



269606

LEGISLATIVE ACTION

Senate

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House

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Floor: 3/AD/2R

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04/02/2009 10:43 AM

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Senator Gaetz moved the following:

Senate Amendment (with title amendment)

Delete lines 405 - 414

and insert:

Section 7. Subsection (1) of section 499.05, Florida Statutes, is amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(a) The definition of terms used in this part, and used in the rules adopted under this part, when the use of the term is not its usual and ordinary meaning.



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- 13 (b) Labeling requirements for drugs, devices, and
14 cosmetics.
- 15 (c) The establishment of fees authorized in this part.
- 16 (d) The identification of permits that require an initial
17 application and onsite inspection or other prerequisites for
18 permitting which demonstrate that the establishment and person
19 are in compliance with the requirements of this part.
- 20 (e) The application processes and forms for product
21 registration.
- 22 (f) Procedures for requesting and issuing certificates of
23 free sale.
- 24 (g) Inspections and investigations conducted under s.
25 499.051, and the identification of information claimed to be a
26 trade secret and exempt from the public records law as provided
27 in s. 499.051(7).
- 28 (h) The establishment of a range of penalties, as provided
29 in s. 499.066; requirements for notifying persons of the
30 potential impact of a violation of this part; and a process for
31 the uncontested settlement of alleged violations.
- 32 (i) Additional conditions that qualify as an emergency
33 medical reason under s. 499.003(54)(b)2 ~~s. 499.003(53)(b)2~~.
- 34 (j) Procedures and forms relating to the pedigree paper
35 requirement of s. 499.01212.
- 36 (k) The protection of the public health, safety, and
37 welfare regarding good manufacturing practices that
38 manufacturers and repackagers must follow to ensure the safety
39 of the products.
- 40 (l) Information required from each retail establishment
41 pursuant to s. 499.012(3), including requirements for



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42 prescriptions or orders.

43 (m) The recordkeeping, storage, and handling with respect
44 to each of the distributions of prescription drugs specified in
45 s. 499.003(54)(a)-(d) ~~s. 499.003(53)(a)-(d)~~.

46 (n) Alternatives to compliance with s. 499.01212 for a
47 prescription drug in the inventory of a permitted prescription
48 drug wholesale distributor as of June 30, 2006, and the return
49 of a prescription drug purchased prior to July 1, 2006. The
50 department may specify time limits for such alternatives.

51 (o) Record retention requirements and procedures for
52 registering and renewing the registration of a qualifying
53 practitioner related to a business entity purchasing and
54 possessing prescription drugs under s. 499.031.

56 ===== T I T L E A M E N D M E N T =====

57 And the title is amended as follows:

58 Delete lines 32 - 33

59 and insert:

60 become void; amending s. 499.05, F.S.; requiring the
61 department to adopt rules regarding record retention
62 requirements and procedures for registering and
63 renewing the registration of certain practitioners;
64 conforming cross-references; amending s. 400.9935,
65 F.S.;