

By the Committee on Health, Aging, and Long-Term Care; and
Senator Margolis

317-954-04

1 A bill to be entitled
2 An act relating to the sale of products
3 containing ephedrine; amending s. 499.033,
4 F.S.; prohibiting the sale or delivery of
5 products containing ephedrine over the counter
6 without a prescription, subject to certain
7 exceptions; repealing s. 501.0583, F.S.,
8 relating to selling, delivering, bartering,
9 furnishing, or giving weight-loss pills to
10 persons under age 18; providing an effective
11 date.

12
13 Be It Enacted by the Legislature of the State of Florida:

14
15 Section 1. Section 499.033, Florida Statutes, is
16 amended to read:

17 499.033 Ephedrine; prescription required.--Ephedrine
18 is declared to be a prescription drug.

19 (1) Except as provided in subsection (2), a person may
20 not sell or deliver over the counter any product intended for
21 ingestion by humans which ~~that~~ contains any quantity of
22 ephedrine, a salt of ephedrine, an optical isomer of
23 ephedrine, or a salt of an optical isomer of ephedrine,
24 including any part of the plant genus ephedra or the plant
25 genus sida cordifolia, and any species thereof, unless ~~may be~~
26 dispensed by a duly licensed pharmacist or dispensing
27 practitioner and only upon the prescription of a duly licensed
28 practitioner authorized by the laws of the state to prescribe
29 medicinal drugs.

30 (2) A product containing ephedrine described in
31 paragraphs (a)-(e) is exempt from subsection (1) if it may

1 lawfully be sold over the counter without a prescription under
2 the federal act; is labeled and marketed in a manner
3 consistent with the pertinent United States Food and Drug
4 Administration Over-the-Counter Tentative Final or Final
5 Monograph; and is manufactured and distributed for legitimate
6 medicinal use in a manner that reduces or eliminates the
7 likelihood of abuse, when considered in the context with: the
8 package sizes and the manner of packaging of the drug product;
9 the name and labeling of the product; the manner of
10 distribution, advertising, and promotion of the product; the
11 duration, scope, health significance, and societal cost of
12 abuse of the particular product; the need to provide medically
13 important ephedrine-containing therapies to the public for
14 United States Food and Drug Administration approved
15 indications on an unrestricted, over-the-counter basis; and
16 other facts as may be relevant to and consistent with public
17 health and safety.

18 (a) Solid oral dosage forms that combine active
19 ingredients in the following ranges for each dosage unit:
20 1. Theophylline (100-130mg), ephedrine (12.5-24mg).
21 2. Theophylline (60-100mg), ephedrine (12.5-24mg),
22 guaifenesin (200-400mg).
23 3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).
24 4. Phenobarbital (not greater than 8mg) in combination
25 with the ingredients of subparagraph 1. or subparagraph 2.

26 (b) Liquid oral dosage forms that combine active
27 ingredients in the following ranges for each (5ml) dose:
28 1. Theophylline (not greater than 45mg), ephedrine
29 (not greater than 36mg), guaifenesin (not greater than 100mg),
30 phenobarbital (not greater than 12mg).

31

1 2. Phenylephrine (not greater than 5mg), ephedrine
2 (not greater than 5mg), chlorpheniramine (not greater than
3 2mg), dextromethorphan (not greater than 10mg), ammonium
4 chloride (not greater than 40mg), ipecac fluid extract (not
5 greater than 0.005ml).

6 (c) Anorectal preparations containing less than 5
7 percent ephedrine.

8 (d) Nasal decongestant compounds, mixtures, or
9 preparations containing 0.5 percent or less ephedrine.

10 (e) Any drug product containing ephedrine that is
11 marketed pursuant to an approved new drug application or legal
12 equivalent under the federal act.

13 (3) The department may administer ~~implement~~ this
14 section by rule.

15 Section 2. Section 501.0583, Florida Statutes, as
16 created by section 1 of chapter 2003-24, Laws of Florida, is
17 repealed.

18 Section 3. This act shall take effect July 1, 2004.

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20 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
21 COMMITTEE SUBSTITUTE FOR
22 Senate Bill 446

23 The committee substitute provides a definition of ephedra and
24 sida cordifolia and clarifies that the prohibition on the sale
25 and delivery of ephedra without a prescription only applies to
products containing ephedra that are intended for ingestion by
humans.

26 The bill repeals s.501.0583, F.S., which prohibits the
27 selling, delivering, bartering, furnishing, or giving of
weight-loss pills to persons under age 18.