

By the Committees on Governmental Oversight and Productivity; Health, Aging, and Long-Term Care; and Senators Margolis and Wasserman Schultz

302-1341-04

1 A bill to be entitled
 2 An act relating to the sale of products
 3 containing ephedra and other dietary supplement
 4 ingredients; amending s. 499.033, F.S.;
 5 prohibiting the sale or delivery of products
 6 containing ephedra over the counter without a
 7 prescription, subject to certain exceptions;
 8 creating the Weight Loss and Athletic
 9 Performance Dietary Supplement Review
 10 Committee; providing duties and membership
 11 requirements; providing for administrative
 12 support; requiring a report to the Legislature;
 13 repealing s. 501.0583, F.S., relating to
 14 selling, delivering, bartering, furnishing, or
 15 giving weight-loss pills to persons under age
 16 18; providing an effective date.

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 18 Be It Enacted by the Legislature of the State of Florida:

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 20 Section 1. Section 499.033, Florida Statutes, is
 21 amended to read:

22 499.033 Ephedrine; prescription required.--Ephedrine
 23 is declared to be a prescription drug.

24 (1) Except as provided in subsection (2), a person may
 25 not sell or deliver over the counter any product intended for
 26 ingestion by humans which ~~that~~ contains any quantity of
 27 ephedrine, a salt of ephedrine, an optical isomer of
 28 ephedrine, or a salt of an optical isomer of ephedrine,
 29 including any part of the plant genus ephedra or the plant
 30 genus sida cordifolia, and any species thereof, unless ~~may be~~
 31 dispensed by a duly licensed pharmacist or dispensing

1 practitioner and only upon the prescription of a duly licensed
2 practitioner authorized by the laws of the state to prescribe
3 medicinal drugs.

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

23 (a) Solid oral dosage forms that combine active
24 ingredients in the following ranges for each dosage unit:

25 1. Theophylline (100-130mg), ephedrine (12.5-24mg).

26 2. Theophylline (60-100mg), ephedrine (12.5-24mg),
27 guaifenesin (200-400mg).

28 3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).

29 4. Phenobarbital (not greater than 8mg) in combination
30 with the ingredients of subparagraph 1. or subparagraph 2.

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1 (b) Liquid oral dosage forms that combine active
2 ingredients in the following ranges for each (5ml) dose:

3 1. Theophylline (not greater than 45mg), ephedrine
4 (not greater than 36mg), guaifenesin (not greater than 100mg),
5 phenobarbital (not greater than 12mg).

6 2. Phenylephrine (not greater than 5mg), ephedrine
7 (not greater than 5mg), chlorpheniramine (not greater than
8 2mg), dextromethorphan (not greater than 10mg), ammonium
9 chloride (not greater than 40mg), ipecac fluid extract (not
10 greater than 0.005ml).

11 (c) Anorectal preparations containing less than 5
12 percent ephedrine.

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

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

18 (3) The department may administer ~~implement~~ this
19 section by rule.

20 Section 2. Weight Loss and Athletic Performance
21 Dietary Supplement Review Committee.--

22 (1) The Weight Loss and Athletic Performance Dietary
23 Supplement Review Committee is created for the purpose of
24 evaluating the safety of ingredients contained in dietary
25 supplements that are sold in Florida and that claim to promote
26 weight loss and athletic performance. The committee shall be
27 established by August 1, 2004, and its evaluation process
28 shall include reviewing scientific research and adverse
29 incident reports relating to weight loss and athletic
30 performance dietary supplements. The committee shall draft a
31 report that summarizes its findings and provides

1 recommendations for future legislative and executive branch
2 action that may be taken to protect the public from dangerous
3 weight loss and athletic performance dietary supplements. This
4 report shall be submitted to the President of the Senate and
5 the Speaker of the House of Representatives by August 1, 2005.

6 (2) The committee shall consist of:

7 (a) The Commissioner of Agriculture, or his or her
8 designee;

9 (b) The Secretary of Health, or his or her designee;

10 (c) Two members, who are health care practitioners as
11 defined in section 456.001, Florida Statutes, or scientists,
12 who possess expertise in the area of weight loss and athletic
13 performance dietary supplements, to be appointed by the
14 Secretary of Health;

15 (d) Two members who possess expertise in the area of
16 dietary supplement regulation, to be appointed by the
17 Commissioner of Agriculture; and

18 (e) Two members who represent the weight loss and
19 athletic performance dietary supplement industry, to be
20 appointed by the Commissioner of Agriculture.

21 (3) Administrative support for the committee shall be
22 jointly and equally provided by existing appropriations and
23 resources of the Department of Agriculture and Consumer
24 Services and the Department of Health.

25 Section 3. Section 501.0583, Florida Statutes, as
26 created by section 1 of chapter 2003-24, Laws of Florida, is
27 repealed.

28 Section 4. This act shall take effect July 1, 2004.
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STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
CS for Senate Bill 446

Creates the "Weight Loss and Athletic Performance Dietary Supplement Review Committee." Specifies committee duties and membership. Requires a report. Provides for administrative support.