplied at a reduced price to a charitable
1042 organization.

1043 (g) The failure to obtain a permit as a prescription drug
1044 wholesale distributor ~~wholesaler~~ when a permit is required by

588-06443-08

20082756c1

1045 this part ~~ss. 499.001-499.081~~ for that activity.

1046 (h) Knowingly possessing any adulterated or misbranded
1047 prescription legend drug outside of a designated quarantine area.

1048 (i) The purchase or sale of a prescription drug ~~drugs~~ for
1049 wholesale distribution in exchange for currency, as defined in s.
1050 560.103(6).

1051 (14) OTHER VIOLATIONS.--(3) Any person who violates any of
1052 the following provisions commits a felony of the second degree,
1053 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
1054 or as otherwise provided in this part: ~~ss. 499.001-499.081~~.

1055 (a) Knowingly manufacturing, repackaging, selling,
1056 delivering, or holding or offering for sale any drug that is
1057 adulterated or misbranded or has otherwise been rendered unfit
1058 for human or animal use.

1059 (b) Knowingly adulterating a drug that is intended for
1060 further distribution.

1061 (c) Knowingly receiving a drug that is adulterated and
1062 delivering or proffering delivery of such drug for pay or
1063 otherwise.

1064 (d) Committing any act that causes a drug to be a
1065 counterfeit drug, or selling, dispensing, or knowingly holding
1066 for sale a counterfeit drug.

1067 (e) Forging, counterfeiting, simulating, or falsely
1068 representing any drug, or, without the authority of the
1069 manufacturer, using any mark, stamp, tag, label, or other
1070 identification device authorized or required by rules adopted
1071 under this part ~~ss. 499.001-499.081~~.

1072 (f) Knowingly obtaining or attempting to obtain a
1073 prescription drug for wholesale distribution by fraud, deceit,

588-06443-08

20082756c1

1074 misrepresentation, or subterfuge, or engaging in
1075 misrepresentation or fraud in the distribution of a drug.

1076 (g) Removing a pharmacy's dispensing label from a dispensed
1077 prescription drug with the intent to further distribute the
1078 prescription drug.

1079 (h) Knowingly distributing a prescription drug that was
1080 previously dispensed by a licensed pharmacy, unless such
1081 distribution was authorized in chapter 465 or the rules adopted
1082 under chapter 465.

1083 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio
1084 broadcast licensee, or agency or medium for the dissemination of
1085 an advertisement, except the manufacturer, repackager, wholesale
1086 distributor ~~wholesaler~~, or seller of the article to which a false
1087 advertisement relates, is not liable under subsection (12),
1088 subsection (13), or subsection (14) ~~this section~~ by reason of the
1089 dissemination by him or her of such false advertisement, unless
1090 he or she has refused, on the request of the department, to
1091 furnish to the department the name and post office address of the
1092 manufacturer, repackager, wholesale distributor ~~wholesaler~~,
1093 seller, or advertising agency that asked him or her to
1094 disseminate such advertisement.

1095 Section 5. Section 499.0054, Florida Statutes, is amended;
1096 section 499.0055, Florida Statutes, is redesignated as subsection
1097 (2) of that section and amended; and section 499.0057, Florida
1098 Statutes, is redesignated as subsection (3) of that section and
1099 amended, to read:

1100 499.0054 Advertising and labeling of drugs, devices, and
1101 cosmetics; exemptions.--

1102 (1) It is a violation of the Florida Drug and Cosmetic Act

588-06443-08

20082756c1

1103 to perform or cause the performance of any of the following acts:

1104 (a)~~(1)~~ The dissemination of any false advertisement of any
1105 drug, device, or cosmetic. An advertisement is false if it is
1106 false or misleading in any way.

1107 (b)~~(2)~~ The distribution in commerce of any drug, device, or
1108 cosmetic, if its labeling or advertising is in violation of this
1109 part ~~ss. 499.001-499.081~~.

1110 (c)~~(3)~~ The manufacturing, repackaging, packaging, selling,
1111 delivery, holding, or offering for sale of any drug, device, or
1112 cosmetic for which the advertising or labeling is false or
1113 misleading.

1114 (d)~~(4)~~ The advertising of any drug, device, or cosmetic
1115 that is adulterated or misbranded.

1116 (e)~~(5)~~ The receiving in commerce of any drug, device, or
1117 cosmetic that is falsely advertised or labeled or the delivering
1118 or proffering for delivery of any such drug, device, or cosmetic.

1119 (f)~~(6)~~ The advertising or labeling of any product
1120 containing ephedrine, a salt of ephedrine, an isomer of
1121 ephedrine, or a salt of an isomer of ephedrine, for the
1122 indication of stimulation, mental alertness, weight loss,
1123 appetite control, energy, or other indications not approved by
1124 the pertinent United States Food and Drug Administration Over-
1125 the-Counter Final or Tentative Final Monograph or approved new
1126 drug application under the federal act. In determining compliance
1127 with this requirement, the department may consider the following
1128 factors:

1129 1.~~(a)~~ The packaging of the product.

1130 2.~~(b)~~ The name and labeling of the product.

1131 3.~~(c)~~ The manner of distribution, advertising, and

588-06443-08

20082756c1

1132 promotion of the product, including verbal representations at the
1133 point of sale.

1134 4.~~(d)~~ The duration, scope, and significance of abuse of the
1135 particular product.

1136 (g)~~(7)~~ The advertising of any drug or device represented to
1137 have any effect in any of the following conditions, disorders,
1138 diseases, or processes:

1139 1.~~(a)~~ Blood disorders.

1140 2.~~(b)~~ Bone or joint diseases.

1141 3.~~(c)~~ Kidney diseases or disorders.

1142 4.~~(d)~~ Cancer.

1143 5.~~(e)~~ Diabetes.

1144 6.~~(f)~~ Gall bladder diseases or disorders.

1145 7.~~(g)~~ Heart and vascular diseases.

1146 8.~~(h)~~ High blood pressure.

1147 9.~~(i)~~ Diseases or disorders of the ear or auditory
1148 apparatus, including hearing loss or deafness.

1149 10.~~(j)~~ Mental disease or mental retardation.

1150 11.~~(k)~~ Paralysis.

1151 12.~~(l)~~ Prostate gland disorders.

1152 13.~~(m)~~ Conditions of the scalp affecting hair loss.

1153 14.~~(n)~~ Baldness.

1154 15.~~(o)~~ Endocrine disorders.

1155 16.~~(p)~~ Sexual impotence.

1156 17.~~(q)~~ Tumors.

1157 18.~~(r)~~ Venereal diseases.

1158 19.~~(s)~~ Varicose ulcers.

1159 20.~~(t)~~ Breast enlargement.

1160 21.~~(u)~~ Purifying blood.

588-06443-08

20082756c1

1161 22.~~(v)~~ Metabolic disorders.
 1162 23.~~(w)~~ Immune system disorders or conditions affecting the
 1163 immune system.

1164 24.~~(x)~~ Extension of life expectancy.

1165 25.~~(y)~~ Stress and tension.

1166 26.~~(z)~~ Brain stimulation or performance.

1167 27.~~(aa)~~ The body's natural defense mechanisms.

1168 28.~~(bb)~~ Blood flow.

1169 29.~~(cc)~~ Depression.

1170 30.~~(dd)~~ Human immunodeficiency virus or acquired immune
 1171 deficiency syndrome or related disorders or conditions.

1172 (h)~~(8)~~ The representation or suggestion in labeling or
 1173 advertising that an article is approved under this part ~~ss.~~
 1174 ~~499.001-499.081~~, when such is not the case.

1175 (2)~~499.0055~~ ~~False or misleading advertisement.~~—In
 1176 determining whether an advertisement is false or misleading, the
 1177 department shall review the representations made or suggested by
 1178 statement, word, design, device, sound, or any combination
 1179 thereof within the advertisement and the extent to which the
 1180 advertisement fails to reveal material facts with respect to
 1181 consequences that can result from the use of the drug, device, or
 1182 cosmetic to which the advertisement relates under the conditions
 1183 of use prescribed in the labeling or advertisement.

1184 (3)~~499.0057~~ ~~Advertisement exemptions.~~—

1185 (a)~~(1)~~ An advertisement that is not prohibited under
 1186 paragraph (1) (a) ~~s. 499.0054(1)~~ is not prohibited under paragraph
 1187 (1) (g) ~~s. 499.0054(7)~~ if it is disseminated:

1188 1. To the public solely to advertise the product for those
 1189 indications that are safe and effective indications and the

588-06443-08

20082756c1

1190 product is safe and effective for self-medication, as established
1191 by the United States Food and Drug Administration; or

1192 2. ~~if it is disseminated~~ Only to members of the medical,
1193 dental, pharmaceutical, or veterinary professions or appears only
1194 in the scientific periodicals of these professions.

1195 (b)(2) Compliance with this part ~~ss. 499.001-499.081~~ and
1196 the rules adopted under this part ~~these sections~~ creates no legal
1197 presumption that a drug or device is safe or effective.

1198 Section 6. Subsections (3), (10), and (11) of section
1199 499.006, Florida Statutes, are amended to read:

1200 499.006 Adulterated drug or device.--A drug or device is
1201 adulterated:

1202 (3) If it is a drug and the methods used in, or the
1203 facilities or controls used for, its manufacture, processing,
1204 packing, or holding do not conform to, or are not operated or
1205 administered in conformity with, current good manufacturing
1206 practices to assure that the drug meets the requirements of this
1207 part ~~ss. 499.001-499.081~~ and that the drug has the identity and
1208 strength, and meets the standard of quality and purity, which it
1209 purports or is represented to possess;

1210 (10) If it is a prescription legend ~~legend~~ drug for which the
1211 required pedigree paper is nonexistent, fraudulent, or incomplete
1212 under the requirements of this part ~~ss. 499.001-499.081~~ or
1213 applicable rules, or that has been purchased, held, sold, or
1214 distributed at any time by a person not authorized under federal
1215 or state law to do so; or

1216 (11) If it is a prescription drug subject to, defined by,
1217 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1218 Act which has been returned by a veterinarian to a limited

588-06443-08

20082756c1

1219 prescription drug veterinary wholesale distributor ~~wholesaler~~.

1220 Section 7. Section 499.007, Florida Statutes, is amended to
1221 read:

1222 499.007 Misbranded drug or device.--A drug or device is
1223 misbranded:

1224 (1) If its labeling is in any way false or misleading.

1225 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1226 label containing:

1227 (a) The name and place of business of the manufacturer,
1228 repackager, or distributor of the finished dosage form of the
1229 drug. For the purpose of this paragraph, the finished dosage form
1230 of a prescription medicinal ~~medicinal~~ drug is that form of the drug which
1231 is, or is intended to be, dispensed or administered to the
1232 patient and requires no further manufacturing or processing other
1233 than packaging, reconstitution, and labeling; and

1234 (b) An accurate statement of the quantity of the contents
1235 in terms of weight, measure, or numerical count.~~;~~ However, under
1236 this section, reasonable variations are permitted, and the
1237 department shall establish by rule exemptions for small packages.

1238 (3) If it is an active pharmaceutical ingredient in bulk
1239 form and does not bear a label containing:

1240 (a) The name and place of business of the manufacturer,
1241 repackager, or distributor; and

1242 (b) An accurate statement of the quantity of the contents
1243 in terms of weight, measure, or numerical count.

1244 ~~(4)-(3)~~ If any word, statement, or other information
1245 required by or under this part ~~ss. 499.001-499.081~~ to appear on
1246 the label or labeling is not prominently placed thereon with such
1247 conspicuousness as compared with other words, statements,

588-06443-08

20082756c1

1248 designs, or devices in the labeling, and in such terms, as to
1249 render the word, statement, or other information likely to be
1250 read and understood under customary conditions of purchase and
1251 use.

1252 (5)~~(4)~~ If it is a drug and is not designated solely by a
1253 name recognized in an official compendium and,~~unless~~ its label
1254 does not bear ~~bears~~:

1255 (a) The common or usual name of the drug, if any; and

1256 (b) In case it is fabricated from two or more ingredients,
1257 the common or usual name and quantity of each active ingredient.

1258 (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

1259 (a) Adequate directions for use; and

1260 (b) Adequate warnings against use in those pathological
1261 conditions in which its use may be dangerous to health or against
1262 use by children if its use may be dangerous to health, or against
1263 unsafe dosage or methods or duration of administration or
1264 application, in such manner and form as are necessary for the
1265 protection of users.

1266 (7)~~(6)~~ If it purports to be a drug the name of which is
1267 recognized in the official compendium and,~~unless~~ it is not
1268 packaged and labeled as prescribed therein.~~;~~ However, the method
1269 of packaging may be modified with the consent of the department.

1270 (8)~~(7)~~ If it has been found by the department to be a drug
1271 liable to deterioration and,~~unless~~ it is not packaged in such
1272 form and manner, and its label bears a statement of such
1273 precautions, as the department by rule requires as necessary to
1274 protect the public health. Such rule may not be established for
1275 any drug recognized in an official compendium until the
1276 department has informed the appropriate body charged with the

588-06443-08

20082756c1

1277 revision of such compendium of the need for such packaging or
1278 labeling requirements and that body has failed within a
1279 reasonable time to prescribe such requirements.

1280 (9)~~(8)~~ If it is:

1281 (a) A drug and its container or finished dosage form is so
1282 made, formed, or filled as to be misleading;

1283 (b) An imitation of another drug; or

1284 (c) Offered for sale under the name of another drug.

1285 (10)~~(9)~~ If it is dangerous to health when used in the
1286 dosage or with the frequency or duration prescribed, recommended,
1287 or suggested in the labeling of the drug.

1288 (11)~~(10)~~ If it is, purports to be, or is represented as a
1289 drug composed wholly or partly of insulin and~~, unless:~~

1290 ~~(a)~~ it is not from a batch with respect to which a
1291 certificate has been issued pursuant to s. 506 of the federal
1292 act, which~~; and~~

1293 ~~(b)~~ ~~The~~ certificate is in effect with respect to the drug.

1294 (12)~~(11)~~ If it is, purports to be, or is represented as a
1295 drug composed wholly or partly of any kind of antibiotic
1296 requiring certification under the federal act and ~~unless:~~

1297 ~~(a)~~ it is not from a batch with respect to which a
1298 certificate has been issued pursuant to s. 507 of the federal
1299 act, which~~; and~~

1300 ~~(b)~~ the certificate is in effect with respect to the drug.~~†~~

1301

1302 However, this subsection does not apply to any drug or class of
1303 drugs exempted by regulations adopted under s. 507(c) or (d) of
1304 the federal act.

1305 (13)~~(12)~~ If it is a drug intended for use by humans which

588-06443-08

20082756c1

1306 is a habit-forming drug or which, because of its toxicity or
1307 other potentiality for harmful effect, or the method of its use,
1308 or the collateral measures necessary to its use, is not safe for
1309 use except under the supervision of a practitioner licensed by
1310 law to administer such drugs, + or which is limited by an
1311 effective application under s. 505 of the federal act to use
1312 under the professional supervision of a practitioner licensed by
1313 law to prescribe such drug, if ~~unless~~ it is not dispensed only:

1314 (a) Upon the written prescription of a practitioner
1315 licensed by law to prescribe such drug;

1316 (b) Upon an oral prescription of such practitioner, which
1317 is reduced promptly to writing and filled by the pharmacist; or

1318 (c) By refilling any such written or oral prescription, if
1319 such refilling is authorized by the prescriber either in the
1320 original prescription or by oral order which is reduced promptly
1321 to writing and filled by the pharmacist.

1322

1323 This subsection does not relieve any person from any requirement
1324 prescribed by law with respect to controlled substances as
1325 defined in the applicable federal and state laws.

1326 ~~(14)-(13)~~ (13)-(12) If it is a drug that is subject to paragraph
1327 ~~(13)-(12)~~ (a), and if, at any time before it is dispensed, its
1328 label does not ~~fails to~~ bear the statement:

1329 (a) "Caution: Federal Law Prohibits Dispensing Without
1330 Prescription";

1331 (b) "Rx Only";

1332 (c) The prescription symbol followed by the word "Only"; or

1333 (d) "Caution: State Law Prohibits Dispensing Without
1334 Prescription."

588-06443-08

20082756c1

1335 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph
1336 ~~(13)-(12)~~(a), if at any time before it is dispensed its label
1337 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.

1338 ~~(16)-(15)~~ If it is a color additive, the intended use of
1339 which in or on drugs is for the purpose of coloring only and,
1340 ~~unless~~ its packaging and labeling are not in conformity with the
1341 packaging and labeling requirements that apply to such color
1342 additive and are prescribed under the federal act.

1343 (17) A drug dispensed by filling or refilling a written or
1344 oral prescription of a practitioner licensed by law to prescribe
1345 such drug is exempt from the requirements of this section, except
1346 subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the
1347 packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the
1348 drug bears a label that contains the name and address of the
1349 dispenser or seller, the prescription number and the date the
1350 prescription was written or filled, the name of the prescriber
1351 and the name of the patient, and the directions for use and
1352 cautionary statements. This exemption does not apply to any drug
1353 dispensed in the course of the conduct of a business of
1354 dispensing drugs pursuant to diagnosis by mail or to any drug
1355 dispensed in violation of subsection (13) ~~(12)~~. The department
1356 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~
1357 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that
1358 subsection is not necessary to protect the public health, safety,
1359 and welfare.

1360 Section 8. Subsection (1) of section 499.008, Florida
1361 Statutes, is amended and subsection (5) is added to that section
1362 to read:

1363 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

588-06443-08

20082756c1

1364 (1) If it bears or contains any poisonous or deleterious
1365 substance that is injurious to users under the conditions of use
1366 prescribed in the labeling or advertisement thereof or under such
1367 conditions of use as are customary or usual; however, this
1368 subsection does not apply to coal-tar hair dye:

1369 (a) The label of which bears the following legend
1370 conspicuously displayed thereon: "Caution: This product contains
1371 ingredients which may cause skin irritation on certain
1372 individuals, and a preliminary test according to accompanying
1373 directions should first be made. This product must not be used
1374 for dyeing the eyelashes or eyebrows; to do so may cause
1375 blindness"; and

1376 (b) The labeling of which bears adequate directions for
1377 such preliminary testing.

1378
1379 ~~For the purposes of this subsection and subsection (4), the term~~
1380 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1381 (5) For the purposes of subsections (1) and (4), the term
1382 "hair dye" does not include eyelash dyes or eyebrow dyes.

1383 Section 9. Subsections (2), (3), and (5) of section
1384 499.009, Florida Statutes, are amended to read:

1385 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1386 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1387 label containing:

1388 (a) The name and place of business of the manufacturer,
1389 packer, or distributor;

1390 (b) An accurate statement of the quantity of the contents
1391 in terms of weight, measure, or numerical count; however, under
1392 this paragraph reasonable variations are permitted, and the

588-06443-08

20082756c1

1393 department shall establish by rule exemptions for small packages;
1394 and

1395 (c) A declaration of ingredients in descending order of
1396 predominance, or as otherwise required by federal law.

1397 (3) If any word, statement, or other information required
1398 by or under authority of this part ~~ss. 499.001-499.081~~ to appear
1399 on the label or labeling is not prominently placed thereon with
1400 such conspicuousness as compared with other words, statements,
1401 designs, or devices in the labeling, and in such terms, as to
1402 render the word, statement, or other information likely to be
1403 read and understood by an individual under customary conditions
1404 of purchase and use.

1405 (5) ~~Unless,~~ If it is a color additive, its packaging and
1406 labeling are not in conformity with the packaging and labeling
1407 requirements applicable to that color additive prescribed under
1408 the federal act. This subsection does not apply to packages of
1409 color additives that, with respect to their use for cosmetics,
1410 are marketed and intended for use only in or on hair dyes.

1411 Section 10. Section 499.01, Florida Statutes, is amended;
1412 the introductory paragraph and paragraphs (a) through (h) of
1413 subsection (2) of section 499.012, Florida Statutes, are
1414 redesignated as the introductory paragraph and paragraphs (d),
1415 (n), (e), (f), (c), (i), (k), and (l), respectively, of
1416 subsection (2) of that section and amended; paragraphs (b)
1417 through (e) of subsection (2) of section 499.013, Florida
1418 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),
1419 respectively, of subsection (2) of that section and amended; and
1420 section 499.014, Florida Statutes, is redesignated as paragraph
1421 (g) of subsection (2) of that section and amended, to read:

588-06443-08

20082756c1

1422 499.01 Permits; ~~applications; renewal; general~~
1423 ~~requirements.--~~

1424 (1) Prior to operating, a permit is required for each
1425 person and establishment that intends to operate as:

1426 (a) A prescription drug manufacturer;
1427 (b) A prescription drug repackager;
1428 (c) A nonresident prescription drug manufacturer;
1429 (d) A prescription drug wholesale distributor;
1430 (e) An out-of-state prescription drug wholesale
1431 distributor;

1432 (f) A retail pharmacy drug wholesale distributor;
1433 (g) A restricted prescription drug distributor;
1434 (h) A complimentary drug distributor;
1435 (i) A freight forwarder;
1436 (j) A veterinary prescription drug retail establishment;
1437 (k) A veterinary prescription drug wholesale distributor;
1438 (l) A limited prescription drug veterinary wholesale
1439 distributor;

1440 (m) A medical oxygen retail establishment;
1441 (n) A compressed medical gas wholesale distributor;
1442 (o) A compressed medical gas manufacturer;
1443

~~(p)(e) An over-the-counter drug manufacturer;~~
1444 ~~(d) A compressed medical gas manufacturer;~~
1445 ~~(q)(e) A device manufacturer; or~~
1446 ~~(r)(f) A cosmetic manufacturer.~~
1447 ~~(g) A prescription drug wholesaler;~~
1448 ~~(h) A veterinary prescription drug wholesaler;~~
1449 ~~(i) A compressed medical gas wholesaler;~~
1450 ~~(j) An out-of-state prescription drug wholesaler;~~

588-06443-08

20082756c1

- 1451 ~~(k) A nonresident prescription drug manufacturer;~~
1452 ~~(l) A freight forwarder;~~
1453 ~~(m) A retail pharmacy drug wholesaler;~~
1454 ~~(n) A veterinary legend drug retail establishment;~~
1455 ~~(o) A medical oxygen retail establishment;~~
1456 ~~(p) A complimentary drug distributor;~~
1457 ~~(q) A restricted prescription drug distributor; or~~
1458 ~~(r) A limited prescription drug veterinary wholesaler.~~

1459 (2) The following ~~types of wholesaler~~ permits are
1460 established:

1461 (a) Prescription drug manufacturer permit.--A prescription
1462 drug manufacturer permit is required for any person that
1463 manufactures a prescription drug in this state.

1464 1. A person that operates an establishment permitted as a
1465 prescription drug manufacturer may engage in wholesale
1466 distribution of prescription drugs manufactured at that
1467 establishment and must comply with all the provisions of this
1468 part and the rules adopted under this part that apply to a
1469 wholesale distributor.

1470 2. A prescription drug manufacturer must comply with all
1471 appropriate state and federal good manufacturing practices.

1472 (b) Prescription drug repackager permit.--A prescription
1473 drug repackager permit is required for any person that repackages
1474 a prescription drug in this state.

1475 1. A person that operates an establishment permitted as a
1476 prescription drug repackager may engage in wholesale distribution
1477 of prescription drugs repackaged at that establishment and must
1478 comply with all the provisions of this part and the rules adopted
1479 under this part that apply to a wholesale distributor.

588-06443-08

20082756c1

1480 2. A prescription drug repackager must comply with all
1481 appropriate state and federal good manufacturing practices.

1482 ~~(c) (e)~~ Nonresident prescription drug manufacturer
1483 permit.--A nonresident prescription drug manufacturer permit is
1484 required for any person that is a manufacturer of prescription
1485 drugs, or the distribution point for a manufacturer of
1486 prescription drugs, and located outside of this state, or that is
1487 an entity to whom an approved new drug application has been
1488 issued by the United States Food and Drug Administration, or the
1489 contracted manufacturer of the approved new drug application
1490 holder, and located outside the United States, which engages in
1491 the wholesale distribution in this state of the prescription
1492 drugs it manufactures or is responsible for manufacturing. Each
1493 such manufacturer or entity must be permitted by the department
1494 and comply with all the provisions required of a wholesale
1495 distributor under this part ss. 499.001-499.081, except s.
1496 499.01212 s. 499.0121(6) (d).

1497 1. A person that distributes prescription drugs that it did
1498 not manufacture must also obtain an out-of-state prescription
1499 drug wholesale distributor wholesaler permit pursuant to this
1500 section to engage in the wholesale distribution of the
1501 prescription drugs manufactured by another person and comply with
1502 the requirements of an out-of-state prescription drug wholesale
1503 distributor wholesaler.

1504 2. Any such person must comply with the licensing or
1505 permitting requirements of the jurisdiction in which the
1506 establishment is located and the federal act, and any product
1507 wholesaled into this state must comply with this part ss.
1508 ~~499.001-499.081~~. If a person intends to import prescription drugs

588-06443-08

20082756c1

1509 | from a foreign country into this state, the nonresident
1510 | prescription drug manufacturer must provide to the department a
1511 | list identifying each prescription drug it intends to import and
1512 | document approval by the United States Food and Drug
1513 | Administration for such importation.

1514 | (d)(a) A Prescription drug wholesale distributor
1515 | ~~wholesaler's~~ permit.--A prescription drug wholesale distributor
1516 | ~~wholesaler~~ is a wholesale distributor that may engage in the
1517 | wholesale distribution of prescription drugs. A prescription drug
1518 | wholesale distributor ~~wholesaler~~ that applies to the department
1519 | for a new permit or the renewal of a permit must submit a bond of
1520 | \$100,000, or other equivalent means of security acceptable to the
1521 | department, such as an irrevocable letter of credit or a deposit
1522 | in a trust account or financial institution, payable to the
1523 | Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
1524 | bond is to secure payment of any administrative penalties imposed
1525 | by the department and any fees and costs incurred by the
1526 | department regarding that permit which are authorized under state
1527 | law and which the permittee fails to pay 30 days after the fine
1528 | or costs become final. The department may make a claim against
1529 | such bond or security until 1 year after the permittee's license
1530 | ceases to be valid or until 60 days after any administrative or
1531 | legal proceeding authorized in this part ~~ss. 499.001-499.081~~
1532 | which involves the permittee is concluded, including any appeal,
1533 | whichever occurs later. The department may adopt rules for
1534 | issuing a prescription drug wholesale distributor-broker
1535 | ~~wholesaler-broker~~ permit to a person who engages in the wholesale
1536 | distribution of prescription drugs and does not take physical
1537 | possession of any prescription drugs.

588-06443-08

20082756c1

1538 (e) ~~(e)~~ An Out-of-state prescription drug wholesale
1539 distributor ~~wholesaler's~~ permit.--An out-of-state prescription
1540 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor
1541 located outside this state which engages in the wholesale
1542 distribution of prescription drugs into this state and which must
1543 be permitted by the department and comply with all the provisions
1544 required of a wholesale distributor under this part ~~ss. 499.001-~~
1545 ~~499.081~~. An out-of-state prescription drug wholesale distributor
1546 ~~wholesaler~~ that applies to the department for a new permit or the
1547 renewal of a permit must submit a bond of \$100,000, or other
1548 equivalent means of security acceptable to the department, such
1549 as an irrevocable letter of credit or a deposit in a trust
1550 account or financial institution, payable to the Florida Drug,
1551 Device, and Cosmetic Trust Fund. The purpose of the bond is to
1552 secure payment of any administrative penalties imposed by the
1553 department and any fees and costs incurred by the department
1554 regarding that permit which are authorized under state law and
1555 which the permittee fails to pay 30 days after the fine or costs
1556 become final. The department may make a claim against such bond
1557 or security until 1 year after the permittee's license ceases to
1558 be valid or until 60 days after any administrative or legal
1559 proceeding authorized in this part ~~ss. 499.001-499.081~~ which
1560 involves the permittee is concluded, including any appeal,
1561 whichever occurs later.

1562 1. The out-of-state prescription drug wholesale distributor
1563 ~~wholesaler~~ must maintain at all times a license or permit to
1564 engage in the wholesale distribution of prescription drugs in
1565 compliance with laws of the state in which it is a resident.

1566 2. An out-of-state prescription drug wholesale distributor

588-06443-08

20082756c1

1567 ~~wholesaler's~~ permit is not required for an intracompany sale or
1568 transfer of a prescription drug from an out-of-state
1569 establishment that is duly licensed as a prescription drug
1570 wholesale distributor ~~wholesaler~~, in its state of residence, to a
1571 licensed prescription drug wholesale distributor ~~wholesaler~~ in
1572 this state, if both wholesale distributors ~~wholesalers~~ conduct
1573 wholesale distributions of prescription drugs under the same
1574 business name. The recordkeeping requirements of ss. s.
1575 499.0121(6) and 499.01212 must be followed for this transaction.

1576 (f) ~~(d)~~ A Retail pharmacy drug wholesale distributor
1577 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale
1578 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale
1579 distribution of prescription drugs within this state under the
1580 following conditions:

1581 1. The pharmacy must obtain a retail pharmacy drug
1582 wholesale distributor ~~wholesaler's~~ permit pursuant to this part
1583 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~
1584 ~~sections~~.

1585 2. The wholesale distribution activity does not exceed 30
1586 percent of the total annual purchases of prescription drugs. If
1587 the wholesale distribution activity exceeds the 30-percent
1588 maximum, the pharmacy must obtain a prescription drug wholesale
1589 distributor ~~wholesaler's~~ permit.

1590 3. The transfer of prescription drugs that appear in any
1591 schedule contained in chapter 893 is subject to chapter 893 and
1592 the federal Comprehensive Drug Abuse Prevention and Control Act
1593 of 1970.

1594 4. The transfer is between a retail pharmacy and another
1595 retail pharmacy, or a Modified Class II institutional pharmacy,

588-06443-08

20082756c1

1596 or a health care practitioner licensed in this state and
1597 authorized by law to dispense or prescribe prescription drugs.

1598 5. All records of sales of prescription drugs subject to
1599 this section must be maintained separate and distinct from other
1600 records and comply with the recordkeeping requirements of this
1601 part ss. ~~499.001-499.081~~.

1602 (g) ~~499.014~~ Restricted prescription drug distributor permit
1603 Distribution of legend drugs by hospitals, health care entities,
1604 charitable organizations, and return or destruction companies;
1605 permits, general requirements.--

1606 ~~(1)~~ A restricted prescription drug distributor permit is
1607 required for any person that engages in the distribution of a
1608 prescription legend drug, which distribution is not considered
1609 "wholesale distribution" under s. 499.003(56)(a) ~~s.~~
1610 ~~499.012(1)(a)1~~.

1611 1. ~~(2)~~ A person who engages in the receipt or distribution
1612 of a prescription legend drug in this state for the purpose of
1613 processing its return or its destruction must obtain a permit as
1614 a restricted prescription drug distributor if such person is not
1615 the person initiating the return, the prescription drug wholesale
1616 supplier of the person initiating the return, or the manufacturer
1617 of the drug.

1618 2. ~~(3)~~ Storage, handling, and recordkeeping of these
1619 distributions must comply with the requirements for wholesale
1620 distributors under s. 499.0121, but not except those set forth in
1621 s. 499.01212 ~~s. 499.0121(6)(d)~~.

1622 3. ~~(4)~~ A person who applies for a permit as a restricted
1623 prescription drug distributor, or for the renewal of such a
1624 permit, must provide to the department the information required

588-06443-08

20082756c1

1625 under s. 499.012 ~~s. 499.01~~.

1626 ~~4.(5)~~ The department may ~~issue permits to restricted~~
1627 ~~prescription drug distributors and may~~ adopt rules regarding the
1628 distribution of prescription drugs by hospitals, health care
1629 entities, charitable organizations, or other persons not involved
1630 in wholesale distribution, which rules are necessary for the
1631 protection of the public health, safety, and welfare.

1632 (h) Complimentary drug distributor permit.--A complimentary
1633 drug distributor permit is required for any person that engages
1634 in the distribution of a complimentary drug, subject to the
1635 requirements of s. 499.028.

1636 (i) ~~(f)~~ Freight forwarder permit.--A freight forwarder
1637 permit is required for any person that engages in the
1638 distribution of a prescription ~~legend~~ drug as a freight forwarder
1639 unless the person is a common carrier. The storage, handling, and
1640 recordkeeping of such distributions must comply with the
1641 requirements for wholesale distributors under s. 499.0121, but
1642 not except those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~. A
1643 freight forwarder must provide the source of the prescription
1644 ~~legend~~ drugs with a validated airway bill, bill of lading, or
1645 other appropriate documentation to evidence the exportation of
1646 the product.

1647 (j) Veterinary prescription drug retail establishment
1648 permit.--A veterinary prescription drug retail establishment
1649 permit is required for any person that sells veterinary
1650 prescription drugs to the public but does not include a pharmacy
1651 licensed under chapter 465.

1652 1. The sale to the public must be based on a valid written
1653 order from a veterinarian licensed in this state who has a valid

588-06443-08

20082756c1

1654 client-veterinarian relationship with the purchaser's animal.

1655 2. Veterinary prescription drugs may not be sold in excess
1656 of the amount clearly indicated on the order or beyond the date
1657 indicated on the order.

1658 3. An order may not be valid for more than 1 year.

1659 4. A veterinary prescription drug retail establishment may
1660 not purchase, sell, trade, or possess human prescription drugs or
1661 any controlled substance as defined in chapter 893.

1662 5. A veterinary prescription drug retail establishment must
1663 sell a veterinary prescription drug in the original, sealed
1664 manufacturer's container with all labeling intact and legible.
1665 The department may adopt by rule additional labeling requirements
1666 for the sale of a veterinary prescription drug.

1667 6. A veterinary prescription drug retail establishment must
1668 comply with all of the wholesale distribution requirements of s.
1669 499.0121.

1670 7. Prescription drugs sold by a veterinary prescription
1671 drug retail establishment pursuant to a practitioner's order may
1672 not be returned into the retail establishment's inventory.

1673 (k) ~~(g)~~ A veterinary prescription drug wholesale distributor
1674 ~~wholesaler~~ permit.--A veterinary prescription drug wholesale
1675 distributor ~~wholesaler~~ permit is required for any person that
1676 engages in the distribution of veterinary prescription drugs in
1677 or into this state. A veterinary prescription drug wholesale
1678 distributor ~~wholesaler~~ that also distributes prescription drugs
1679 subject to, defined by, or described by s. 503(b) of the Federal
1680 Food, Drug, and Cosmetic Act which it did not manufacture must
1681 obtain a permit as a prescription drug wholesale distributor
1682 ~~wholesaler~~, an out-of-state prescription drug wholesale

588-06443-08

20082756c1

1683 distributor ~~wholesaler~~, or a limited prescription drug veterinary
1684 wholesale distributor ~~wholesaler~~ in lieu of the veterinary
1685 prescription drug wholesale distributor ~~wholesaler~~ permit. A
1686 veterinary prescription drug wholesale distributor ~~wholesaler~~
1687 must comply with the requirements for wholesale distributors
1688 under s. 499.0121, but not ~~except~~ those set forth in s. 499.01212
1689 ~~s. 499.0121(6)(d)~~.

1690 (1) ~~(h)~~ Limited prescription drug veterinary wholesale
1691 distributor ~~wholesaler~~ permit.--Unless engaging in the activities
1692 of and permitted as a prescription drug manufacturer, nonresident
1693 prescription drug manufacturer, prescription drug wholesale
1694 distributor ~~wholesaler~~, or out-of-state prescription drug
1695 wholesale distributor ~~wholesaler~~, a limited prescription drug
1696 veterinary wholesale distributor ~~wholesaler~~ permit is required
1697 for any person that engages in the distribution in or into this
1698 state of veterinary prescription drugs and prescription drugs
1699 subject to, defined by, or described by s. 503(b) of the Federal
1700 Food, Drug, and Cosmetic Act under the following conditions:

1701 1. The person is engaged in the business of wholesaling
1702 prescription and veterinary prescription ~~legend~~ drugs to persons:

1703 a. Licensed as veterinarians practicing on a full-time
1704 basis;

1705 b. Regularly and lawfully engaged in instruction in
1706 veterinary medicine;

1707 c. Regularly and lawfully engaged in law enforcement
1708 activities;

1709 d. For use in research not involving clinical use; or

1710 e. For use in chemical analysis or physical testing or for
1711 purposes of instruction in law enforcement activities, research,

588-06443-08

20082756c1

1712 | or testing.

1713 | 2. No more than 30 percent of total annual prescription
1714 | drug sales may be prescription drugs approved for human use which
1715 | are subject to, defined by, or described by s. 503(b) of the
1716 | Federal Food, Drug, and Cosmetic Act.

1717 | 3. The person does not distribute ~~is not permitted,~~
1718 | ~~licensed, or otherwise authorized~~ in any jurisdiction state to
1719 | ~~wholesale~~ prescription drugs subject to, defined by, or described
1720 | by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any
1721 | person who is authorized to sell, distribute, purchase, trade, or
1722 | use these drugs on or for humans.

1723 | 4. A limited prescription drug veterinary wholesale
1724 | distributor ~~wholesaler~~ that applies to the department for a new
1725 | permit or the renewal of a permit must submit a bond of \$20,000,
1726 | or other equivalent means of security acceptable to the
1727 | department, such as an irrevocable letter of credit or a deposit
1728 | in a trust account or financial institution, payable to the
1729 | Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
1730 | bond is to secure payment of any administrative penalties imposed
1731 | by the department and any fees and costs incurred by the
1732 | department regarding that permit which are authorized under state
1733 | law and which the permittee fails to pay 30 days after the fine
1734 | or costs become final. The department may make a claim against
1735 | such bond or security until 1 year after the permittee's license
1736 | ceases to be valid or until 60 days after any administrative or
1737 | legal proceeding authorized in this part ~~ss. 499.001-499.081~~
1738 | which involves the permittee is concluded, including any appeal,
1739 | whichever occurs later.

1740 | 5. A limited prescription drug veterinary wholesale

588-06443-08

20082756c1

1741 distributor ~~wholesaler~~ must maintain at all times a license or
1742 permit to engage in the wholesale distribution of prescription
1743 drugs in compliance with laws of the state in which it is a
1744 resident.

1745 6. A limited prescription drug veterinary wholesale
1746 distributor ~~wholesaler~~ must comply with the requirements for
1747 wholesale distributors under ss. s. 499.0121 and 499.01212,
1748 except that a limited prescription drug veterinary wholesale
1749 distributor ~~wholesaler~~ is not required to provide a pedigree
1750 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the
1751 wholesale distribution of a prescription drug to a veterinarian.

1752 7. A limited prescription drug veterinary wholesale
1753 distributor ~~wholesaler~~ may not return to inventory for subsequent
1754 wholesale distribution any prescription drug subject to, defined
1755 by, or described by s. 503(b) of the Federal Food, Drug, and
1756 Cosmetic Act which has been returned by a veterinarian.

1757 ~~8. An out-of-state prescription drug wholesaler's permit or~~
1758 A limited prescription drug veterinary wholesale distributor
1759 ~~wholesaler~~ permit is not required for an intracompany sale or
1760 transfer of a prescription drug from an out-of-state
1761 establishment that is duly licensed to engage in the wholesale
1762 distribution of prescription drugs in its state of residence to a
1763 licensed limited prescription drug veterinary wholesale
1764 distributor ~~wholesaler~~ in this state if both wholesale
1765 distributors ~~wholesalers~~ conduct wholesale distributions of
1766 prescription drugs under the same business name. The
1767 recordkeeping requirements of ss. s. 499.0121(6) and 499.01212
1768 must be followed for this transaction.

1769 (m) Medical oxygen retail establishment permit.--A medical

588-06443-08

20082756c1

1770 oxygen retail establishment permit is required for any person
1771 that sells medical oxygen to patients only. The sale must be
1772 based on an order from a practitioner authorized by law to
1773 prescribe. The term does not include a pharmacy licensed under
1774 chapter 465.

1775 1. A medical oxygen retail establishment may not possess,
1776 purchase, sell, or trade any prescription drug other than medical
1777 oxygen.

1778 2. A medical oxygen retail establishment may refill medical
1779 oxygen for an individual patient based on an order from a
1780 practitioner authorized by law to prescribe. A medical oxygen
1781 retail establishment that refills medical oxygen must comply with
1782 all appropriate state and federal good manufacturing practices.

1783 3. A medical oxygen retail establishment must comply with
1784 all of the wholesale distribution requirements of s. 499.0121.

1785 4. Prescription medical oxygen sold by a medical oxygen
1786 retail establishment pursuant to a practitioner's order may not
1787 be returned into the retail establishment's inventory.

1788 (n) ~~(b)~~ A compressed medical gas wholesale distributor
1789 ~~wholesaler's~~ permit.--A compressed medical gas wholesale
1790 distributor ~~wholesaler~~ is a wholesale distributor that is limited
1791 to the wholesale distribution of compressed medical gases to
1792 other than the consumer or patient. The compressed medical gas
1793 must be in the original sealed container that was purchased by
1794 that wholesale distributor ~~wholesaler~~. A compressed medical gas
1795 wholesale distributor ~~wholesaler~~ may not possess or engage in the
1796 wholesale distribution of any prescription drug other than
1797 compressed medical gases. The department shall adopt rules that
1798 govern the wholesale distribution of prescription medical oxygen

588-06443-08

20082756c1

1799 for emergency use. With respect to the emergency use of
1800 prescription medical oxygen, those rules may not be inconsistent
1801 with rules and regulations of federal agencies unless the
1802 Legislature specifically directs otherwise.

1803 (o)~~(e)~~ Compressed medical gas manufacturer permit.--A
1804 compressed medical gas manufacturer ~~manufacturer's~~ permit is
1805 required for any person that engages in the manufacture of
1806 compressed medical gases or repackages compressed medical gases
1807 from one container to another.

1808 1. A compressed medical gas manufacturer ~~permittee~~ may not
1809 manufacture or possess any prescription drug other than
1810 compressed medical gases.

1811 2. A compressed medical gas manufacturer ~~permittee~~ may
1812 engage in wholesale distribution of compressed medical gases
1813 manufactured at that establishment and must comply with all the
1814 provisions of this part ~~ss. 499.001-499.081~~ and the rules adopted
1815 under this part ~~these sections~~ that apply to a wholesale
1816 distributor.

1817 3. A compressed medical gas manufacturer ~~permittee~~ must
1818 comply with all appropriate state and federal good manufacturing
1819 practices.

1820 (p)~~(b)~~ Over-the-counter drug manufacturer permit.--An over-
1821 the-counter drug manufacturer ~~manufacturer's~~ permit is required
1822 for any person that engages in the manufacture or repackaging of
1823 an over-the-counter drug.

1824 1. An over-the-counter drug manufacturer ~~permittee~~ may not
1825 possess or purchase prescription drugs.

1826 2. A pharmacy is exempt from obtaining an over-the-counter
1827 drug manufacturer ~~manufacturer's~~ permit if it is operating in

588-06443-08

20082756c1

1828 compliance with pharmacy practice standards as defined in chapter
1829 465 and the rules adopted under that chapter.

1830 3. An over-the-counter drug manufacturer ~~permitter~~ must
1831 comply with all appropriate state and federal good manufacturing
1832 practices.

1833 (q)(d) Device manufacturer permit.--A device manufacturer
1834 ~~manufacturer's~~ permit is required for any person that engages in
1835 the manufacture, repackaging, or assembly of medical devices for
1836 human use in this state, except that a permit is not required if
1837 the person is engaged only in manufacturing, repackaging, or
1838 assembling a medical device pursuant to a practitioner's order
1839 for a specific patient.

1840 1. A manufacturer or repackager of medical devices in this
1841 state must comply with all appropriate state and federal good
1842 manufacturing practices and quality system rules.

1843 2. The department shall adopt rules related to storage,
1844 handling, and recordkeeping requirements for manufacturers of
1845 medical devices for human use.

1846 (r)(e) Cosmetic manufacturer permit.--A cosmetic
1847 manufacturer ~~manufacturer's~~ permit is required for any person
1848 that manufactures or repackages cosmetics in this state. A person
1849 that only labels or changes the labeling of a cosmetic but does
1850 not open the container sealed by the manufacturer of the product
1851 is exempt from obtaining a permit under this paragraph.

1852 Section 11. Section 499.012, Florida Statutes, is amended
1853 and subsections (2) through (8) of section 499.01, Florida
1854 States, are redesignated as subsections (1) through (7) of that
1855 section and amended, to read:

1856 499.012 Permit application ~~Wholesale distribution;~~

588-06443-08

20082756c1

1857 ~~definitions; permits; applications; general~~ requirements.--

1858 (1) ~~As used in this section, the term:~~

1859 ~~(2)~~ (a) A permit issued pursuant to this part ~~ss. 499.001-~~
1860 ~~499.081~~ may be issued only to a natural person who is at least 18
1861 years of age or to an applicant that is not a natural person if
1862 each person who, directly or indirectly, manages, controls, or
1863 oversees the operation of that applicant is at least 18 years of
1864 age.

1865 (b) An establishment that is a place of residence may not
1866 receive a permit and may not operate under this part ~~ss. 499.001-~~
1867 ~~499.081~~.

1868 (c) A person that applies for or renews a permit to
1869 manufacture or distribute prescription ~~legend~~ drugs may not use a
1870 name identical to the name used by any other establishment or
1871 licensed person authorized to purchase prescription drugs in this
1872 state, except that a restricted drug distributor permit issued to
1873 a health care entity will be issued in the name in which the
1874 institutional pharmacy permit is issued and a retail pharmacy
1875 drug wholesale distributor ~~wholesaler~~ will be issued a permit in
1876 the name of its retail pharmacy permit.

1877 (d) A permit for a prescription drug manufacturer,
1878 prescription drug repackager, prescription drug wholesale
1879 distributor ~~wholesaler~~, limited prescription drug veterinary
1880 wholesale distributor ~~wholesaler~~, or retail pharmacy drug
1881 wholesale distributor ~~wholesaler~~ may not be issued to the address
1882 of a health care entity or to a pharmacy licensed under chapter
1883 465, except as provided in this paragraph. The department may
1884 issue a prescription drug manufacturer permit to an applicant at
1885 the same address as a licensed nuclear pharmacy, which is a

588-06443-08

20082756c1

1886 health care entity, for the purpose of manufacturing prescription
1887 drugs used in positron emission tomography or other
1888 radiopharmaceuticals, as listed in a rule adopted by the
1889 department pursuant to this paragraph. The purpose of this
1890 exemption is to assure availability of state-of-the-art
1891 pharmaceuticals that would pose a significant danger to the
1892 public health if manufactured at a separate establishment address
1893 from the nuclear pharmacy from which the prescription drugs are
1894 dispensed. The department may also issue a retail pharmacy drug
1895 wholesale distributor ~~wholesaler~~ permit to the address of a
1896 community pharmacy licensed under chapter 465 which does not meet
1897 the definition of a closed pharmacy in s. 499.003.

1898 (e) A county or municipality may not issue an occupational
1899 license for any licensing period beginning on or after October 1,
1900 2003, for any establishment that requires a permit pursuant to
1901 this part ss. 499.001-499.081, unless the establishment exhibits
1902 a current permit issued by the department for the establishment.
1903 Upon presentation of the requisite permit issued by the
1904 department, an occupational license may be issued by the
1905 municipality or county in which application is made. The
1906 department shall furnish to local agencies responsible for
1907 issuing occupational licenses a current list of all
1908 establishments licensed pursuant to this part ss. 499.001-
1909 499.081.

1910 (2) ~~(3)~~ Notwithstanding subsection (6) ~~(7)~~, a permitted
1911 person in good standing may change the type of permit issued to
1912 that person by completing a new application for the requested
1913 permit, paying the amount of the difference in the permit fees if
1914 the fee for the new permit is more than the fee for the original

588-06443-08

20082756c1

1915 permit, and meeting the applicable permitting conditions for the
1916 new permit type. The new permit expires on the expiration date of
1917 the original permit being changed; however, a new permit for a
1918 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
1919 state prescription drug wholesale distributor ~~wholesaler~~, or a
1920 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall
1921 expire on the expiration date of the original permit or 1 year
1922 after the date of issuance of the new permit, whichever is
1923 earlier. A refund may not be issued if the fee for the new permit
1924 is less than the fee that was paid for the original permit.

1925 (3)~~(4)~~ A written application for a permit or to renew a
1926 permit must be filed with the department on forms furnished by
1927 the department. The department shall establish, by rule, the form
1928 and content of the application to obtain or renew a permit. The
1929 applicant must submit to the department with the application a
1930 statement that swears or affirms that the information is true and
1931 correct.

1932 (4)~~(5)~~(a) Except for a permit for a prescription drug
1933 wholesale distributor ~~wholesaler~~ or an out-of-state prescription
1934 drug wholesale distributor ~~wholesaler~~, an application for a
1935 permit must include:

1936 1. The name, full business address, and telephone number of
1937 the applicant;

1938 2. All trade or business names used by the applicant;

1939 3. The address, telephone numbers, and the names of contact
1940 persons for each facility used by the applicant for the storage,
1941 handling, and distribution of prescription drugs;

1942 4. The type of ownership or operation, such as a
1943 partnership, corporation, or sole proprietorship; and

588-06443-08

20082756c1

1944 5. The names of the owner and the operator of the
1945 establishment, including:

1946 a. If an individual, the name of the individual;

1947 b. If a partnership, the name of each partner and the name
1948 of the partnership;

1949 c. If a corporation, the name and title of each corporate
1950 officer and director, the corporate names, and the name of the
1951 state of incorporation;

1952 d. If a sole proprietorship, the full name of the sole
1953 proprietor and the name of the business entity;

1954 e. If a limited liability company, the name of each member,
1955 the name of each manager, the name of the limited liability
1956 company, and the name of the state in which the limited liability
1957 company was organized; and

1958 f. Any other relevant information that the department
1959 requires.

1960 (b) Upon approval of the application by the department and
1961 payment of the required fee, the department shall issue a permit
1962 to the applicant, if the applicant meets the requirements of this
1963 part ss. 499.001-499.081 and rules adopted under this part ~~these~~
1964 ~~sections~~.

1965 (c) Any change in information required under paragraph (a)
1966 must be submitted to the department before the change occurs.

1967 (d) The department shall consider, at a minimum, the
1968 following factors in reviewing the qualifications of persons to
1969 be permitted under this part ss. 499.001-499.081:

1970 1. The applicant's having been found guilty, regardless of
1971 adjudication, in a court of this state or other jurisdiction, of
1972 a violation of a law that directly relates to a drug, device, or

588-06443-08

20082756c1

1973 cosmetic. A plea of nolo contendere constitutes a finding of
1974 guilt for purposes of this subparagraph.

1975 2. The applicant's having been disciplined by a regulatory
1976 agency in any state for any offense that would constitute a
1977 violation of this part ~~ss. 499.001-499.081~~.

1978 3. Any felony conviction of the applicant under a federal,
1979 state, or local law;

1980 4. The applicant's past experience in manufacturing or
1981 distributing drugs, devices, or cosmetics;

1982 5. The furnishing by the applicant of false or fraudulent
1983 material in any application made in connection with manufacturing
1984 or distributing drugs, devices, or cosmetics;

1985 6. Suspension or revocation by a federal, state, or local
1986 government of any permit currently or previously held by the
1987 applicant for the manufacture or distribution of any drugs,
1988 devices, or cosmetics;

1989 7. Compliance with permitting requirements under any
1990 previously granted permits;

1991 8. Compliance with requirements to maintain or make
1992 available to the state permitting authority or to federal, state,
1993 or local law enforcement officials those records required under
1994 this section; and

1995 9. Any other factors or qualifications the department
1996 considers relevant to and consistent with the public health and
1997 safety.

1998 ~~(5)-(6)~~ Except for a permit ~~permits~~ for a prescription drug
1999 wholesale distributor ~~wholesalers~~ or an out-of-state prescription
2000 drug wholesale distributor ~~wholesalers~~:

2001 (a) The department shall adopt rules for the biennial

588-06443-08

20082756c1

2002 | renewal of permits.

2003 | (b) The department shall renew a permit upon receipt of the
2004 | renewal application and renewal fee if the applicant meets the
2005 | requirements established under this part ~~ss. 499.001-499.081~~ and
2006 | the rules adopted under this part ~~those sections~~.

2007 | (c) A permit, unless sooner suspended or revoked,
2008 | automatically expires 2 years after the last day of the
2009 | anniversary month in which the permit was originally issued. A
2010 | permit issued under this part ~~ss. 499.001-499.081~~ may be renewed
2011 | by making application for renewal on forms furnished by the
2012 | department and paying the appropriate fees. If a renewal
2013 | application and fee are submitted and postmarked after the
2014 | expiration date of the permit, the permit may be renewed only
2015 | upon payment of a late renewal delinquent fee of \$100, plus the
2016 | required renewal fee, not later than 60 days after the expiration
2017 | date.

2018 | (d) Failure to renew a permit in accordance with this
2019 | section precludes any future renewal of that permit. If a permit
2020 | issued pursuant to this part ~~section~~ has expired and cannot be
2021 | renewed, before an establishment may engage in activities that
2022 | require a permit under this part ~~ss. 499.001-499.081~~, the
2023 | establishment must submit an application for a new permit, pay
2024 | the applicable application fee, the initial permit fee, and all
2025 | applicable penalties, and be issued a new permit by the
2026 | department.

2027 | ~~(6)-(7)~~ A permit issued by the department is
2028 | nontransferable. Each permit is valid only for the person or
2029 | governmental unit to which it is issued and is not subject to
2030 | sale, assignment, or other transfer, voluntarily or

588-06443-08

20082756c1

2031 involuntarily; nor is a permit valid for any establishment other
2032 than the establishment for which it was originally issued.

2033 (a) A person permitted under this part ~~ss. 499.001-499.081~~
2034 must notify the department before making a change of address. The
2035 department shall set a change of location fee not to exceed \$100.

2036 (b)1. An application for a new permit is required when a
2037 majority of the ownership or controlling interest of a permitted
2038 establishment is transferred or assigned or when a lessee agrees
2039 to undertake or provide services to the extent that legal
2040 liability for operation of the establishment will rest with the
2041 lessee. The application for the new permit must be made before
2042 the date of the sale, transfer, assignment, or lease.

2043 2. A permittee that is authorized to distribute
2044 prescription ~~legend~~ drugs may transfer such drugs to the new
2045 owner or lessee under subparagraph 1. only after the new owner or
2046 lessee has been approved for a permit to distribute prescription
2047 ~~legend~~ drugs.

2048 (c) If an establishment permitted under this part ~~ss.~~
2049 ~~499.001-499.081~~ closes, the owner must notify the department in
2050 writing before the effective date of closure and must:

2051 1. Return the permit to the department;

2052 2. If the permittee is authorized to distribute
2053 prescription ~~legend~~ drugs, indicate the disposition of such
2054 drugs, including the name, address, and inventory, and provide
2055 the name and address of a person to contact regarding access to
2056 records that are required to be maintained under this part ~~ss.~~
2057 ~~499.001-499.081~~. Transfer of ownership of prescription ~~legend~~
2058 drugs may be made only to persons authorized to possess
2059 prescription ~~legend~~ drugs under this part ~~ss. 499.001-499.081~~.

588-06443-08

20082756c1

2060

2061 The department may revoke the permit of any person that fails to
2062 comply with the requirements of this subsection.

2063 (7)~~(8)~~ A permit must be posted in a conspicuous place on
2064 the licensed premises.

2065 (8)~~(3)~~ An application for a permit or to renew a permit for
2066 a prescription drug wholesale distributor ~~wholesaler~~ or an out-
2067 of-state prescription drug wholesale distributor ~~wholesaler~~
2068 submitted to the department must include:

2069 (a) The name, full business address, and telephone number
2070 of the applicant.

2071 (b) All trade or business names used by the applicant.

2072 (c) The address, telephone numbers, and the names of
2073 contact persons for each facility used by the applicant for the
2074 storage, handling, and distribution of prescription drugs.

2075 (d) The type of ownership or operation, such as a
2076 partnership, corporation, or sole proprietorship.

2077 (e) The names of the owner and the operator of the
2078 establishment, including:

2079 1. If an individual, the name of the individual.

2080 2. If a partnership, the name of each partner and the name
2081 of the partnership.

2082 3. If a corporation:

2083 a. The name, address, and title of each corporate officer
2084 and director.

2085 b. The name and address of the corporation, resident agent
2086 of the corporation, the resident agent's address, and the
2087 corporation's state of incorporation.

2088 c. The name and address of each shareholder of the

588-06443-08

20082756c1

2089 corporation that owns 5 percent or more of the outstanding stock
2090 of the corporation.

2091 4. If a sole proprietorship, the full name of the sole
2092 proprietor and the name of the business entity.

2093 5. If a limited liability company:

2094 a. The name and address of each member.

2095 b. The name and address of each manager.

2096 c. The name and address of the limited liability company,
2097 the resident agent of the limited liability company, and the name
2098 of the state in which the limited liability company was
2099 organized.

2100 (f) If applicable, the name and address of each member of
2101 the affiliated group of which the applicant is a member.

2102 (g)1. For an application for a new permit, the estimated
2103 annual dollar volume of prescription drug sales of the applicant,
2104 the estimated annual percentage of the applicant's total company
2105 sales that are prescription drugs, the applicant's estimated
2106 annual total dollar volume of purchases of prescription drugs,
2107 and the applicant's estimated annual total dollar volume of
2108 prescription drug purchases directly from manufacturers.

2109 2. For an application to renew a permit, the total dollar
2110 volume of prescription drug sales in the previous year, the total
2111 dollar volume of prescription drug sales made in the previous 6
2112 months, the percentage of total company sales that were
2113 prescription drugs in the previous year, the total dollar volume
2114 of purchases of prescription drugs in the previous year, and the
2115 total dollar volume of prescription drug purchases directly from
2116 manufacturers in the previous year.

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588-06443-08

20082756c1

2118 Such portions of the information required pursuant to this
2119 paragraph which are a trade secret, as defined in s. 812.081,
2120 shall be maintained by the department as trade secret information
2121 is required to be maintained under s. 499.051.

2122 (h) The tax year of the applicant.

2123 (i) A copy of the deed for the property on which
2124 applicant's establishment is located, if the establishment is
2125 owned by the applicant, or a copy of the applicant's lease for
2126 the property on which applicant's establishment is located that
2127 has an original term of not less than 1 calendar year, if the
2128 establishment is not owned by the applicant.

2129 (j) A list of all licenses and permits issued to the
2130 applicant by any other state which authorize the applicant to
2131 purchase or possess prescription drugs.

2132 (k) The name of the manager of the establishment that is
2133 applying for the permit or to renew the permit, the next four
2134 highest ranking employees responsible for prescription drug
2135 wholesale operations for the establishment, and the name of all
2136 affiliated parties for the establishment, together with the
2137 personal information statement and fingerprints required pursuant
2138 to subsection (9) ~~(4)~~ for each of such persons.

2139 (l) The name of each of the applicant's designated
2140 representatives as required by subsection (16) ~~(11)~~, together
2141 with the personal information statement and fingerprints required
2142 pursuant to subsection (9) ~~(4)~~ for each such person.

2143 (m) For an applicant that is a secondary wholesale
2144 distributor ~~wholesaler~~, each of the following:

2145 1. A personal background information statement containing
2146 the background information and fingerprints required pursuant to

588-06443-08

20082756c1

2147 subsection (9) ~~(4)~~ for each person named in the applicant's
2148 response to paragraphs (k) and (l) and for each affiliated party
2149 of the applicant.

2150 2. If any of the five largest shareholders of the
2151 corporation seeking the permit is a corporation, the name,
2152 address, and title of each corporate officer and director of each
2153 such corporation; the name and address of such corporation; the
2154 name of such corporation's resident agent, such corporation's
2155 resident agent's address, and such corporation's state of its
2156 incorporation; and the name and address of each shareholder of
2157 such corporation that owns 5 percent or more of the stock of such
2158 corporation.

2159 3. The name and address of all financial institutions in
2160 which the applicant has an account which is used to pay for the
2161 operation of the establishment or to pay for drugs purchased for
2162 the establishment, together with the names of all persons that
2163 are authorized signatories on such accounts. The portions of the
2164 information required pursuant to this subparagraph which are a
2165 trade secret, as defined in s. 812.081, shall be maintained by
2166 the department as trade secret information is required to be
2167 maintained under s. 499.051.

2168 4. The sources of all funds and the amounts of such funds
2169 used to purchase or finance purchases of prescription drugs or to
2170 finance the premises on which the establishment is to be located.

2171 5. If any of the funds identified in subparagraph 4. were
2172 borrowed, copies of all promissory notes or loans used to obtain
2173 such funds.

2174 (n) Any other relevant information that the department
2175 requires, including, but not limited to, any information related

588-06443-08

20082756c1

2176 to whether the applicant satisfies the definition of a primary
2177 wholesale distributor ~~wholesaler~~ or a secondary wholesale
2178 distributor ~~wholesaler~~.

2179 (9)~~(4)~~(a) Each person required by subsection (8) ~~(3)~~ to
2180 provide a personal information statement and fingerprints shall
2181 provide the following information to the department on forms
2182 prescribed by the department:

2183 1. The person's places of residence for the past 7 years.

2184 2. The person's date and place of birth.

2185 3. The person's occupations, positions of employment, and
2186 offices held during the past 7 years.

2187 4. The principal business and address of any business,
2188 corporation, or other organization in which each such office of
2189 the person was held or in which each such occupation or position
2190 of employment was carried on.

2191 5. Whether the person has been, during the past 7 years,
2192 the subject of any proceeding for the revocation of any license
2193 and, if so, the nature of the proceeding and the disposition of
2194 the proceeding.

2195 6. Whether, during the past 7 years, the person has been
2196 enjoined, either temporarily or permanently, by a court of
2197 competent jurisdiction from violating any federal or state law
2198 regulating the possession, control, or distribution of
2199 prescription drugs, together with details concerning any such
2200 event.

2201 7. A description of any involvement by the person with any
2202 business, including any investments, other than the ownership of
2203 stock in a publicly traded company or mutual fund, during the
2204 past 7 years, which manufactured, administered, prescribed,

588-06443-08

20082756c1

2205 distributed, or stored pharmaceutical products and any lawsuits
2206 in which such businesses were named as a party.

2207 8. A description of any felony criminal offense of which
2208 the person, as an adult, was found guilty, regardless of whether
2209 adjudication of guilt was withheld or whether the person pled
2210 guilty or nolo contendere. A criminal offense committed in
2211 another jurisdiction which would have been a felony in this state
2212 must be reported. If the person indicates that a criminal
2213 conviction is under appeal and submits a copy of the notice of
2214 appeal of that criminal offense, the applicant must, within 15
2215 days after the disposition of the appeal, submit to the
2216 department a copy of the final written order of disposition.

2217 9. A photograph of the person taken in the previous 30
2218 days.

2219 10. A set of fingerprints for the person on a form and
2220 under procedures specified by the department, together with
2221 payment of an amount equal to the costs incurred by the
2222 department for the criminal record check of the person.

2223 11. The name, address, occupation, and date and place of
2224 birth for each member of the person's immediate family who is 18
2225 years of age or older. As used in this subparagraph, the term
2226 "member of the person's immediate family" includes the person's
2227 spouse, children, parents, siblings, the spouses of the person's
2228 children, and the spouses of the person's siblings.

2229 12. Any other relevant information that the department
2230 requires.

2231 (b) The information required pursuant to paragraph (a)
2232 shall be provided under oath.

2233 (c) The department shall submit the fingerprints provided

588-06443-08

20082756c1

2234 | by a person for initial licensure to the Department of Law
2235 | Enforcement for a statewide criminal record check and for
2236 | forwarding to the Federal Bureau of Investigation for a national
2237 | criminal record check of the person. The department shall submit
2238 | the fingerprints provided by a person as a part of a renewal
2239 | application to the Department of Law Enforcement for a statewide
2240 | criminal record check, and for forwarding to the Federal Bureau
2241 | of Investigation for a national criminal record check, for the
2242 | initial renewal of a permit after January 1, 2004; for any
2243 | subsequent renewal of a permit, the department shall submit the
2244 | required information for a statewide and national criminal record
2245 | check of the person. Any person who as a part of an initial
2246 | permit application or initial permit renewal after January 1,
2247 | 2004, submits to the department a set of fingerprints required
2248 | for the criminal record check required in this paragraph shall
2249 | not be required to provide a subsequent set of fingerprints for a
2250 | criminal record check to the department, if the person has
2251 | undergone a criminal record check as a condition of the issuance
2252 | of an initial permit or the initial renewal of a permit of an
2253 | applicant after January 1, 2004.

2254 | (10)(5) The department may deny an application for a permit
2255 | or refuse to renew a permit for a prescription drug wholesale
2256 | distributor ~~wholesaler~~ or an out-of-state prescription drug
2257 | wholesale distributor ~~wholesaler~~ if:

2258 | (a) The applicant has not met the requirements for the
2259 | permit.

2260 | (b) The management, officers, or directors of the applicant
2261 | or any affiliated party are found by the department to be
2262 | incompetent or untrustworthy.

588-06443-08

20082756c1

2263 (c) The applicant is so lacking in experience in managing a
2264 wholesale distributor as to make the issuance of the proposed
2265 permit hazardous to the public health.

2266 (d) The applicant is so lacking in experience in managing a
2267 wholesale distributor as to jeopardize the reasonable promise of
2268 successful operation of the wholesale distributor.

2269 (e) The applicant is lacking in experience in the
2270 distribution of prescription drugs.

2271 (f) The applicant's past experience in manufacturing or
2272 distributing prescription drugs indicates that the applicant
2273 poses a public health risk.

2274 (g) The applicant is affiliated directly or indirectly
2275 through ownership, control, or other business relations, with any
2276 person or persons whose business operations are or have been
2277 detrimental to the public health.

2278 (h) The applicant, or any affiliated party, has been found
2279 guilty of or has pleaded guilty or nolo contendere to any felony
2280 or crime punishable by imprisonment for 1 year or more under the
2281 laws of the United States, any state, or any other country,
2282 regardless of whether adjudication of guilt was withheld.

2283 (i) The applicant or any affiliated party has been charged
2284 with a felony in a state or federal court and the disposition of
2285 that charge is pending during the application review or renewal
2286 review period.

2287 (j) The applicant has furnished false or fraudulent
2288 information or material in any application made in this state or
2289 any other state in connection with obtaining a permit or license
2290 to manufacture or distribute drugs, devices, or cosmetics.

2291 (k) That a federal, state, or local government permit

588-06443-08

20082756c1

2292 currently or previously held by the applicant, or any affiliated
2293 party, for the manufacture or distribution of any drugs, devices,
2294 or cosmetics has been disciplined, suspended, or revoked and has
2295 not been reinstated.

2296 (l) The applicant does not possess the financial or
2297 physical resources to operate in compliance with the permit being
2298 sought, this chapter, and the rules adopted under this chapter.

2299 (m) The applicant or any affiliated party receives,
2300 directly or indirectly, financial support and assistance from a
2301 person who was an affiliated party of a permittee whose permit
2302 was subject to discipline or was suspended or revoked, other than
2303 through the ownership of stock in a publicly traded company or a
2304 mutual fund.

2305 (n) The applicant or any affiliated party receives,
2306 directly or indirectly, financial support and assistance from a
2307 person who has been found guilty of any violation of this part
2308 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,
2309 any rules adopted under any of this part ~~those sections~~ or those
2310 chapters, any federal or state drug law, or any felony where the
2311 underlying facts related to drugs, regardless of whether the
2312 person has been pardoned, had her or his civil rights restored,
2313 or had adjudication withheld, other than through the ownership of
2314 stock in a publicly traded company or a mutual fund.

2315 (o) The applicant for renewal of a permit under s.
2316 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(c)~~
2317 has not actively engaged in the wholesale distribution of
2318 prescription drugs, as demonstrated by the regular and systematic
2319 distribution of prescription drugs throughout the year as
2320 evidenced by not fewer than 12 wholesale distributions in the

588-06443-08

20082756c1

2321 | previous year and not fewer than three wholesale distributions in
2322 | the previous 6 months.

2323 | (p) Information obtained in response to s. 499.01(2)(d)
2324 | ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~ demonstrates
2325 | it would not be in the best interest of the public health,
2326 | safety, and welfare to issue a permit.

2327 | (q) The applicant does not possess the financial standing
2328 | and business experience for the successful operation of the
2329 | applicant.

2330 | (r) The applicant or any affiliated party has failed to
2331 | comply with the requirements for manufacturing or distributing
2332 | prescription drugs under this part ~~ss. 499.001-499.081~~, similar
2333 | federal laws, similar laws in other states, or the rules adopted
2334 | under such laws.

2335 | ~~(11)(6)~~ Upon approval of the application by the department
2336 | and payment of the required fee, the department shall issue or
2337 | renew a prescription drug wholesale distributor ~~wholesaler~~ or an
2338 | out-of-state prescription drug wholesale distributor ~~wholesaler~~
2339 | permit to the applicant.

2340 | ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug
2341 | wholesale distributor ~~wholesalers~~ or an out-of-state prescription
2342 | drug wholesale distributor ~~wholesalers~~:

2343 | (a) The department shall adopt rules for the annual renewal
2344 | of permits. At least 90 days before the expiration of a permit,
2345 | the department shall forward a permit renewal notification and
2346 | renewal application to the prescription drug wholesale
2347 | distributor ~~wholesaler~~ or out-of-state prescription drug
2348 | wholesale distributor ~~wholesaler~~ at the mailing address of the
2349 | permitted establishment on file with the department. The permit

588-06443-08

20082756c1

2350 renewal notification must state conspicuously the date on which
2351 the permit for the establishment will expire and that the
2352 establishment may not operate unless the permit for the
2353 establishment is renewed timely.

2354 (b) A permit, unless sooner suspended or revoked,
2355 automatically expires 1 year after the last day of the
2356 anniversary month in which the permit was originally issued. A
2357 permit may be renewed by making application for renewal on forms
2358 furnished by the department and paying the appropriate fees. If a
2359 renewal application and fee are submitted and postmarked after 45
2360 days prior to the expiration date of the permit, the permit may
2361 be renewed only upon payment of a late renewal fee of \$100, plus
2362 the required renewal fee. A permittee that has submitted a
2363 renewal application in accordance with this paragraph may
2364 continue to operate under its permit, unless the permit is
2365 suspended or revoked, until final disposition of the renewal
2366 application.

2367 (c) Failure to renew a permit in accordance with this
2368 section precludes any future renewal of that permit. If a permit
2369 issued pursuant to this section has expired and cannot be
2370 renewed, before an establishment may engage in activities that
2371 require a permit under this part ~~ss. 499.001-499.081~~, the
2372 establishment must submit an application for a new permit; pay
2373 the applicable application fee, initial permit fee, and all
2374 applicable penalties; and be issued a new permit by the
2375 department.

2376 ~~(13)-(8)~~ A person that engages in wholesale distribution of
2377 prescription drugs in this state must have a wholesale
2378 distributor's permit issued by the department, except as noted in

588-06443-08

20082756c1

2379 | this section. Each establishment must be separately permitted
2380 | except as noted in this subsection.

2381 | (a) A separate establishment permit is not required when a
2382 | permitted prescription drug wholesale distributor ~~wholesaler~~
2383 | consigns a prescription drug to a pharmacy that is permitted
2384 | under chapter 465 and located in this state, provided that:

2385 | 1. The consignor wholesale distributor ~~wholesaler~~ notifies
2386 | the department in writing of the contract to consign prescription
2387 | drugs to a pharmacy along with the identity and location of each
2388 | consignee pharmacy;

2389 | 2. The pharmacy maintains its permit under chapter 465;

2390 | 3. The consignor wholesale distributor ~~wholesaler~~, which
2391 | has no legal authority to dispense prescription drugs, complies
2392 | with all wholesale distribution requirements of ss. s. ~~499.0121~~
2393 | and 499.01212 with respect to the consigned drugs and maintains
2394 | records documenting the transfer of title or other completion of
2395 | the wholesale distribution of the consigned prescription drugs;
2396 | 4. The distribution of the prescription drug is otherwise
2397 | lawful under this chapter and other applicable law;

2398 | 5. Open packages containing prescription drugs within a
2399 | pharmacy are the responsibility of the pharmacy, regardless of
2400 | how the drugs are titled; and

2401 | 6. The pharmacy dispenses the consigned prescription drug
2402 | in accordance with the limitations of its permit under chapter
2403 | 465 or returns the consigned prescription drug to the consignor
2404 | wholesale distributor ~~wholesaler~~. In addition, a person who holds
2405 | title to prescription drugs may transfer the drugs to a person
2406 | permitted or licensed to handle the reverse distribution or
2407 | destruction of drugs. Any other distribution by and means of the

588-06443-08

20082756c1

2408 | consigned prescription drug by any person, not limited to the
2409 | consignor wholesale distributor ~~wholesaler~~ or consignee pharmacy,
2410 | to any other person is prohibited.

2411 | (b) A wholesale distributor's permit is not required for
2412 | the one-time transfer of title of a pharmacy's lawfully acquired
2413 | prescription drug inventory by a pharmacy with a valid permit
2414 | issued under chapter 465 to a consignor prescription drug
2415 | wholesale distributor ~~wholesaler~~, permitted under this chapter,
2416 | in accordance with a written consignment agreement between the
2417 | pharmacy and that wholesale distributor ~~wholesaler~~ if: the
2418 | permitted pharmacy and the permitted prescription drug wholesale
2419 | distributor ~~wholesaler~~ comply with all of the provisions of
2420 | paragraph (a) and the prescription drugs continue to be within
2421 | the permitted pharmacy's inventory for dispensing in accordance
2422 | with the limitations of the pharmacy permit under chapter 465. A
2423 | consignor drug wholesale distributor ~~wholesaler~~ may not use the
2424 | pharmacy as a wholesale distributor through which it distributes
2425 | the prescription ~~legend~~ drugs to other pharmacies. Nothing in
2426 | this section is intended to prevent a wholesale ~~drug~~ distributor
2427 | from obtaining this inventory in the event of nonpayment by the
2428 | pharmacy.

2429 | (c) The department shall require information from each
2430 | wholesale distributor as part of the permit and renewal of such
2431 | permit, as required under ~~s. 499.01~~ or this section.

2432 | (14) ~~(9)~~ Personnel employed in wholesale distribution must
2433 | have appropriate education and experience to enable them to
2434 | perform their duties in compliance with state permitting
2435 | requirements.

2436 | (15) ~~(10)~~ The name of a permittee or establishment on a

588-06443-08

20082756c1

2437 prescription drug wholesale distributor ~~wholesaler~~ permit or an
2438 out-of-state prescription drug wholesale distributor ~~wholesaler~~
2439 permit may not include any indicia of attainment of any
2440 educational degree, any indicia that the permittee or
2441 establishment possesses a professional license, or any name or
2442 abbreviation that the department determines is likely to cause
2443 confusion or mistake or that the department determines is
2444 deceptive, including that of any other entity authorized to
2445 purchase prescription drugs.

2446 (16)~~(11)~~(a) Each establishment that is issued an initial or
2447 renewal permit as a prescription drug wholesale distributor
2448 ~~wholesaler~~ or an out-of-state prescription drug wholesale
2449 distributor ~~wholesaler~~ must designate in writing to the
2450 department at least one natural person to serve as the designated
2451 representative of the wholesale distributor ~~wholesaler~~. Such
2452 person must have an active certification as a designated
2453 representative from the department.

2454 (b) To be certified as a designated representative, a
2455 natural person must:

- 2456 1. Submit an application on a form furnished by the
2457 department and pay the appropriate fees;
- 2458 2. Be at least 18 years of age;
- 2459 3. Have not less than 2 years of verifiable full-time work
2460 experience in a pharmacy licensed in this state or another state,
2461 where the person's responsibilities included, but were not
2462 limited to, recordkeeping for prescription drugs, or have not
2463 less than 2 years of verifiable full-time managerial experience
2464 with a prescription drug wholesale distributor ~~wholesaler~~
2465 licensed in this state or in another state;

588-06443-08

20082756c1

2466 4. Receive a passing score of at least 75 percent on an
2467 examination given by the department regarding federal laws
2468 governing distribution of prescription drugs and this part ~~ss.~~
2469 ~~499.001-499.081~~ and the rules adopted by the department governing
2470 the wholesale distribution of prescription drugs. This
2471 requirement shall be effective 1 year after the results of the
2472 initial examination are mailed to the persons that took the
2473 examination. The department shall offer such examinations at
2474 least four times each calendar year; and

2475 5. Provide the department with a personal information
2476 statement and fingerprints pursuant to subsection (9) ~~(4)~~.

2477 (c) The department may deny an application for
2478 certification as a designated representative or may suspend or
2479 revoke a certification of a designated representative pursuant to
2480 s. 499.067.

2481 (d) A designated representative:

2482 1. Must be actively involved in and aware of the actual
2483 daily operation of the wholesale distributor.

2484 2. Must be employed full time in a managerial position by
2485 the wholesale distributor.

2486 3. Must be physically present at the establishment during
2487 normal business hours, except for time periods when absent due to
2488 illness, family illness or death, scheduled vacation, or other
2489 authorized absence.

2490 4. May serve as a designated representative for only one
2491 wholesale distributor at any one time.

2492 (e) A wholesale distributor must notify the department when
2493 a designated representative leaves the employ of the wholesale
2494 distributor. Such notice must be provided to the department

588-06443-08

20082756c1

2495 within 10 business days after the last day of designated
2496 representative's employment with the wholesale distributor.

2497 (f) A wholesale distributor may not operate under a
2498 prescription drug wholesale distributor ~~wholesaler~~ permit or an
2499 out-of-state prescription drug wholesale distributor ~~wholesaler~~
2500 permit for more than 10 business days after the designated
2501 representative leaves the employ of the wholesale distributor,
2502 unless the wholesale distributor employs another designated
2503 representative and notifies the department within 10 business
2504 days of the identity of the new designated representative.

2505 Section 12. Section 499.01201, Florida Statutes, is amended
2506 to read:

2507 499.01201 Agency for Health Care Administration review and
2508 use of statute and rule violation or compliance
2509 data.--Notwithstanding any other provisions of law to the
2510 contrary, the Agency for Health Care Administration may not:

2511 (1) Review or use any violation or alleged violation of s.
2512 499.0121(6) or s. 499.01212, or any rules adopted under those
2513 sections ~~that section~~, as a ground for denying or withholding any
2514 payment of a Medicaid reimbursement to a pharmacy licensed under
2515 chapter 465; or

2516 (2) Review or use compliance with s. 499.0121(6) or s.
2517 499.01212, or any rules adopted under those sections ~~that~~
2518 ~~section~~, as the subject of any audit of Medicaid-related records
2519 held by a pharmacy licensed under chapter 465.

2520 Section 13. Section 499.0121, Florida Statutes, is amended,
2521 and subsection (4) of section 499.013, Florida Statutes, is
2522 redesignated as paragraph (d) of subsection (6) of that section
2523 and amended, to read:

588-06443-08

20082756c1

2524 499.0121 Storage and handling of prescription drugs;
2525 recordkeeping.--The department shall adopt rules to implement
2526 this section as necessary to protect the public health, safety,
2527 and welfare. Such rules shall include, but not be limited to,
2528 requirements for the storage and handling of prescription drugs
2529 and for the establishment and maintenance of prescription drug
2530 distribution records.

2531 (1) ESTABLISHMENTS.--An establishment at which prescription
2532 drugs are stored, warehoused, handled, held, offered, marketed,
2533 or displayed must:

2534 (a) Be of suitable size and construction to facilitate
2535 cleaning, maintenance, and proper operations;

2536 (b) Have storage areas designed to provide adequate
2537 lighting, ventilation, temperature, sanitation, humidity, space,
2538 equipment, and security conditions;

2539 (c) Have a quarantine area for storage of prescription
2540 drugs that are outdated, damaged, deteriorated, misbranded, or
2541 adulterated, or that are in immediate or sealed, secondary
2542 containers that have been opened;

2543 (d) Be maintained in a clean and orderly condition; and

2544 (e) Be free from infestation by insects, rodents, birds, or
2545 vermin of any kind.

2546 (2) SECURITY.--

2547 (a) An establishment that is used for wholesale drug
2548 distribution must be secure from unauthorized entry.

2549 1. Access from outside the premises must be kept to a
2550 minimum and be well-controlled.

2551 2. The outside perimeter of the premises must be well-
2552 lighted.

588-06443-08

20082756c1

2553 3. Entry into areas where prescription drugs are held must
2554 be limited to authorized personnel.

2555 (b) An establishment that is used for wholesale drug
2556 distribution must be equipped with:

2557 1. An alarm system to detect entry after hours; however,
2558 the department may exempt by rule establishments that only hold a
2559 permit as prescription drug wholesale distributor-brokers
2560 ~~wholesaler-brokers~~ and establishments that only handle medical
2561 oxygen; and

2562 2. A security system that will provide suitable protection
2563 against theft and diversion. When appropriate, the security
2564 system must provide protection against theft or diversion that is
2565 facilitated or hidden by tampering with computers or electronic
2566 records.

2567 (c) Any vehicle that contains prescription drugs must be
2568 secure from unauthorized access to the prescription drugs in the
2569 vehicle.

2570 (3) STORAGE.--All prescription drugs shall be stored at
2571 appropriate temperatures and under appropriate conditions in
2572 accordance with requirements, if any, in the labeling of such
2573 drugs, or with requirements in the official compendium.

2574 (a) If no storage requirements are established for a
2575 prescription drug, the drug may be held at "controlled" room
2576 temperature, as defined in the official compendium, to help
2577 ensure that its identity, strength, quality, and purity are not
2578 adversely affected.

2579 (b) Appropriate manual, electromechanical, or electronic
2580 temperature and humidity recording equipment, devices, or logs
2581 must be used to document proper storage of prescription drugs.

588-06443-08

20082756c1

2582 (c) The recordkeeping requirements in subsection (6) must
2583 be followed for all stored prescription drugs.

2584 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2585 (a) Upon receipt, each outside shipping container must be
2586 visually examined for identity and to prevent the acceptance of
2587 contaminated prescription drugs that are otherwise unfit for
2588 distribution. This examination must be adequate to reveal
2589 container damage that would suggest possible contamination or
2590 other damage to the contents.

2591 (b) Each outgoing shipment must be carefully inspected for
2592 identity of the prescription drug products and to ensure that
2593 there is no delivery of prescription drugs that have expired or
2594 been damaged in storage or held under improper conditions.

2595 (c) The recordkeeping requirements in subsection (6) must
2596 be followed for all incoming and outgoing prescription drugs.

2597 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must
2598 review records required under this section for the acquisition of
2599 prescription drugs for accuracy and completeness, considering the
2600 total facts and circumstances surrounding the transactions and
2601 the wholesale distributors involved. This includes authenticating
2602 each transaction listed on a pedigree paper, as defined in s.
2603 499.003(37) ~~s. 499.001(31)~~.

2604 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2605 (a)1. Prescription drugs that are outdated, damaged,
2606 deteriorated, misbranded, or adulterated must be quarantined and
2607 physically separated from other prescription drugs until they are
2608 destroyed or returned to their supplier. A quarantine section
2609 must be separate and apart from other sections where prescription
2610 drugs are stored so that prescription drugs in this section are

588-06443-08

20082756c1

2611 not confused with usable prescription drugs.

2612 2. Prescription drugs must be examined at least every 12
2613 months, and drugs for which the expiration date has passed must
2614 be removed and quarantined.

2615 (b) Any prescription drugs of which the immediate or sealed
2616 outer containers or sealed secondary containers have been opened
2617 or used must be identified as such and must be quarantined and
2618 physically separated from other prescription drugs until they are
2619 either destroyed or returned to the supplier.

2620 (c) If the conditions under which a prescription drug has
2621 been returned cast doubt on the drug's safety, identity,
2622 strength, quality, or purity, the drug must be destroyed or
2623 returned to the supplier, unless examination, testing, or other
2624 investigation proves that the drug meets appropriate standards of
2625 safety, identity, strength, quality, and purity. In determining
2626 whether the conditions under which a drug has been returned cast
2627 doubt on the drug's safety, identity, strength, quality, or
2628 purity, the wholesale ~~drug~~ distributor must consider, among other
2629 things, the conditions under which the drug has been held,
2630 stored, or shipped before or during its return and the conditions
2631 of the drug and its container, carton, or labeling, as a result
2632 of storage or shipping.

2633 (d) The recordkeeping requirements in subsection (6) must
2634 be followed for all outdated, damaged, deteriorated, misbranded,
2635 or adulterated prescription drugs.

2636 (6) RECORDKEEPING.--The department shall adopt rules that
2637 require keeping such records of prescription drugs as are
2638 necessary for the protection of the public health.

2639 (a) Wholesale ~~drug~~ distributors must establish and maintain

588-06443-08

20082756c1

2640 inventories and records of all transactions regarding the receipt
2641 and distribution or other disposition of prescription drugs.

2642 These records must provide a complete audit trail from receipt to
2643 sale or other disposition, be readily retrievable for inspection,
2644 and include, at a minimum, the following information:

2645 1. The source of the drugs, including the name and
2646 principal address of the seller or transferor, and the address of
2647 the location from which the drugs were shipped;

2648 2. The name, principal address, and state license permit or
2649 registration number of the person authorized to purchase
2650 prescription drugs;

2651 3. The name, strength, dosage form, and quantity of the
2652 drugs received and distributed or disposed of;

2653 4. The dates of receipt and distribution or other
2654 disposition of the drugs; and

2655 5. Any financial documentation supporting the transaction.

2656 (b) Inventories and records must be made available for
2657 inspection and photocopying by authorized federal, state, or
2658 local officials for a period of 2 years following disposition of
2659 the drugs or 3 years after the creation of the records, whichever
2660 period is longer.

2661 (c) Records described in this section that are kept at the
2662 inspection site or that can be immediately retrieved by computer
2663 or other electronic means must be readily available for
2664 authorized inspection during the retention period. Records that
2665 are kept at a central location outside of this state and that are
2666 not electronically retrievable must be made available for
2667 inspection within 2 working days after a request by an authorized
2668 official of a federal, state, or local law enforcement agency.

588-06443-08

20082756c1

2669 Records that are maintained at a central location within this
2670 state must be maintained at an establishment that is permitted
2671 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily
2672 available.

2673 (d)(4) Each manufacturer or repackager of medical devices,
2674 over-the-counter drugs, or cosmetics must maintain records that
2675 include the name and principal address of the seller or
2676 transferor of the product, the address of the location from which
2677 the product was shipped, the date of the transaction, the name
2678 and quantity of the product involved, and the name and principal
2679 address of the person who purchased the product.

2680 (e) A wholesale distributor must maintain pedigree papers
2681 separate and distinct from other records required under this
2682 chapter.

2683 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~
2684 ~~the wholesale distribution of a prescription drug and who is not~~
2685 ~~the manufacturer of that drug must, before each wholesale~~
2686 ~~distribution of such drug, provide to the person who receives the~~
2687 ~~drug a pedigree paper as defined in s. 499.003(31).~~

2688 ~~2. A repackager must comply with this paragraph.~~

2689 ~~3. The pedigree paper requirements in this paragraph do not~~
2690 ~~apply to compressed medical gases or veterinary legend drugs.~~

2691 ~~4. Each wholesale distributor of prescription drugs must~~
2692 ~~maintain separate and distinct from other required records all~~
2693 ~~statements that are required under subparagraph 1.~~

2694 ~~5. Subparagraph 1. is satisfied when a wholesale~~
2695 ~~distributor takes title to, but not possession of, a prescription~~
2696 ~~drug and the prescription drug's manufacturer ships the~~
2697 ~~prescription drug directly to a person authorized by law to~~

588-06443-08

20082756c1

2698 ~~purchase prescription drugs for the purpose of administering or~~
2699 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~
2700 ~~affiliated group, as described in paragraph (f), with the~~
2701 ~~exception of a repackager.~~

2702 ~~a. The wholesale distributor must deliver to the recipient~~
2703 ~~of the prescription drug, within 14 days after the shipment~~
2704 ~~notification from the manufacturer, an invoice and the following~~
2705 ~~sworn statement: "This wholesale distributor purchased the~~
2706 ~~specific unit of the prescription drug listed on the invoice~~
2707 ~~directly from the manufacturer, and the specific unit of~~
2708 ~~prescription drug was shipped by the manufacturer directly to a~~
2709 ~~person authorized by law to administer or dispense the legend~~
2710 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~
2711 ~~an affiliated group, as described in s. 499.0121(6) (f), Florida~~
2712 ~~Statutes, with the exception of a repackager." The invoice must~~
2713 ~~contain a unique cross-reference to the shipping document sent by~~
2714 ~~the manufacturer to the recipient of the prescription drug.~~

2715 ~~b. The manufacturer of the prescription drug shipped~~
2716 ~~directly to the recipient under this section must provide and the~~
2717 ~~recipient of the prescription drug must acquire, within 14 days~~
2718 ~~after receipt of the prescription drug, a shipping document from~~
2719 ~~the manufacturer that contains, at a minimum:~~

2720 ~~(I) The name and address of the manufacturer, including the~~
2721 ~~point of origin of the shipment, and the names and addresses of~~
2722 ~~the wholesaler and the purchaser.~~

2723 ~~(II) The name of the prescription drug as it appears on the~~
2724 ~~label.~~

2725 ~~(III) The quantity, dosage form, and strength of the~~
2726 ~~prescription drug.~~

588-06443-08

20082756c1

2727 ~~(IV) The date of the shipment from the manufacturer.~~
2728 ~~e. The wholesale distributor must also maintain and make~~
2729 ~~available to the department, upon request, the lot number of such~~
2730 ~~drug if not contained in the shipping document acquired by the~~
2731 ~~recipient.~~

2732 ~~6. Failure of the manufacturer to provide, the recipient to~~
2733 ~~acquire, or the wholesale distributor to deliver, the~~
2734 ~~documentation required under subparagraph 5. shall constitute~~
2735 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~
2736 ~~Forgery by the manufacturer, the recipient, or the wholesale~~
2737 ~~distributor of the documentation required to be acquired or~~
2738 ~~delivered under subparagraph 5. shall constitute forgery of a~~
2739 ~~pedigree paper under s. 499.0051.~~

2740 ~~7. The department may, by rule, specify alternatives to~~
2741 ~~compliance with subparagraph 1. for a prescription drug in the~~
2742 ~~inventory of a permitted prescription drug wholesaler as of June~~
2743 ~~30, 2006, and the return of a prescription drug purchased prior~~
2744 ~~to July 1, 2006. The department may specify time limits for such~~
2745 ~~alternatives.~~

2746 ~~(7)(e)~~ PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale
2747 distributor, except for a manufacturer, shall annually provide
2748 the department with a written list of all wholesale distributors
2749 and manufacturers from whom the wholesale distributor purchases
2750 prescription drugs. A wholesale distributor, except a
2751 manufacturer, shall notify the department not later than 10 days
2752 after any change to either list. Such portions of the information
2753 required pursuant to this subsection ~~paragraph~~ which are a trade
2754 secret, as defined in s. 812.081, shall be maintained by the
2755 department as trade secret information is required to be

588-06443-08

20082756c1

2756 maintained under s. 499.051.

2757 ~~(f)1. This paragraph applies only to an affiliated group,~~
2758 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~
2759 ~~amended, which is composed of chain drug entities, including at~~
2760 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~
2761 ~~members of the same affiliated group, if the affiliated group:~~

2762 ~~a. Discloses to the department the names of all its~~
2763 ~~members; and~~

2764 ~~b. Agrees in writing to provide records on prescription~~
2765 ~~drug purchases by members of the affiliated group not later than~~
2766 ~~48 hours after the department requests such records, regardless~~
2767 ~~of the location where the records are stored.~~

2768 ~~2. Each warehouse within the affiliated group must comply~~
2769 ~~with all applicable federal and state drug wholesale permit~~
2770 ~~requirements and must purchase, receive, hold, and distribute~~
2771 ~~prescription drugs only to a retail pharmacy or warehouse within~~
2772 ~~the affiliated group. Such a warehouse is exempt from providing a~~
2773 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~
2774 ~~group member warehouse or retail pharmacy, provided that:~~

2775 ~~a. Any affiliated group member that purchases or receives a~~
2776 ~~prescription drug from outside the affiliated group must receive~~
2777 ~~a pedigree paper if the prescription drug is distributed in or~~
2778 ~~into this state and a pedigree paper is required under this~~
2779 ~~section and must authenticate the documentation as required in~~
2780 ~~subsection (4), regardless of whether the affiliated group member~~
2781 ~~is directly subject to regulation under this chapter; and~~

2782 ~~b. The affiliated group makes available to the department~~
2783 ~~on request all records related to the purchase or acquisition of~~
2784 ~~prescription drugs by members of the affiliated group, regardless~~

588-06443-08

20082756c1

2785 ~~of the location where the records are stored, if the prescription~~
2786 ~~drugs were distributed in or into this state.~~

2787 ~~3. If a repackager repackages prescription drugs solely for~~
2788 ~~distribution to its affiliated group members for the exclusive~~
2789 ~~distribution to and among retail pharmacies that are members of~~
2790 ~~the affiliated group to which the repackager is a member:~~

2791 ~~a. The repackager must:~~

2792 ~~(I) In lieu of the written statement required by paragraph~~
2793 ~~(d), for all repackaged prescription drugs distributed in or into~~
2794 ~~this state, state in writing under oath with each distribution of~~
2795 ~~a repackaged prescription drug to an affiliated group member~~
2796 ~~warehouse or repackager: "All repackaged prescription drugs are~~
2797 ~~purchased by the affiliated group directly from the manufacturer~~
2798 ~~or from a prescription drug wholesaler that purchased the~~
2799 ~~prescription drugs directly from the manufacturer.";~~

2800 ~~(II) Purchase all prescription drugs it repackages:~~

2801 ~~(A) Directly from the manufacturer; or~~

2802 ~~(B) From a prescription drug wholesaler that purchased the~~
2803 ~~prescription drugs directly from the manufacturer; and~~

2804 ~~(III) Maintain records in accordance with this section to~~
2805 ~~document that it purchased the prescription drugs directly from~~
2806 ~~the manufacturer or that its prescription drug wholesale supplier~~
2807 ~~purchased the prescription drugs directly from the manufacturer.~~

2808 ~~b. All members of the affiliated group must provide to~~
2809 ~~agents of the department on request records of purchases by all~~
2810 ~~members of the affiliated group of prescription drugs that have~~
2811 ~~been repackaged, regardless of the location where the records are~~
2812 ~~stored or where the repackager is located.~~

2813 ~~(8)(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale drug

588-06443-08

20082756c1

2814 distributors must establish, maintain, and adhere to written
2815 policies and procedures, which must be followed for the receipt,
2816 security, storage, inventory, and distribution of prescription
2817 drugs, including policies and procedures for identifying,
2818 recording, and reporting losses or thefts, and for correcting all
2819 errors and inaccuracies in inventories. Wholesale ~~drug~~
2820 distributors must include in their written policies and
2821 procedures:

2822 (a) A procedure whereby the oldest approved stock of a
2823 prescription drug product is distributed first. The procedure may
2824 permit deviation from this requirement, if the deviation is
2825 temporary and appropriate.

2826 (b) A procedure to be followed for handling recalls and
2827 withdrawals of prescription drugs. Such procedure must be
2828 adequate to deal with recalls and withdrawals due to:

2829 1. Any action initiated at the request of the Food and Drug
2830 Administration or any other federal, state, or local law
2831 enforcement or other government agency, including the department.

2832 2. Any voluntary action by the manufacturer or repackager
2833 to remove defective or potentially defective drugs from the
2834 market; or

2835 3. Any action undertaken to promote public health and
2836 safety by replacing existing merchandise with an improved product
2837 or new package design.

2838 (c) A procedure to ensure that wholesale ~~drug~~ distributors
2839 prepare for, protect against, and handle any crisis that affects
2840 security or operation of any facility if a strike, fire, flood,
2841 or other natural disaster, or a local, state, or national
2842 emergency, occurs.

588-06443-08

20082756c1

2843 (d) A procedure to ensure that any outdated prescription
2844 drugs are segregated from other drugs and either returned to the
2845 manufacturer or repackager or destroyed. This procedure must
2846 provide for written documentation of the disposition of outdated
2847 prescription drugs. This documentation must be maintained for 2
2848 years after disposition of the outdated drugs.

2849 (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors
2850 must establish and maintain lists of officers, directors,
2851 managers, designated representatives, and other persons in charge
2852 of wholesale drug distribution, storage, and handling, including
2853 a description of their duties and a summary of their
2854 qualifications.

2855 (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A
2856 wholesale ~~drug~~ distributor must operate in compliance with
2857 applicable federal, state, and local laws and regulations.

2858 (a) A wholesale ~~drug~~ distributor must allow the department
2859 and authorized federal, state, and local officials to enter and
2860 inspect its premises and delivery vehicles, and to audit its
2861 records and written operating procedures, at reasonable times and
2862 in a reasonable manner, to the extent authorized by law.

2863 (b) A wholesale ~~drug~~ distributor that deals in controlled
2864 substances must register with the Drug Enforcement Administration
2865 and must comply with all applicable state, local, and federal
2866 laws. A wholesale ~~drug~~ distributor that distributes any substance
2867 controlled under chapter 893 must notify the department when
2868 registering with the Drug Enforcement Administration pursuant to
2869 that chapter and must provide the department with its DEA number.

2870 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~
2871 distributor is subject to any applicable federal, state, or local

588-06443-08

20082756c1

2872 laws or regulations that relate to prescription drug product
2873 salvaging or reprocessing.

2874 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person
2875 responsible for shipment and transportation of a prescription
2876 drug in a wholesale distribution may use a common carrier; its
2877 own vehicle or employee acting within the scope of employment if
2878 authorized under s. 499.03 for the possession of prescription
2879 drugs in this state; or, in the case of a prescription drug
2880 intended for domestic distribution, an independent contractor who
2881 must be the agent of the authorized seller or recipient
2882 responsible for shipping and transportation as set forth in a
2883 written contract between the parties. A person selling a
2884 prescription drug for export must obtain documentation, such as a
2885 validated airway bill, bill of lading, or other appropriate
2886 documentation that the prescription drug was exported. A person
2887 responsible for shipping or transporting prescription drugs is
2888 not required to maintain documentation from a common carrier that
2889 the designated recipient received the prescription drugs;
2890 however, the person must obtain such documentation from the
2891 common carrier and make it available to the department upon
2892 request of the department.

2893 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
2894 any prescription drugs from another wholesale ~~drug~~ distributor, a
2895 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
2896 state prescription drug wholesale distributor ~~wholesaler~~, or a
2897 prescription drug repackager must:

2898 (a) Enter an agreement with the selling wholesale ~~drug~~
2899 distributor by which the selling wholesale ~~drug~~ distributor will
2900 indemnify the purchasing wholesale ~~drug~~ distributor for any loss

588-06443-08

20082756c1

2901 | caused to the purchasing wholesale ~~drug~~ distributor related to
2902 | the purchase of drugs from the selling wholesale ~~drug~~ distributor
2903 | which are determined to be counterfeit or to have been
2904 | distributed in violation of any federal or state law governing
2905 | the distribution of drugs.

2906 | (b) Determine that the selling wholesale ~~drug~~ distributor
2907 | has insurance coverage of not less than the greater of 1 percent
2908 | of the amount of total dollar volume of the prescription drug
2909 | sales reported to the department under s. 499.012(8)(g) ~~s.~~
2910 | ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed
2911 | \$2 million.

2912 | (c) Obtain information from the selling wholesale ~~drug~~
2913 | distributor, including the length of time the selling wholesale
2914 | ~~drug~~ distributor has been licensed in this state, a copy of the
2915 | selling wholesale ~~drug~~ distributor's licenses or permits, and
2916 | background information concerning the ownership of the selling
2917 | wholesale ~~drug~~ distributor, including the experience of the
2918 | wholesale distributor in the wholesale distribution of
2919 | prescription drugs.

2920 | (d) Verify that the selling wholesale ~~drug~~ distributor's
2921 | Florida permit is valid.

2922 | (e) Inspect the selling wholesale ~~drug~~ distributor's
2923 | licensed establishment to document that it has a policies and
2924 | procedures manual relating to the distribution of drugs, the
2925 | appropriate temperature controlled environment for drugs
2926 | requiring temperature control, an alarm system, appropriate
2927 | access restrictions, and procedures to ensure that records
2928 | related to the wholesale distribution of prescription drugs are
2929 | maintained as required by law:

588-06443-08

20082756c1

2930 1. Before purchasing any drug from the wholesale ~~drug~~
2931 distributor, and at least once each subsequent year; or

2932 2. Before purchasing any drug from the wholesale ~~drug~~
2933 distributor, and each subsequent year obtain a complete copy of
2934 the most recent inspection report for the establishment which was
2935 prepared by the department or the regulatory authority
2936 responsible for wholesale ~~drug~~ distributors in the state in which
2937 the establishment is located.

2938 Section 14. Section 499.01211, Florida Statutes, is amended
2939 to read:

2940 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory
2941 Council.--

2942 (1) There is created the Drug Wholesale Distributor
2943 ~~Wholesaler~~ Advisory Council within the department. The council
2944 shall meet at least once each calendar quarter. Staff for the
2945 council shall be provided by the department. The council shall
2946 consist of 11 members who shall serve without compensation. The
2947 council shall elect a chairperson and a vice chairperson
2948 annually.

2949 (2) The State Surgeon General, or his or her designee, and
2950 the Secretary of Health Care Administration, or her or his
2951 designee, shall be members of the council. The State Surgeon
2952 General shall appoint nine additional members to the council who
2953 shall be appointed to a term of 4 years each, as follows:

2954 (a) Three different persons each of whom is employed by a
2955 different prescription drug wholesale distributor ~~wholesaler~~
2956 licensed under this part ~~chapter~~ which operates nationally and is
2957 a primary wholesale distributor ~~wholesaler~~, as defined in s.
2958 499.003(49) ~~s. 499.012(1)(d)~~.

588-06443-08

20082756c1

2959 (b) One person employed by a prescription drug wholesale
2960 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is
2961 a secondary wholesale distributor ~~wholesaler~~, as defined in s.
2962 499.003(54) ~~s. 499.012(1)(f)~~.

2963 (c) One person employed by a retail pharmacy chain located
2964 in this state.

2965 (d) One person who is a member of the Board of Pharmacy and
2966 is a pharmacist licensed under chapter 465.

2967 (e) One person who is a physician licensed pursuant to
2968 chapter 458 or chapter 459.

2969 (f) One person who is an employee of a hospital licensed
2970 pursuant to chapter 395 and is a pharmacist licensed pursuant to
2971 chapter 465.

2972 (g) One person who is an employee of a pharmaceutical
2973 manufacturer.

2974 (3) The council shall review this part ~~ss. 499.001-499.081~~
2975 and the rules adopted to administer this part ~~ss. 499.001-499.081~~
2976 annually, provide input to the department regarding all proposed
2977 rules to administer this part ~~ss. 499.001-499.081~~, make
2978 recommendations to the department to improve the protection of
2979 the prescription drugs and public health, make recommendations to
2980 improve coordination with other states' regulatory agencies and
2981 the federal government concerning the wholesale distribution of
2982 drugs, and make recommendations to minimize the impact of
2983 regulation of the wholesale distribution industry while ensuring
2984 protection of the public health.

2985 Section 15. Section 499.01212, Florida Statutes, is created
2986 to read:

2987 499.01212 Pedigree paper.--

588-06443-08

20082756c1

2988 (1) APPLICATION.--Each person who is engaged in the
2989 wholesale distribution of a prescription drug must, prior to or
2990 simultaneous with each wholesale distribution, provide a pedigree
2991 paper to the person who receives the drug.

2992 (2) FORMAT.--A pedigree paper must contain the following
2993 information:

2994 (a) For the wholesale distribution of a prescription drug
2995 within the normal distribution chain:

2996 1. The following statement: "This wholesale distributor
2997 purchased the specific unit of the prescription drug directly
2998 from the manufacturer."

2999 2. The name of the prescription drug as it appears on the
3000 label.

3001 3. The quantity, dosage form, and strength of the
3002 prescription drug.

3003
3004 The wholesale distributor must also maintain and make available
3005 to the department, upon request, the point of origin of the
3006 prescription drugs, including intracompany transfers, the date of
3007 the shipment from the manufacturer to the wholesale distributor,
3008 the lot numbers of such drugs, and the invoice numbers from the
3009 manufacturer.

3010 (b) For all other wholesale distributions of prescription
3011 drugs:

3012 1. The quantity, dosage form, and strength of the
3013 prescription drugs.

3014 2. The lot numbers of the prescription drugs.

3015 3. The name and address of each owner of the prescription
3016 drug and his or her signature.

588-06443-08

20082756c1

3017 4. Shipping information, including the name and address of
3018 each person certifying delivery or receipt of the prescription
3019 drug.

3020 5. An invoice number, a shipping document number, or
3021 another number uniquely identifying the transaction.

3022 6. A certification that the recipient wholesale distributor
3023 has authenticated the pedigree papers.

3024 7. The unique serialization of the prescription drug, if
3025 the manufacturer or repackager has uniquely serialized the
3026 individual prescription drug unit.

3027 8. The name, address, telephone number, and, if available,
3028 e-mail contact information of each wholesale distributor involved
3029 in the chain of the prescription drug's custody.

3030 (3) EXCEPTIONS.--A pedigree paper is not required for:

3031 (a) The wholesale distribution of a prescription drug by
3032 the manufacturer.

3033 (b) The wholesale distribution of a compressed medical gas.

3034 (c) The wholesale distribution of a veterinary prescription
3035 drug.

3036 (d) A drop shipment, provided:

3037 1. The wholesale distributor delivers to the recipient of
3038 the prescription drug, within 14 days after the shipment
3039 notification from the manufacturer, an invoice and the following
3040 sworn statement: "This wholesale distributor purchased the
3041 specific unit of the prescription drug listed on the invoice
3042 directly from the manufacturer, and the specific unit of
3043 prescription drug was shipped by the manufacturer directly to a
3044 person authorized by law to administer or dispense the legend
3045 drug, as defined in s. 465.003, Florida Statutes, or a member of

588-06443-08

20082756c1

3046 an affiliated group, with the exception of a repackager." The
3047 invoice must contain a unique cross-reference to the shipping
3048 document sent by the manufacturer to the recipient of the
3049 prescription drug.

3050 2. The manufacturer of the prescription drug shipped
3051 directly to the recipient provides and the recipient of the
3052 prescription drug acquires, within 14 days after receipt of the
3053 prescription drug, a shipping document from the manufacturer that
3054 contains, at a minimum:

3055 a. The name and address of the manufacturer, including the
3056 point of origin of the shipment, and the names and addresses of
3057 the wholesale distributor and the purchaser.

3058 b. The name of the prescription drug as it appears on the
3059 label.

3060 c. The quantity, dosage form, and strength of the
3061 prescription drug.

3062 d. The date of the shipment from the manufacturer.

3063 3. The wholesale distributor maintains and makes available
3064 to the department, upon request, the lot number of such drug if
3065 not contained in the shipping document acquired by the recipient.

3066
3067 Failure of the manufacturer to provide, the recipient to acquire,
3068 or the wholesale distributor to deliver the documentation
3069 required under this paragraph shall constitute failure to acquire
3070 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.

3071 Forgery by the manufacturer, the recipient, or the wholesale
3072 distributor of the documentation required to be acquired or
3073 delivered under this paragraph shall constitute forgery of a
3074 pedigree paper under s. 499.0051.

588-06443-08

20082756c1

3075 4. The wholesale distributor that takes title to, but not
3076 possession of, the prescription drug is not a member of the
3077 affiliated group that receives the prescription drug directly
3078 from the manufacturer.

3079 (e) The wholesale distribution of a prescription drug by a
3080 warehouse within an affiliated group to a warehouse or retail
3081 pharmacy within its affiliated group, provided:

3082 1. Any affiliated group member that purchases or receives a
3083 prescription drug from outside the affiliated group must receive
3084 a pedigree paper if the prescription drug is distributed in or
3085 into this state and a pedigree paper is required under this
3086 section and must authenticate the documentation as required in s.
3087 499.0121(4), regardless of whether the affiliated group member is
3088 directly subject to regulation under this part; and

3089 2. The affiliated group makes available, within 48 hours,
3090 to the department on request to one or more of its members all
3091 records related to the purchase or acquisition of prescription
3092 drugs by members of the affiliated group, regardless of the
3093 location where the records are stored, if the prescription drugs
3094 were distributed in or into this state.

3095 (f) The repackaging of prescription drugs by a repackager
3096 solely for distribution to its affiliated group members for the
3097 exclusive distribution to and among retail pharmacies that are
3098 members of the affiliated group to which the repackager is a
3099 member.

3100 1. The repackager must:

3101 a. For all repackaged prescription drugs distributed in or
3102 into this state, state in writing under oath with each
3103 distribution of a repackaged prescription drug to an affiliated

588-06443-08

20082756c1

3104 group member warehouse or repackager: "All repackaged
3105 prescription drugs are purchased by the affiliated group directly
3106 from the manufacturer or from a prescription drug wholesale
3107 distributor that purchased the prescription drugs directly from
3108 the manufacturer."

3109 b. Purchase all prescription drugs it repackages:

3110 (I) Directly from the manufacturer; or

3111 (II) From a prescription drug wholesale distributor that
3112 purchased the prescription drugs directly from the manufacturer.

3113 c. Maintain records in accordance with this section to
3114 document that it purchased the prescription drugs directly from
3115 the manufacturer or that its prescription drug wholesale supplier
3116 purchased the prescription drugs directly from the manufacturer.

3117 2. All members of the affiliated group must provide, within
3118 48 hours, to agents of the department on request to one or more
3119 of its members records of purchases by all members of the
3120 affiliated group of prescription drugs that have been repackaged,
3121 regardless of the location at which the records are stored or at
3122 which the repackager is located.

3123 Section 16. Section 499.0122, Florida Statutes, is
3124 repealed.

3125 Section 17. Section 499.013, Florida Statutes, is repealed.

3126 Section 18. Subsections (1), (3), (4), (6), (8), and (9) of
3127 section 499.015, Florida Statutes, are amended to read:

3128 499.015 Registration of drugs, devices, and cosmetics;
3129 issuance of certificates of free sale.--

3130 (1)(a) Except for those persons exempted from the
3131 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any
3132 person who manufactures, packages, repackages, labels, or

588-06443-08

20082756c1

3133 relabels a drug, device, or cosmetic in this state must register
3134 such drug, device, or cosmetic biennially with the department;
3135 pay a fee in accordance with the fee schedule provided by s.
3136 499.041; and comply with this section. The registrant must list
3137 each separate and distinct drug, device, or cosmetic at the time
3138 of registration.

3139 (b) The department may not register any product that does
3140 not comply with the Federal Food, Drug, and Cosmetic Act, as
3141 amended, or Title 21 C.F.R. Registration of a product by the
3142 department does not mean that the product does in fact comply
3143 with all provisions of the Federal Food, Drug, and Cosmetic Act,
3144 as amended.

3145 (3) Except for those persons exempted from the definition
3146 of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, a person may
3147 not sell any product that he or she has failed to register in
3148 conformity with this section. Such failure to register subjects
3149 such drug, device, or cosmetic product to seizure and
3150 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and
3151 subjects such person to the penalties and remedies provided in
3152 this part ~~ss. 499.001-499.081~~.

3153 (4) Unless a registration is renewed, it expires 2 years
3154 after the last day of the month in which it was issued. The
3155 department may issue a stop-sale notice or order against a person
3156 that is subject to the requirements of this section and that
3157 fails to comply with this section within 31 days after the date
3158 the registration expires. The notice or order shall prohibit such
3159 person from selling or causing to be sold any drugs, devices, or
3160 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or
3161 she complies with the requirements of this section.

588-06443-08

20082756c1

3162 (6) The department may issue a certificate of free sale for
3163 any product that is required to be registered under this part ~~ss.~~
3164 ~~499.001-499.081~~.

3165 (8) Notwithstanding any requirements set forth in this part
3166 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is
3167 registered with the federal Food and Drug Administration is
3168 exempt from this section and s. 499.041(6) if:

3169 (a) The manufacturer's medical devices are approved for
3170 marketing by, or listed with the federal Food and Drug
3171 Administration in accordance with federal law for commercial
3172 distribution; or

3173 (b) The manufacturer subcontracts with a manufacturer of
3174 medical devices to manufacture components of such devices.

3175 (9) However, the manufacturer must submit evidence of such
3176 registration, listing, or approval with its initial application
3177 for a permit to do business in this state, as required in s.
3178 499.01 ~~s. 499.013~~ and any changes to such information previously
3179 submitted at the time of renewal of the permit. Evidence of
3180 approval, listing, and registration by the federal Food and Drug
3181 Administration must include:

3182 (a) For Class II devices, a copy of the pre-market
3183 notification letter (510K);

3184 (b) For Class III devices, a Federal Drug Administration
3185 pre-market approval number;

3186 (c) For a manufacturer who subcontracts with a manufacturer
3187 of medical devices to manufacture components of such devices, a
3188 Federal Drug Administration registration number; or

3189 (d) For a manufacturer of medical devices whose devices are
3190 exempt from pre-market approval by the Federal Drug

588-06443-08

20082756c1

3191 Administration, a Federal Drug Administration registration
3192 number.

3193 Section 19. Subsections (3), (5), and (6) of section
3194 499.024, Florida Statutes, are amended to read:

3195 499.024 Drug product classification.--The State Surgeon
3196 General shall adopt rules to classify drug products intended for
3197 use by humans which the United States Food and Drug
3198 Administration has not classified in the federal act or the Code
3199 of Federal Regulations.

3200 (3) Any product that falls under the definition of drug in
3201 s. 499.003(19) definition, s. 499.003(17), may be classified
3202 under the authority of this section. This section does not
3203 subject portable emergency oxygen inhalators to classification;
3204 however, this section does not exempt any person from ss. 499.01
3205 and 499.015.

3206 (5) The department may by rule reclassify drugs subject to
3207 this part ss. 499.001-499.081 when such classification action is
3208 necessary to protect the public health.

3209 (6) The department may adopt rules that exempt from any
3210 labeling or packaging requirements of this part ss. 499.001-
3211 499.081 drugs classified under this section if those requirements
3212 are not necessary to protect the public health.

3213 Section 20. Subsections (7), (12), and (15) of section
3214 499.028, Florida Statutes, are amended to read:

3215 499.028 Drug samples or complimentary drugs; starter packs;
3216 permits to distribute.--

3217 (7) A drug manufacturer or distributor must report to the
3218 department any conviction of itself or of its assigns, agents,
3219 employees, or representatives for a violation of s. 503(c)(1) of

588-06443-08

20082756c1

3220 the federal act or of this part ~~ss. 499.001-499.081~~ because of
3221 the sale, purchase, or trade of a drug sample or the offer to
3222 sell, purchase, or trade a drug sample.

3223 (12) The department may suspend or revoke a permit issued
3224 under this section, after giving notice and an opportunity to be
3225 heard pursuant to chapter 120, when:

3226 (a) Such permit was obtained by misrepresentation or fraud
3227 or through a mistake of the department.

3228 (b) The holder of the permit has distributed or disposed of
3229 any prescription legend ~~legend~~ drug, directly or through its agents,
3230 employees, or independent contractors, to any person not
3231 authorized to possess such drug.

3232 (c) The holder of the permit, or its agents, employees, or
3233 independent contractors, has distributed or possessed any
3234 prescription legend ~~legend~~ drug except in the usual course of its
3235 business.

3236 (d) The holder of the permit, or its agents, employees, or
3237 independent contractors, has distributed any prescription legend ~~legend~~
3238 drug that is misbranded or adulterated under this part ~~ss.~~
3239 ~~499.001-499.081~~.

3240 (e) The holder of the permit, or its agents, employees, or
3241 independent contractors, has distributed any prescription legend ~~legend~~
3242 drug without written request, when a written request is required
3243 by this section.

3244 (f) The holder of the permit has in its employ, or uses as
3245 agent or independent contractor for the purpose of distributing
3246 or disposing of drugs, any person who has:

3247 1. Violated the requirements of this section or any rule
3248 adopted under this section.

588-06443-08

20082756c1

3249 2. Been convicted in any of the courts of this state, the
3250 United States, or any other state of a felony or any other crime
3251 involving moral turpitude or involving those drugs named or
3252 described in chapter 893.

3253 (15) A person may not possess a prescription drug sample
3254 unless:

3255 (a) The drug sample was prescribed to her or him as
3256 evidenced by the label required in s. 465.0276(5).

3257 (b) She or he is the employee of a complimentary drug
3258 distributor that holds a permit issued under this part ~~ss.~~
3259 ~~499.001-499.081~~.

3260 (c) She or he is a person to whom prescription drug samples
3261 may be distributed pursuant to this section.

3262 (d) He or she is an officer or employee of a federal,
3263 state, or local government acting within the scope of his or her
3264 employment.

3265 Section 21. Subsections (2) and (3) of section 499.029,
3266 Florida Statutes, are amended to read:

3267 499.029 Cancer Drug Donation Program.--

3268 (2) There is created a Cancer Drug Donation Program within
3269 the department of ~~Health~~ for the purpose of authorizing and
3270 facilitating the donation of cancer drugs and supplies to
3271 eligible patients.

3272 (3) As used in this section:

3273 (a) "Cancer drug" means a prescription drug that has been
3274 approved under s. 505 of the federal Food, Drug, and Cosmetic Act
3275 and is used to treat cancer or its side effects or is used to
3276 treat the side effects of a prescription drug used to treat
3277 cancer or its side effects. "Cancer drug" does not include a

588-06443-08

20082756c1

3278 substance listed in Schedule II, Schedule III, Schedule IV, or
3279 Schedule V of s. 893.03.

3280 (b) "Closed drug delivery system" means a system in which
3281 the actual control of the unit-dose medication package is
3282 maintained by the facility rather than by the individual patient.

3283 ~~(c) "Department" means the Department of Health.~~

3284 (c) ~~(d)~~ "Donor" means a patient or patient representative
3285 who donates cancer drugs or supplies needed to administer cancer
3286 drugs that have been maintained within a closed drug delivery
3287 system; health care facilities, nursing homes, hospices, or
3288 hospitals with closed drug delivery systems; or pharmacies, drug
3289 manufacturers, medical device manufacturers or suppliers, or
3290 wholesalers of drugs or supplies, in accordance with this
3291 section. "Donor" includes a physician licensed under chapter 458
3292 or chapter 459 who receives cancer drugs or supplies directly
3293 from a drug manufacturer, wholesale distributor ~~drug wholesaler~~,
3294 or pharmacy.

3295 (d) ~~(e)~~ "Eligible patient" means a person who the department
3296 determines is eligible to receive cancer drugs from the program.

3297 (e) ~~(k)~~ "Participant facility" means a class II hospital
3298 pharmacy that has elected to participate in the program and that
3299 accepts donated cancer drugs and supplies under the rules adopted
3300 by the department for the program.

3301 ~~(e) "Prescription drug" means a drug as defined in s.~~
3302 ~~465.003(8).~~

3303 (f) ~~(p)~~ "Program" means the Cancer Drug Donation Program
3304 created by this section.

3305 (g) ~~(q)~~ "Supplies" means any supplies used in the
3306 administration of a cancer drug.

588-06443-08

20082756c1

3307 Section 22. Subsection (1) of section 499.03, Florida
3308 Statutes, is amended to read:

3309 499.03 Possession of certain drugs without prescriptions
3310 unlawful; exemptions and exceptions.--

3311 (1) A person may not possess, or possess with intent to
3312 sell, dispense, or deliver, any habit-forming, toxic, harmful, or
3313 new drug subject to s. 499.003(33) ~~s. 499.003(29)~~, or
3314 prescription legend drug as defined in s. 499.003(45) ~~s.~~
3315 ~~499.003(25)~~, unless the possession of the drug has been obtained
3316 by a valid prescription of a practitioner licensed by law to
3317 prescribe the drug. However, this section does not apply to the
3318 delivery of such drugs to persons included in any of the classes
3319 named in this subsection, or to the agents or employees of such
3320 persons, for use in the usual course of their businesses or
3321 practices or in the performance of their official duties, as the
3322 case may be; nor does this section apply to the possession of
3323 such drugs by those persons or their agents or employees for such
3324 use:

3325 (a) A licensed pharmacist or any person under the licensed
3326 pharmacist's supervision while acting within the scope of the
3327 licensed pharmacist's practice;

3328 (b) A licensed practitioner authorized by law to prescribe
3329 prescription legend drugs or any person under the licensed
3330 practitioner's supervision while acting within the scope of the
3331 licensed practitioner's practice;

3332 (c) A qualified person who uses prescription legend drugs
3333 for lawful research, teaching, or testing, and not for resale;

3334 (d) A licensed hospital or other institution that procures
3335 such drugs for lawful administration or dispensing by

588-06443-08

20082756c1

3336 practitioners;

3337 (e) An officer or employee of a federal, state, or local
3338 government; or

3339 (f) A person that holds a valid permit issued by the
3340 department pursuant to this part ~~ss. 499.001-499.081~~ which
3341 authorizes that person to possess prescription drugs.

3342 Section 23. Section 499.032, Florida Statutes, is amended
3343 to read:

3344 499.032 Phenylalanine; prescription
3345 required.--Phenylalanine restricted formula is declared to be a
3346 prescription ~~legend~~ drug and may be dispensed only upon the
3347 prescription of a practitioner authorized by law to prescribe
3348 prescription medicinal drugs.

3349 Section 24. Subsection (1) of section 499.033, Florida
3350 Statutes, is amended to read:

3351 499.033 Ephedrine; prescription required.--Ephedrine is
3352 declared to be a prescription drug.

3353 (1) Except as provided in subsection (2), any product that
3354 contains any quantity of ephedrine, a salt of ephedrine, an
3355 optical isomer of ephedrine, or a salt of an optical isomer of
3356 ephedrine may be dispensed only upon the prescription of a duly
3357 licensed practitioner authorized by the laws of the state to
3358 prescribe prescription medicinal drugs.

3359 Section 25. Subsections (1) and (3) of section 499.039,
3360 Florida Statutes, are amended to read:

3361 499.039 Sale, distribution, or transfer of harmful chemical
3362 substances; penalties; authority for enforcement.--It is unlawful
3363 for a person to sell, deliver, or give to a person under the age
3364 of 18 years any compound, liquid, or chemical containing toluol,

588-06443-08

20082756c1

3365 hexane, trichloroethylene, acetone, toluene, ethyl acetate,
3366 methyl ethyl ketone, trichloroethane, isopropanol, methyl
3367 isobutyl ketone, ethylene glycol monomethyl ether acetate,
3368 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites
3369 (butyl nitrite), or any similar substance for the purpose of
3370 inducing by breathing, inhaling, or ingesting a condition of
3371 intoxication or which is intended to distort or disturb the
3372 auditory, visual, or other physical or mental processes.

3373 (1) On the first violation of this section, the department
3374 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the
3375 violation has not caused temporary or permanent physical or
3376 mental injury to the user.

3377 (3) The department ~~of Health~~ shall adopt rules to implement
3378 this section.

3379 Section 26. Section 499.04, Florida Statutes, is amended to
3380 read:

3381 499.04 Fee authority.--The department may collect fees for
3382 all drug, device, and cosmetic applications, permits, product
3383 registrations, and free-sale certificates. The total amount of
3384 fees collected from all permits, applications, product
3385 registrations, and free-sale certificates must be adequate to
3386 fund the expenses incurred by the department in carrying out this
3387 part ~~ss. 499.001-499.081~~. The department shall, by rule,
3388 establish a schedule of fees that are within the ranges provided
3389 in this section and shall adjust those fees from time to time
3390 based on the costs associated with administering this part ~~ss.~~
3391 ~~499.001-499.081~~. The fees are payable to the department to be
3392 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
3393 for the sole purpose of carrying out the provisions of this part

588-06443-08

20082756c1

3394 ~~ss. 499.001-499.081.~~

3395 Section 27. Subsections (1) through (5), (8), and (10) of
3396 section 499.041, Florida Statutes, are amended to read:

3397 499.041 Schedule of fees for drug, device, and cosmetic
3398 applications and permits, product registrations, and free-sale
3399 certificates.--

3400 (1) The department shall assess applicants requiring a
3401 manufacturing permit an annual fee within the ranges established
3402 in this section for the specific type of manufacturer.

3403 (a) The fee for a prescription drug manufacturer
3404 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750
3405 annually.

3406 (b) The fee for a device manufacturer ~~manufacturer's~~ permit
3407 may not be less than \$500 or more than \$600 annually.

3408 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
3409 permit may not be less than \$250 or more than \$400 annually.

3410 (d) The fee for an over-the-counter drug manufacturer
3411 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400
3412 annually.

3413 (e) The fee for a compressed medical gas manufacturer
3414 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500
3415 annually.

3416 (f) The fee for a prescription drug repackager ~~repackager's~~
3417 permit may not be less than \$500 or more than \$750 annually.

3418 (g) A manufacturer may not be required to pay more than one
3419 fee per establishment to obtain an additional manufacturing
3420 permit, but each manufacturer must pay the highest fee applicable
3421 to his or her operation in each establishment.

3422 (2) The department shall assess an applicant that is

588-06443-08

20082756c1

3423 required to have a wholesaling permit an annual fee within the
3424 ranges established in this section for the specific type of
3425 wholesaling.

3426 (a) The fee for a prescription drug wholesale distributor
3427 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
3428 annually.

3429 (b) The fee for a compressed medical gas wholesale
3430 distributor ~~wholesaler's~~ permit may not be less than \$200 or more
3431 than \$300 annually.

3432 (c) The fee for an out-of-state prescription drug wholesale
3433 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
3434 than \$800 annually.

3435 (d) The fee for a nonresident prescription drug
3436 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or
3437 more than \$500 annually.

3438 (e) The fee for a retail pharmacy drug wholesale
3439 distributor ~~wholesaler's~~ permit may not be less than \$35 or more
3440 than \$50 annually.

3441 (f) The fee for a freight forwarder ~~forwarder's~~ permit may
3442 not be less than \$200 or more than \$300 annually.

3443 (g) The fee for a veterinary prescription drug wholesale
3444 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
3445 than \$500 annually.

3446 (h) The fee for a limited prescription drug veterinary
3447 wholesale distributor ~~wholesaler's~~ permit may not be less than
3448 \$300 or more than \$500 annually.

3449 (3) The department shall assess an applicant that is
3450 required to have a retail establishment permit an annual fee
3451 within the ranges established in this section for the specific

588-06443-08

20082756c1

3452 type of retail establishment.

3453 (a) The fee for a veterinary prescription ~~legend~~ drug
3454 retail establishment permit may not be less than \$200 or more
3455 than \$300 annually.

3456 (b) The fee for a medical oxygen retail establishment
3457 permit may not be less than \$200 or more than \$300 annually.

3458 (4) The department shall assess an applicant that is
3459 required to have a restricted prescription drug distributor
3460 ~~distributor's~~ permit an annual fee of not less than \$200 or more
3461 than \$300.

3462 (5) In addition to the fee charged for a permit required by
3463 this part ss. 499.001-499.081, the department shall assess
3464 applicants an initial application fee of \$150 for each new permit
3465 issued by the department which requires an onsite inspection.

3466 (8) The department shall assess an out-of-state
3467 prescription drug wholesale distributor ~~wholesaler~~ applicant or
3468 permittee an onsite inspection fee of not less than \$1,000 or
3469 more than \$3,000 annually, to be based on the actual cost of the
3470 inspection if an onsite inspection is performed by agents of the
3471 department.

3472 (10) The department shall assess other fees as provided in
3473 this part ss. 499.001-499.081.

3474 Section 28. Section 499.05, Florida Statutes, is amended;
3475 subsection (3) of section 499.013, Florida Statutes, is
3476 redesignated as paragraph (k) of subsection (1) of that section
3477 and amended; paragraph (b) of subsection (2) of section 499.0122,
3478 Florida Statutes, is redesignated as paragraph (l) of subsection
3479 (1) of that section and amended; and subsection (12) of section
3480 499.012, Florida Statutes, is redesignated as paragraph (m) of

588-06443-08

20082756c1

3481 subsection (1) of that section and amended, to read:

3482 499.05 Rules.--

3483 (1) The department shall adopt rules to implement and
3484 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3485 (a) The definition of terms used in this part ~~ss. 499.001-~~
3486 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~
3487 ~~499.001-499.081~~, when the use of the term is not its usual and
3488 ordinary meaning.

3489 (b) Labeling requirements for drugs, devices, and
3490 cosmetics.

3491 (c) The establishment of fees authorized in this part ~~ss.~~
3492 ~~499.001-499.081~~.

3493 (d) The identification of permits that require an initial
3494 application and onsite inspection or other prerequisites for
3495 permitting which demonstrate that the establishment and person
3496 are in compliance with the requirements of this part ~~ss. 499.001-~~
3497 ~~499.081~~.

3498 (e) The application processes and forms for product
3499 registration.

3500 (f) Procedures for requesting and issuing certificates of
3501 free sale.

3502 (g) Inspections and investigations conducted under s.
3503 499.051, and the identification of information claimed to be a
3504 trade secret and exempt from the public records law as provided
3505 in s. 499.051(7).

3506 (h) The establishment of a range of penalties, as provided
3507 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of
3508 the potential impact of a violation of this part ~~ss. 499.001-~~
3509 ~~499.081~~; and a process for the uncontested settlement of alleged

588-06443-08

20082756c1

3510 | violations.

3511 | (i) Additional conditions that qualify as an emergency
3512 | medical reason under s. 499.003(56)(b)2. ~~s. 499.012(1)(a)2.b.~~

3513 | (j) Procedures and forms relating to the pedigree paper
3514 | requirement of s. 499.01212.

3515 | ~~(k)(3) The department may adopt such rules as are necessary~~
3516 | ~~for~~ The protection of the public health, safety, and welfare
3517 | regarding good manufacturing practices that manufacturers and
3518 | repackagers must follow to ensure the safety of the products.

3519 | ~~(l)(b) The department shall adopt rules relating to~~
3520 | Information required from each retail establishment pursuant to
3521 | s. 499.012(3) ~~s. 499.01(4)~~, including requirements for
3522 | prescriptions or orders.

3523 | ~~(m)(12) The department may adopt rules governing~~ The
3524 | recordkeeping, storage, and handling with respect to each of the
3525 | distributions of prescription drugs specified in s.
3526 | 499.003(56)(a)-(d) subparagraphs (1)(a)1.-4.

3527 | (n) Alternatives to compliance with s. 499.01212 for a
3528 | prescription drug in the inventory of a permitted prescription
3529 | drug wholesale distributor as of June 30, 2006, and the return of
3530 | a prescription drug purchased prior to July 1, 2006. The
3531 | department may specify time limits for such alternatives.

3532 | (2) With respect to products in interstate commerce, those
3533 | rules must not be inconsistent with rules and regulations of
3534 | federal agencies unless specifically otherwise directed by the
3535 | Legislature.

3536 | (3) The department shall adopt rules regulating
3537 | recordkeeping for and the storage, handling, and distribution of
3538 | medical devices and over-the-counter drugs to protect the public

588-06443-08

20082756c1

3539 | from adulterated products.

3540 | Section 29. Section 499.051, Florida Statutes, is amended
3541 | to read:

3542 | 499.051 Inspections and investigations.--

3543 | (1) The agents of the department ~~of Health~~ and of the
3544 | Department of Law Enforcement, after they present proper
3545 | identification, may inspect, monitor, and investigate any
3546 | establishment permitted pursuant to this part ~~ss. 499.001-499.081~~
3547 | during business hours for the purpose of enforcing this part ~~ss.~~
3548 | ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the
3549 | department that protect the public health, safety, and welfare.

3550 | (2) In addition to the authority set forth in subsection
3551 | (1), the department and any duly designated officer or employee
3552 | of the department may enter and inspect any other establishment
3553 | for the purpose of determining compliance with this part ~~ss.~~
3554 | ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~
3555 | regarding any drug, device, or cosmetic product.

3556 | (3) Any application for a permit or product registration or
3557 | for renewal of such permit or registration made pursuant to this
3558 | part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~
3559 | ~~sections~~ constitutes permission for any entry or inspection of
3560 | the premises in order to verify compliance with this part ~~those~~
3561 | ~~sections~~ and rules; to discover, investigate, and determine the
3562 | existence of compliance; or to elicit, receive, respond to, and
3563 | resolve complaints and violations.

3564 | (4) Any application for a permit made pursuant to s.
3565 | 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that
3566 | section ~~those sections~~ constitutes permission for agents of the
3567 | department ~~of Health~~ and the Department of Law Enforcement, after

588-06443-08

20082756c1

3568 presenting proper identification, to inspect, review, and copy
3569 any financial document or record related to the manufacture,
3570 repackaging, or distribution of a drug as is necessary to verify
3571 compliance with this part ~~ss. 499.001-499.081~~ and the rules
3572 adopted by the department to administer this part ~~those sections~~,
3573 in order to discover, investigate, and determine the existence of
3574 compliance, or to elicit, receive, respond to, and resolve
3575 complaints and violations.

3576 (5) The authority to inspect under this section includes
3577 the authority to access, review, and copy any and all financial
3578 documents related to the activity of manufacturing, repackaging,
3579 or distributing prescription drugs.

3580 (6) The authority to inspect under this section includes
3581 the authority to secure:

3582 (a) Samples or specimens of any drug, device, or cosmetic;
3583 or

3584 (b) Such other evidence as is needed for any action to
3585 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under
3586 this part ~~those sections~~.

3587 (7) The complaint and all information obtained pursuant to
3588 the investigation by the department are confidential and exempt
3589 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the
3590 State Constitution until the investigation and the enforcement
3591 action are completed. However, trade secret information contained
3592 therein as defined by s. 812.081(1)(c) shall remain confidential
3593 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
3594 I of the State Constitution, as long as the information is
3595 retained by the department. This subsection does not prohibit the
3596 department from using such information for regulatory or

588-06443-08

20082756c1

3597 enforcement proceedings under this chapter or from providing such
3598 information to any law enforcement agency or any other regulatory
3599 agency. However, the receiving agency shall keep such records
3600 confidential and exempt as provided in this subsection. In
3601 addition, this subsection is not intended to prevent compliance
3602 with the provisions of s. 499.01212 ~~s. 499.0121(6)(d)~~, and the
3603 pedigree papers required in that section ~~subsection~~ shall not be
3604 deemed a trade secret.

3605 Section 30. Section 499.052, Florida Statutes, is amended
3606 to read:

3607 499.052 Records of interstate shipment.--For the purpose of
3608 enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in
3609 interstate commerce and persons receiving drugs, devices, or
3610 cosmetics in interstate commerce must, upon the request, in the
3611 manner set out below, by an officer or employee duly designated
3612 by the department, permit the officer or employee to have access
3613 to and to copy all records showing the movement in interstate
3614 commerce of any drug, device, or cosmetic, and the quantity,
3615 shipper, and consignee thereof.

3616 Section 31. Subsection (4) of section 499.055, Florida
3617 Statutes, is amended to read:

3618 499.055 Reports and dissemination of information by
3619 department.--

3620 (4) The department shall publish on the department's
3621 website and update at least monthly:

3622 (a) A list of the prescription drug wholesale distributors
3623 ~~wholesalers~~, out-of-state prescription drug wholesale
3624 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
3625 distributors ~~wholesalers~~ against whom the department has

588-06443-08

20082756c1

3626 initiated enforcement action pursuant to this part ~~ss. 499.001-~~
3627 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
3628 otherwise file an administrative complaint and the permit number
3629 of each such wholesale distributor ~~wholesaler~~.

3630 (b) A list of the prescription drug wholesale distributors
3631 ~~wholesalers~~, out-of-state prescription drug wholesale
3632 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
3633 distributors ~~wholesalers~~ to which the department has issued a
3634 permit, including the date on which each permit will expire.

3635 (c) A list of the prescription drug wholesale distributor
3636 ~~wholesalers~~, out-of-state prescription drug wholesale distributor
3637 ~~wholesalers~~, and retail pharmacy drug wholesale distributor
3638 ~~wholesalers~~ permits that have been returned to the department,
3639 were suspended, were revoked, have expired, or were not renewed
3640 in the previous year.

3641 Section 32. Subsections (1) and (3) of section 499.06,
3642 Florida Statutes, are amended to read:

3643 499.06 Embargoing, detaining, or destroying article or
3644 processing equipment which is in violation of law or rule.--

3645 (1) When a duly authorized agent of the department finds,
3646 or has probable cause to believe, that any drug, device, or
3647 cosmetic is in violation of any provision of this part ~~ss.~~
3648 ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~
3649 so as to be dangerous, unwholesome, or fraudulent within the
3650 meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and
3651 enforce a stop-sale, stop-use, removal, or hold order, which
3652 order gives notice that such article or processing equipment is,
3653 or is suspected of being, in violation and has been detained or
3654 embargoed, and which order warns all persons not to remove, use,

588-06443-08

20082756c1

3655 or dispose of such article or processing equipment by sale or
3656 otherwise until permission for removal, use, or disposal is given
3657 by such agent or the court. It is unlawful for any person to
3658 remove, use, or dispose of such detained or embargoed article or
3659 processing equipment by sale or otherwise without such
3660 permission; and such act is a felony of the second degree,
3661 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3662 (3) If the court finds that the detained or embargoed
3663 article or processing equipment is in violation, such article or
3664 processing equipment shall, after entry of the court order, be
3665 destroyed or made sanitary at the expense of the claimant
3666 thereof, under the supervision of such agent; and all court
3667 costs, fees, and storage and other proper expenses shall be taxed
3668 against the claimant of such article or processing equipment or
3669 her or his agent. However, when the violation can be corrected by
3670 proper labeling of the article or sanitizing of the processing
3671 equipment, and after such costs, fees, and expenses have been
3672 paid and a good and sufficient bond, conditioned that such
3673 article be so labeled or processed or such processing equipment
3674 be so sanitized, has been executed, the court may by order direct
3675 that such article or processing equipment be delivered to the
3676 claimant thereof for such labeling, processing, or sanitizing,
3677 under the supervision of an agent of the department. The expense
3678 of such supervision shall be paid by the claimant. Such bond
3679 shall be returned to the claimant of the article or processing
3680 equipment upon representation to the court by the department that
3681 the article or processing equipment is no longer in violation of
3682 this part ~~ss. 499.001-499.081~~ and that the expenses of such
3683 supervision have been paid.

588-06443-08

20082756c1

3684 Section 33. Section 499.062, Florida Statutes, is amended;
3685 section 499.063, Florida Statutes, is redesignated as section (2)
3686 of that section and amended; and section 499.064, Florida
3687 Statutes, is redesignated as paragraphs (a) and (b) of subsection
3688 (2) of that section and amended, to read:

3689 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
3690 devices, or cosmetics.--

3691 (1) Any article of any drug, device, or cosmetic that is
3692 adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is
3693 subject to seizure and condemnation by the department or by its
3694 duly authorized agents designated for that purpose in regard to
3695 drugs, devices, or cosmetics.

3696 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~
3697 ~~disposal of article; penalty.~~ Whenever a duly authorized officer
3698 or employee of the department finds cause, or has probable cause
3699 to believe that cause exists, for the seizure of any drug,
3700 device, or cosmetic, as set out in this part ~~ss. 499.001-499.081~~,
3701 he or she shall affix to the article a tag, stamp, or other
3702 appropriate marking, giving notice that the article is, or is
3703 suspected of being, subject to seizure under this part ~~ss.~~
3704 ~~499.001-499.081~~ and that the article has been detained and seized
3705 by the department. Such officer or employee shall also warn all
3706 persons not to remove or dispose of the article, by sale or
3707 otherwise, until permission is given by the department or the
3708 court. Any person who violates this subsection ~~section~~ is guilty
3709 of a felony of the second degree, punishable as provided in s.
3710 775.082, s. 775.083, or s. 775.084.

3711 (a) ~~499.064 Condemnation and sale; release of seized~~
3712 ~~article.--~~ (1) When any article detained or seized under this

588-06443-08

20082756c1

3713 subsection s. 499.063 has been found by the department to be
3714 subject to seizure and condemnation ~~under s. 499.063~~, the
3715 department shall petition the court for an order of condemnation
3716 or sale, as the court directs. The proceeds of the sale of drugs,
3717 devices, and cosmetics, less the legal costs and charges, shall
3718 be deposited into the Florida Drug, Device, and Cosmetic Trust
3719 Fund.

3720 ~~(b)(2)~~ If the department finds that any article seized
3721 under this subsection s. 499.063 was not subject to seizure ~~under~~
3722 ~~that section~~, the department or the designated officer or
3723 employee shall remove the tag or marking.

3724 Section 34. Section 499.065, Florida Statutes, is amended
3725 to read:

3726 499.065 Inspections; imminent danger.--

3727 (1) Notwithstanding s. 499.051, the department shall
3728 inspect each prescription drug wholesale distributor
3729 establishment, prescription drug repackager establishment,
3730 veterinary prescription drug wholesale distributor establishment,
3731 limited prescription drug veterinary wholesale distributor
3732 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale
3733 distributor ~~wholesaler~~ establishment that is required to be
3734 permitted under this part ~~chapter~~ as often as necessary to ensure
3735 compliance with applicable laws and rules. The department shall
3736 have the right of entry and access to these facilities at any
3737 reasonable time.

3738 (2) To protect the public from prescription drugs that are
3739 adulterated or otherwise unfit for human or animal consumption,
3740 the department may examine, sample, seize, and stop the sale or
3741 use of prescription drugs to determine the condition of those

588-06443-08

20082756c1

3742 | drugs. The department may immediately seize and remove any
3743 | prescription drugs if the State Surgeon General or his or her
3744 | designee determines that the prescription drugs represent a
3745 | threat to the public health. The owner of any property seized
3746 | under this section may, within 10 days after the seizure, apply
3747 | to a court of competent jurisdiction for whatever relief is
3748 | appropriate. At any time after 10 days, the department may
3749 | destroy the drugs as contraband.

3750 | (3) The department may determine that a prescription drug
3751 | wholesale distributor establishment, prescription drug repackager
3752 | establishment, veterinary prescription drug wholesale distributor
3753 | establishment, limited prescription drug veterinary wholesale
3754 | distributor ~~wholesaler~~ establishment, or retail pharmacy drug
3755 | wholesale distributor ~~wholesaler~~ establishment that is required
3756 | to be permitted under this part ~~chapter~~ is an imminent danger to
3757 | the public health and shall require its immediate closure if the
3758 | establishment fails to comply with applicable laws and rules and,
3759 | because of the failure, presents an imminent threat to the
3760 | public's health, safety, or welfare. Any establishment so deemed
3761 | and closed shall remain closed until allowed by the department or
3762 | by judicial order to reopen.

3763 | (4) For purposes of this section, a refusal to allow entry
3764 | to the department for inspection at reasonable times, or a
3765 | failure or refusal to provide the department with required
3766 | documentation for purposes of inspection, constitutes an imminent
3767 | danger to the public health.

3768 | Section 35. Subsections (1) through (4) of section 499.066,
3769 | Florida Statutes, are amended to read:

3770 | 499.066 Penalties; remedies.--In addition to other

588-06443-08

20082756c1

3771 penalties and other enforcement provisions:

3772 (1) The department may institute such suits or other legal
3773 proceedings as are required to enforce any provision of this part
3774 ~~ss. 499.001-499.081~~. If it appears that a person has violated any
3775 provision of this part ~~ss. 499.001-499.081~~ for which criminal
3776 prosecution is provided, the department may provide the
3777 appropriate state attorney or other prosecuting agency having
3778 jurisdiction with respect to such prosecution with the relevant
3779 information in the department's possession.

3780 (2) If any person engaged in any activity covered by this
3781 part ~~ss. 499.001-499.081~~ violates any provision of this part
3782 ~~those sections~~, any rule adopted under this part ~~those sections~~,
3783 or a cease and desist order as provided by this part ~~those~~
3784 ~~sections~~, the department may obtain an injunction in the circuit
3785 court of the county in which the violation occurred or in which
3786 the person resides or has its principal place of business, and
3787 may apply in that court for such temporary and permanent orders
3788 as the department considers necessary to restrain the person from
3789 engaging in any such activities until the person complies with
3790 this part ~~ss. 499.001-499.081~~, the rules adopted under this part
3791 ~~those sections~~, and the orders of the department authorized by
3792 this part ~~those sections~~ or to mandate compliance with this part
3793 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~
3794 ~~sections~~, and any order or permit issued by the department under
3795 this part ~~those sections~~.

3796 (3) The department may impose an administrative fine, not
3797 to exceed \$5,000 per violation per day, for the violation of any
3798 provision of this part ~~ss. 499.001-499.081~~ or rules adopted under
3799 this part ~~those sections~~. Each day a violation continues

588-06443-08

20082756c1

3800 constitutes a separate violation, and each separate violation is
3801 subject to a separate fine. All amounts collected pursuant to
3802 this section shall be deposited into the Florida Drug, Device,
3803 and Cosmetic Trust Fund and are appropriated for the use of the
3804 department in administering this part ~~ss. 499.001-499.081~~. In
3805 determining the amount of the fine to be levied for a violation,
3806 the department shall consider:

3807 (a) The severity of the violation;

3808 (b) Any actions taken by the person to correct the
3809 violation or to remedy complaints; and

3810 (c) Any previous violations.

3811 (4) The department shall deposit any rewards, fines, or
3812 collections that are due the department and which derive from
3813 joint enforcement activities with other state and federal
3814 agencies which relate to this part ~~ss. 499.001-499.081~~, chapter
3815 893, or the federal act, into the Florida Drug, Device, and
3816 Cosmetic Trust Fund. The proceeds of those rewards, fines, and
3817 collections are appropriated for the use of the department in
3818 administering this part ~~ss. 499.001-499.081~~.

3819 Section 36. Section 499.0661, Florida Statutes, is amended
3820 to read:

3821 499.0661 Cease and desist orders; removal of certain
3822 persons.--

3823 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3824 (a) In addition to any authority otherwise provided in this
3825 chapter, the department may issue and serve a complaint stating
3826 charges upon any permittee or upon any affiliated party, whenever
3827 the department has reasonable cause to believe that the person or
3828 individual named therein is engaging in or has engaged in conduct

588-06443-08

20082756c1

3829 | that is:

3830 | 1. An act that demonstrates a lack of fitness or
3831 | trustworthiness to engage in the business authorized under the
3832 | permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
3833 | hazardous to the public health, or constitutes business
3834 | operations that are a detriment to the public health;

3835 | 2. A violation of any provision of this part ~~ss. 499.001-~~
3836 | ~~499.081~~;

3837 | 3. A violation of any rule of the department;

3838 | 4. A violation of any order of the department; or

3839 | 5. A breach of any written agreement with the department.

3840 | (b) The complaint must contain a statement of facts and
3841 | notice of opportunity for a hearing pursuant to ss. 120.569 and
3842 | 120.57.

3843 | (c) If a hearing is not requested within the time allowed
3844 | by ss. 120.569 and 120.57, or if a hearing is held and the
3845 | department finds that any of the charges are proven, the
3846 | department may enter an order directing the permittee or the
3847 | affiliated party named in the complaint to cease and desist from
3848 | engaging in the conduct complained of and take corrective action
3849 | to remedy the effects of past improper conduct and assure future
3850 | compliance.

3851 | (d) A contested or default cease and desist order is
3852 | effective when reduced to writing and served upon the permittee
3853 | or affiliated party named therein. An uncontested cease and
3854 | desist order is effective as agreed.

3855 | (e) Whenever the department finds that conduct described in
3856 | paragraph (a) is likely to cause an immediate threat to the
3857 | public health, it may issue an emergency cease and desist order

588-06443-08

20082756c1

3858 requiring the permittee or any affiliated party to immediately
3859 cease and desist from engaging in the conduct complained of and
3860 to take corrective and remedial action. The emergency order is
3861 effective immediately upon service of a copy of the order upon
3862 the permittee or affiliated party named therein and remains
3863 effective for 90 days. If the department begins nonemergency
3864 cease and desist proceedings under this subsection, the emergency
3865 order remains effective until the conclusion of the proceedings
3866 under ss. 120.569 and 120.57.

3867 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3868 (a) The department may issue and serve a complaint stating
3869 charges upon any affiliated party and upon the permittee involved
3870 whenever the department has reason to believe that an affiliated
3871 party is engaging in or has engaged in conduct that constitutes:

3872 1. An act that demonstrates a lack of fitness or
3873 trustworthiness to engage in the business authorized under the
3874 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
3875 hazardous to the public health, or constitutes business
3876 operations that are a detriment to the public health;

3877 2. A willful violation of this part ~~ss. 499.001-499.081~~;
3878 however, if the violation constitutes a misdemeanor, a complaint
3879 may not be served as provided in this section until the
3880 affiliated party is notified in writing of the matter of the
3881 violation and has been afforded a reasonable period of time, as
3882 set forth in the notice, to correct the violation and has failed
3883 to do so;

3884 3. A violation of any other law involving fraud or moral
3885 turpitude which constitutes a felony;

3886 4. A willful violation of any rule of the department;

588-06443-08

20082756c1

3887 5. A willful violation of any order of the department; or
3888 6. A material misrepresentation of fact, made knowingly and
3889 willfully or made with reckless disregard for the truth of the
3890 matter.

3891 (b) The complaint must contain a statement of facts and
3892 notice of opportunity for a hearing pursuant to ss. 120.569 and
3893 120.57.

3894 (c) If a hearing is not requested within the time allotted
3895 by ss. 120.569 and 120.57, or if a hearing is held and the
3896 department finds that any of the charges in the complaint are
3897 proven true, the department may enter an order removing the
3898 affiliated party or restricting or prohibiting participation by
3899 the person in the affairs of that permittee or of any other
3900 permittee.

3901 (d) A contested or default order of removal, restriction,
3902 or prohibition is effective when reduced to writing and served on
3903 the permittee and the affiliated party. An uncontested order of
3904 removal, restriction, or prohibition is effective as agreed.

3905 (e)1. The chief executive officer, designated
3906 representative, or the person holding the equivalent office, of a
3907 permittee shall promptly notify the department if she or he has
3908 actual knowledge that any affiliated party is charged with a
3909 felony in a state or federal court.

3910 2. Whenever any affiliated party is charged with a felony
3911 in a state or federal court or with the equivalent of a felony in
3912 the courts of any foreign country with which the United States
3913 maintains diplomatic relations, and the charge alleges violation
3914 of any law involving prescription drugs, pharmaceuticals, fraud,
3915 theft, or moral turpitude, the department may enter an emergency

588-06443-08

20082756c1

3916 | order suspending the affiliated party or restricting or
3917 | prohibiting participation by the affiliated party in the affairs
3918 | of the particular permittee or of any other permittee upon
3919 | service of the order upon the permittee and the affiliated party
3920 | charged. The order must contain notice of opportunity for a
3921 | hearing pursuant to ss. 120.569 and 120.57, where the affiliated
3922 | party may request a postsuspension hearing to show that continued
3923 | service to or participation in the affairs of the permittee does
3924 | not pose a threat to the public health or the interests of the
3925 | permittee and does not threaten to impair public confidence in
3926 | the permittee. In accordance with applicable departmental rules,
3927 | the department shall notify the affiliated party whether the
3928 | order suspending or prohibiting the person from participation in
3929 | the affairs of a permittee will be rescinded or otherwise
3930 | modified. The emergency order remains in effect, unless otherwise
3931 | modified by the department, until the criminal charge is disposed
3932 | of. The acquittal of the person charged, or the final, unappealed
3933 | dismissal of all charges against the person, dissolves the
3934 | emergency order but does not prohibit the department from
3935 | instituting proceedings under paragraph (a). If the person
3936 | charged is convicted or pleads guilty or nolo contendere, whether
3937 | or not an adjudication of guilt is entered by the court, the
3938 | emergency order shall become final.

3939 | (f) Any affiliated party removed pursuant to this section
3940 | is not eligible for reemployment by the permittee or to be an
3941 | affiliated party of any permittee except upon the written consent
3942 | of the department. Any affiliated party who is removed,
3943 | restricted, or prohibited from participating in the affairs of a
3944 | permittee pursuant to this section may petition the department

588-06443-08

20082756c1

3945 for modification or termination of the removal, restriction, or
3946 prohibition.

3947 Section 37. Section 499.067, Florida Statutes, is amended
3948 to read:

3949 499.067 Denial, suspension, or revocation of permit,
3950 certification, or registration.--

3951 (1) (a) The department may deny, suspend, or revoke a permit
3952 if it finds that there has been a substantial failure to comply
3953 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,
3954 or chapter 893, the rules adopted under this part ~~any of those~~
3955 ~~sections~~ or those chapters, any final order of the department, or
3956 applicable federal laws or regulations or other state laws or
3957 rules governing drugs, devices, or cosmetics.

3958 (b) The department may deny an application for a permit or
3959 certification, or suspend or revoke a permit or certification, if
3960 the department finds that:

3961 1. The applicant is not of good moral character or that it
3962 would be a danger or not in the best interest of the public
3963 health, safety, and welfare if the applicant were issued a permit
3964 or certification.

3965 2. The applicant has not met the requirements for the
3966 permit or certification.

3967 3. The applicant is not eligible for a permit or
3968 certification for any of the reasons enumerated in s. 499.012 ~~s.~~
3969 ~~499.01~~ ~~or s. 499.012(5)~~.

3970 4. The applicant, permittee, or person certified under s.
3971 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions
3972 enumerated in s. 499.012 ~~s. 499.01~~ ~~or s. 499.012(5)~~.

3973 5. The applicant, permittee, or person certified under s.

588-06443-08

20082756c1

3974 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.
3975 499.005-499.0054.

3976 (2) The department may deny, suspend, or revoke any
3977 registration required by the provisions of this part ~~ss. 499.001-~~
3978 ~~499.081~~ for the violation of any provision of this part ~~ss.~~
3979 ~~499.001-499.081~~ or of any rules adopted under this part ~~these~~
3980 ~~sections~~.

3981 (3) The department may revoke or suspend a permit:

3982 (a) If the permit was obtained by misrepresentation or
3983 fraud or through a mistake of the department;

3984 (b) If the permit was procured, or attempted to be
3985 procured, for any other person by making or causing to be made
3986 any false representation; or

3987 (c) If the permittee has violated any provision of this
3988 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~
3989 ~~sections~~.

3990 (4) If any permit issued under this part ~~ss. 499.001-~~
3991 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or
3992 proprietor of the establishment shall cease to operate as the
3993 permit authorized, from the effective date of the suspension or
3994 revocation until the person is again registered with the
3995 department and possesses the required permit. If a permit is
3996 revoked or suspended, the owner, manager, or proprietor shall
3997 remove all signs and symbols that identify the operation as
3998 premises permitted as a drug wholesaling establishment; drug,
3999 device, or cosmetic manufacturing establishment; or retail
4000 establishment. The department shall determine the length of time
4001 for which the permit is to be suspended. If a permit is revoked,
4002 the person that owns or operates the establishment may not apply

588-06443-08

20082756c1

4003 for any permit under this part ~~ss. 499.001-499.081~~ for a period
4004 of 1 year after the date of the revocation. A revocation of a
4005 permit may be permanent if the department considers that to be in
4006 the best interest of the public health.

4007 (5) The department may deny, suspend, or revoke a permit
4008 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
4009 permittee to purchase prescription drugs, if any owner, officer,
4010 employee, or other person who participates in administering or
4011 operating the establishment has been found guilty of any
4012 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
4013 chapter 501, or chapter 893, any rules adopted under this part
4014 ~~any of those sections~~ or those chapters, or any federal or state
4015 drug law, regardless of whether the person has been pardoned, had
4016 her or his civil rights restored, or had adjudication withheld.

4017 (6) The department shall deny, suspend, or revoke the
4018 permit of any person or establishment if the assignment, sale,
4019 transfer, or lease of an establishment permitted under this part
4020 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
4021 action, or criminal prosecution.

4022 (7) Notwithstanding s. 120.60(5), if a permittee fails to
4023 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke
4024 the permit of the permittee and shall provide notice of the
4025 intended agency action by posting a notice at the department's
4026 headquarters and by mailing a copy of the notice of intended
4027 agency action by certified mail to the most recent mailing
4028 address on record with the department and, if the permittee is
4029 not a natural person, to the permittee's registered agent on file
4030 with the Department of State.

4031 Section 38. Paragraph (a) of subsection (1) of section

588-06443-08

20082756c1

4032 409.9201, Florida Statutes, is amended to read:

4033 409.9201 Medicaid fraud.--

4034 (1) As used in this section, the term:

4035 (a) "Legend drug" means any drug, including, but not
4036 limited to, finished dosage forms or active ingredients that are
4037 subject to, defined by, or described by s. 503(b) of the Federal
4038 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.007(13)
4039 ~~s. 499.007(12)~~, or s. 499.003(48) or (55) ~~s. 499.0122(1)(b) or~~
4040 ~~(c)~~.

4041

4042 The value of individual items of the legend drugs or goods or
4043 services involved in distinct transactions committed during a
4044 single scheme or course of conduct, whether involving a single
4045 person or several persons, may be aggregated when determining the
4046 punishment for the offense.

4047 Section 39. Paragraph (c) of subsection (9) of section

4048 460.403, Florida Statutes, is amended to read:

4049 460.403 Definitions.--As used in this chapter, the term:

4050 (9)

4051 (c)1. Chiropractic physicians may adjust, manipulate, or
4052 treat the human body by manual, mechanical, electrical, or
4053 natural methods; by the use of physical means or physiotherapy,
4054 including light, heat, water, or exercise; by the use of
4055 acupuncture; or by the administration of foods, food
4056 concentrates, food extracts, and items for which a prescription
4057 is not required and may apply first aid and hygiene, but
4058 chiropractic physicians are expressly prohibited from prescribing
4059 or administering to any person any legend drug except as
4060 authorized under subparagraph 2., from performing any surgery

588-06443-08

20082756c1

4061 | except as stated herein, or from practicing obstetrics.

4062 | 2. Notwithstanding the prohibition against prescribing and
4063 | administering legend drugs under subparagraph 1.~~7~~ or s.

4064 | 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic
4065 | physicians may order, store, and administer, for emergency
4066 | purposes only at the chiropractic physician's office or place of
4067 | business, prescription medical oxygen and may also order, store,
4068 | and administer the following topical anesthetics in aerosol form:

4069 | a. Any solution consisting of 25 percent ethylchloride and
4070 | 75 percent dichlorodifluoromethane.

4071 | b. Any solution consisting of 15 percent
4072 | dichlorodifluoromethane and 85 percent
4073 | trichloromonofluoromethane.

4074 |
4075 | However, this paragraph does not authorize a chiropractic
4076 | physician to prescribe medical oxygen as defined in chapter 499.

4077 | Section 40. Subsection (3) of section 465.0265, Florida
4078 | Statutes, is amended to read:

4079 | 465.0265 Centralized prescription filling.--

4080 | (3) The filling, delivery, and return of a prescription by
4081 | one pharmacy for another pursuant to this section shall not be
4082 | construed as the filling of a transferred prescription as set
4083 | forth in s. 465.026 or as a wholesale distribution as set forth
4084 | in s. 499.003(56) ~~s. 499.012(1)(a)~~.

4085 | Section 41. Section 794.075, Florida Statutes, is amended
4086 | to read:

4087 | 794.075 Sexual predators; erectile dysfunction drugs.--

4088 | (1) A person may not possess a prescription drug, as
4089 | defined in s. 499.003(45) ~~s. 499.003(25)~~, for the purpose of

588-06443-08

20082756c1

4090 | treating erectile dysfunction if the person is designated as a
4091 | sexual predator under s. 775.21.

4092 | (2) A person who violates a provision of this section for
4093 | the first time commits a misdemeanor of the second degree,
4094 | punishable as provided in s. 775.082 or s. 775.083. A person who
4095 | violates a provision of this section a second or subsequent time
4096 | commits a misdemeanor of the first degree, punishable as provided
4097 | in s. 775.082 or s. 775.083.

4098 | Section 42. Paragraph (a) of subsection (1) of section
4099 | 895.02, Florida Statutes, is amended to read:

4100 | 895.02 Definitions.--As used in ss. 895.01-895.08, the
4101 | term:

4102 | (1) "Racketeering activity" means to commit, to attempt to
4103 | commit, to conspire to commit, or to solicit, coerce, or
4104 | intimidate another person to commit:

4105 | (a) Any crime that is chargeable by indictment or
4106 | information under the following provisions of the Florida
4107 | Statutes:

4108 | 1. Section 210.18, relating to evasion of payment of
4109 | cigarette taxes.

4110 | 2. Section 403.727(3)(b), relating to environmental
4111 | control.

4112 | 3. Section 409.920 or s. 409.9201, relating to Medicaid
4113 | fraud.

4114 | 4. Section 414.39, relating to public assistance fraud.

4115 | 5. Section 440.105 or s. 440.106, relating to workers'
4116 | compensation.

4117 | 6. Section 443.071(4), relating to creation of a fictitious
4118 | employer scheme to commit unemployment compensation fraud.

588-06443-08

20082756c1

- 4119 7. Section 465.0161, relating to distribution of medicinal
4120 drugs without a permit as an Internet pharmacy.
- 4121 8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~
4122 ~~499.00545, and 499.0691,~~ relating to crimes involving contraband
4123 and adulterated drugs.
- 4124 9. Part IV of chapter 501, relating to telemarketing.
- 4125 10. Chapter 517, relating to sale of securities and
4126 investor protection.
- 4127 11. Section 550.235, s. 550.3551, or s. 550.3605, relating
4128 to dogracing and horseracing.
- 4129 12. Chapter 550, relating to jai alai frontons.
- 4130 13. Section 551.109, relating to slot machine gaming.
- 4131 14. Chapter 552, relating to the manufacture, distribution,
4132 and use of explosives.
- 4133 15. Chapter 560, relating to money transmitters, if the
4134 violation is punishable as a felony.
- 4135 16. Chapter 562, relating to beverage law enforcement.
- 4136 17. Section 624.401, relating to transacting insurance
4137 without a certificate of authority, s. 624.437(4)(c)1., relating
4138 to operating an unauthorized multiple-employer welfare
4139 arrangement, or s. 626.902(1)(b), relating to representing or
4140 aiding an unauthorized insurer.
- 4141 18. Section 655.50, relating to reports of currency
4142 transactions, when such violation is punishable as a felony.
- 4143 19. Chapter 687, relating to interest and usurious
4144 practices.
- 4145 20. Section 721.08, s. 721.09, or s. 721.13, relating to
4146 real estate timeshare plans.
- 4147 21. Chapter 782, relating to homicide.

588-06443-08

20082756c1

- 4148 22. Chapter 784, relating to assault and battery.
- 4149 23. Chapter 787, relating to kidnapping or human
4150 trafficking.
- 4151 24. Chapter 790, relating to weapons and firearms.
- 4152 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
4153 796.05, or s. 796.07, relating to prostitution and sex
4154 trafficking.
- 4155 26. Chapter 806, relating to arson.
- 4156 27. Section 810.02(2)(c), relating to specified burglary of
4157 a dwelling or structure.
- 4158 28. Chapter 812, relating to theft, robbery, and related
4159 crimes.
- 4160 29. Chapter 815, relating to computer-related crimes.
- 4161 30. Chapter 817, relating to fraudulent practices, false
4162 pretenses, fraud generally, and credit card crimes.
- 4163 31. Chapter 825, relating to abuse, neglect, or
4164 exploitation of an elderly person or disabled adult.
- 4165 32. Section 827.071, relating to commercial sexual
4166 exploitation of children.
- 4167 33. Chapter 831, relating to forgery and counterfeiting.
- 4168 34. Chapter 832, relating to issuance of worthless checks
4169 and drafts.
- 4170 35. Section 836.05, relating to extortion.
- 4171 36. Chapter 837, relating to perjury.
- 4172 37. Chapter 838, relating to bribery and misuse of public
4173 office.
- 4174 38. Chapter 843, relating to obstruction of justice.
- 4175 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
4176 s. 847.07, relating to obscene literature and profanity.

588-06443-08

20082756c1

4177 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
4178 849.25, relating to gambling.

4179 41. Chapter 874, relating to criminal street gangs.

4180 42. Chapter 893, relating to drug abuse prevention and
4181 control.

4182 43. Chapter 896, relating to offenses related to financial
4183 transactions.

4184 44. Sections 914.22 and 914.23, relating to tampering with
4185 a witness, victim, or informant, and retaliation against a
4186 witness, victim, or informant.

4187 45. Sections 918.12 and 918.13, relating to tampering with
4188 jurors and evidence.

4189 Section 43. Paragraphs (d), (f), (h), (i), and (j) of
4190 subsection (3) of section 921.0022, Florida Statutes, are amended
4191 to read:

4192 921.0022 Criminal Punishment Code; offense severity ranking
4193 chart.--

4194 (3) OFFENSE SEVERITY RANKING CHART

4195 (d) LEVEL 4

4196

Florida	Felony	Description
Statute	Degree	

4197

316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
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4198

588-06443-08

20082756c1

4199	499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
4200	499.0051(2)	3rd	Failure to authenticate pedigree papers.
4201	499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> legend drugs.
4202	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4203	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4204	784.075	3rd	Battery on detention or commitment facility staff.
4205	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4206	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
4207	784.081(3)	3rd	Battery on specified official or employee.

588-06443-08

20082756c1

4208	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
4209	784.083 (3)	3rd	Battery on code inspector.
4210	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4211	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4212	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4213	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4214	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4215	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
	790.115 (2) (c)	3rd	Possessing firearm on school property.

588-06443-08

20082756c1

4216	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4217	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4218	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4219	810.06	3rd	Burglary; possession of tools.
4220	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4221	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4222	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4223	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4224	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon,

588-06443-08

20082756c1

			excluding s. 893.03(5) drugs.
4225	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
4226	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
4227	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4228	837.02 (1)	3rd	Perjury in official proceedings.
4229	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4230	838.022	3rd	Official misconduct.
4231	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4232	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4233	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4234	843.025	3rd	Deprive law enforcement, correctional,

588-06443-08

20082756c1

			or correctional probation officer of means of protection or communication.
4235	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
4236	874.05(1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4237	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
4238	914.14(2)	3rd	Witnesses accepting bribes.
4239	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
4240	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4241	918.12	3rd	Tampering with jurors.
4242	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4243			
4244	(f)	LEVEL 6	
4245			

588-06443-08

20082756c1

	Florida Statute	Felony Degree	Description
4246	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4247	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4248	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> legend drug from unauthorized person.
4249	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> legend drug to unauthorized person.
4250	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
4251	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4252	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4253	784.041	3rd	Felony battery; domestic battery by strangulation.
4254	784.048 (3)	3rd	Aggravated stalking; credible threat.
4255			

588-06443-08

20082756c1

4256	784.048 (5)	3rd	Aggravated stalking of person under 16.
4257	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
4258	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
4259	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
4260	784.081 (2)	2nd	Aggravated assault on specified official or employee.
4261	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4262	784.083 (2)	2nd	Aggravated assault on code inspector.
4263	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4264	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4265	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.

588-06443-08

20082756c1

4266	790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4267	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4268	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4269	794.05(1)	2nd	Unlawful sexual activity with specified minor.
4270	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
4271	800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4272	806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4273	810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.

588-06443-08

20082756c1

4274	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
4275	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
4276	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
4277	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
4278	817.034 (4) (a) 1.	1st	Communications fraud, value greater than \$50,000.
4279	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
4280	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
4281	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
4282	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4283			

588-06443-08

20082756c1

4284	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4285	827.03(1)	3rd	Abuse of a child.
4286	827.03(3)(c)	3rd	Neglect of a child.
4287	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4288	836.05	2nd	Threats; extortion.
4289	836.10	2nd	Written threats to kill or do bodily injury.
4290	843.12	3rd	Aids or assists person to escape.
4291	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4292	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
	944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community

588-06443-08

20082756c1

supervision, resulting in great bodily harm.

4293

944.40 2nd Escapes.

4294

944.46 3rd Harboring, concealing, aiding escaped prisoners.

4295

944.47(1)(a)5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

4296

951.22(1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

4297

4298 (h) LEVEL 8

4299

Florida	Felony	Description
Statute	Degree	

4300

316.193(3)(c)3.a. 2nd DUI manslaughter.

4301

316.1935(4)(b) 1st Aggravated fleeing or attempted eluding with serious bodily injury or death.

4302

327.35(3)(c)3. 2nd Vessel BUI manslaughter.

4303

499.0051(8) 1st Knowing forgery of prescription

588-06443-08

20082756c1

	499.0051(7)		<u>labels</u> or <u>prescription</u> legend drug labels.
4304	<u>499.0051(7)</u>	1st	<u>Knowing</u> trafficking in contraband <u>prescription</u> legend drugs.
4305	499.0052		
	560.123 (8) (b) 2.	2nd	Failure to report currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000 by money transmitter.
4306	560.125 (5) (b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
4307	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4308	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4309	782.04 (4)	2nd	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary,

588-06443-08

20082756c1

			kidnapping, aircraft piracy, or unlawfully discharging bomb.
4310	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4311	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4312	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4313	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4314	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4315	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4316	800.04 (4)	2nd	Lewd or lascivious battery.

588-06443-08

20082756c1

4317	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4318	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4319	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4320	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4321	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4322	812.13 (2) (b)	1st	Robbery with a weapon.
4323	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4324	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4325	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.

588-06443-08

20082756c1

4326	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4327	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4328	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4329	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4330	860.121 (2) (c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4331	860.16	1st	Aircraft piracy.
4332	893.13 (1) (b)	1st	Sell or deliver in excess of 10 grams of any substance specified in s. 893.03(1) (a) or (b).
4333	893.13 (2) (b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1) (a) or (b).

588-06443-08

20082756c1

4334	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4335	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4336	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4337	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4338	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4339	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4340	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4341	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4342	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less

588-06443-08

20082756c1

			than 10 kilograms.
4343	893.135 (1) (j) 1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4344	893.135 (1) (k) 2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4345	895.03 (1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4346	895.03 (2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
4347	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4348	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4349	896.104 (4) (a) 2.	2nd	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$20,000 but

588-06443-08

20082756c1

less than \$100,000.

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(i) LEVEL 9

Florida Statute	Felony Degree	Description
316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
<u>499.0051 (9)</u> 499.00535	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in great bodily harm.
560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.

588-06443-08

20082756c1

4359 | 775.0844 | 1st | Aggravated white collar crime.

4360 | 782.04 (1) | 1st | Attempt, conspire, or solicit to
commit premeditated murder.

4361 | 782.04 (3) | 1st, PBL | Accomplice to murder in connection
with arson, sexual battery, robbery,
burglary, and other specified
felonies.

4362 | 782.051 (1) | 1st | Attempted felony murder while
perpetrating or attempting to
perpetrate a felony enumerated in s.
782.04 (3).

4363 | 782.07 (2) | 1st | Aggravated manslaughter of an elderly
person or disabled adult.

4364 | 787.01 (1) (a) 1. | 1st, PBL | Kidnapping; hold for ransom or reward
or as a shield or hostage.

4365 | 787.01 (1) (a) 2. | 1st, PBL | Kidnapping with intent to commit or
facilitate commission of any felony.

4366 | 787.01 (1) (a) 4. | 1st, PBL | Kidnapping with intent to interfere
with performance of any governmental
or political function.

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588-06443-08

20082756c1

4368	787.02 (3) (a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4369	790.161	1st	Attempted capital destructive device offense.
4370	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
4371	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4372	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4373	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4374	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.

588-06443-08

20082756c1

4375	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4376	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4377	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4378	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4379	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4380	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
4381	827.03 (2)	1st	Aggravated child abuse.
4382	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.

588-06443-08

20082756c1

4383	859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
4384	893.135	1st	Attempted capital trafficking offense.
4385	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4386	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4387	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4388	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4389	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4390	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
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588-06443-08

20082756c1

4392	893.135(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4393	893.135(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4394	893.135(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4395	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4396	896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
4397	(j)	LEVEL 10	
4398	Florida Statute	Felony Degree	Description
4399	<u>499.0051(10)</u> 499.00545	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in death.
4400	782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.

588-06443-08

20082756c1

4401 | 787.01(1)(a)3. 1st,PBL Kidnapping; inflict bodily harm upon or
terrorize victim.

4402 | 787.01(3)(a) Life Kidnapping; child under age 13,
perpetrator also commits aggravated
child abuse, sexual battery, or lewd or
lascivious battery, molestation,
conduct, or exhibition.

4403 | 782.07(3) 1st Aggravated manslaughter of a child.

4404 | 794.011(3) Life Sexual battery; victim 12 years or
older, offender uses or threatens to use
deadly weapon or physical force to cause
serious injury.

4405 | 812.135(2)(a) 1st,PBL Home-invasion robbery with firearm or
other deadly weapon.

4406 | 876.32 1st Treason against the state.

4407 |

4408 | Section 44. This act shall take effect July 1, 2008.