

CHAMBER ACTION

1 The Committee on Health Care recommends the following:

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3 **Committee Substitute**

4 Remove the entire bill and insert:

5 A bill to be entitled

6 An act relating to the sale of products containing
7 ephedrine or ephedra; amending s. 499.033, F.S.;
8 prohibiting the sale or delivery of products containing
9 ephedrine or ephedra over the counter without a
10 prescription, subject to certain exceptions; amending s.
11 500.04, F.S.; prohibiting the sale or delivery of dietary
12 supplements or other foods containing ephedrine or
13 ephedra; reenacting and amending s. 500.177(1), F.S., to
14 incorporate the amendment to s. 500.04, F.S., in
15 references thereto; providing penalties; creating the
16 Weight Loss and Athletic Performance Dietary Supplement
17 Review Committee; providing duties; requiring a report to
18 the Legislature; providing for membership; providing an
19 appropriation for meeting attendance; providing for
20 administrative support; repealing s. 501.0583, F.S.,
21 relating to selling, delivering, bartering, furnishing, or
22 giving weight-loss pills to persons under age 18;
23 providing an effective date.

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

Section 1. Subsections (1) and (2) of section 499.033, Florida Statutes, are amended to read:

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

(1) Except as provided in subsection (2), a person may not sell or deliver over the counter any drug product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine, including any part of the plant genus ephedra or the plant genus sida cordifolia, and any species thereof, unless ~~may~~ be dispensed by a duly licensed pharmacist or dispensing practitioner and only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe medicinal drugs.

(2) A drug product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the drug product; the manner of distribution, advertising, and

52 | promotion of the drug product; the duration, scope, health
 53 | significance, and societal cost of abuse of the particular drug
 54 | product; the need to provide medically important ephedrine-
 55 | containing therapies to the public for United States Food and
 56 | Drug Administration approved indications on an unrestricted,
 57 | over-the-counter basis; and other facts as may be relevant to
 58 | and consistent with public health and safety.

59 | (a) Solid oral dosage forms that combine active
 60 | ingredients in the following ranges for each dosage unit:

- 61 | 1. Theophylline (100-130mg), ephedrine (12.5-24mg).
- 62 | 2. Theophylline (60-100mg), ephedrine (12.5-24mg),
- 63 | guaifenesin (200-400mg).
- 64 | 3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).
- 65 | 4. Phenobarbital (not greater than 8mg) in combination
- 66 | with the ingredients of subparagraph 1. or subparagraph 2.

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

- 69 | 1. Theophylline (not greater than 45mg), ephedrine (not
- 70 | greater than 36mg), guaifenesin (not greater than 100mg),
- 71 | phenobarbital (not greater than 12mg).
- 72 | 2. Phenylephrine (not greater than 5mg), ephedrine (not
- 73 | greater than 5mg), chlorpheniramine (not greater than 2mg),
- 74 | dextromethorphan (not greater than 10mg), ammonium chloride (not
- 75 | greater than 40mg), ipecac fluid extract (not greater than
- 76 | 0.005ml).

77 | (c) Anorectal preparations containing less than 5 percent
 78 | ephedrine.

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

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

84 Section 2. Subsection (12) is added to section 500.04,
85 Florida Statutes, to read:

86 500.04 Prohibited acts.--The following acts and the
87 causing thereof within the state are prohibited:

88 (12) The sale or delivery of any dietary supplement or any
89 other food which contains any quantity of ephedrine, a salt of
90 ephedrine, an optical isomer of ephedrine, or a salt of any
91 optical isomer of ephedrine, including any part of the plant
92 genus ephedra or the plant genus sida cordifolia, and any
93 species thereof.

94 Section 3. For the purpose of incorporating the amendment
95 to section 500.04, Florida Statutes, in references thereto,
96 subsection (1) of section 500.177, Florida Statutes, is
97 reenacted and amended to read:

98 500.177 Penalty for violation of s. 500.04; dissemination
99 of false advertisement.--

100 (1) Any person who violates any provision of s. 500.04
101 commits ~~is guilty of~~ a misdemeanor of the second degree,
102 punishable as provided in s. 775.082 or s. 775.083; but, if the
103 violation is committed after a conviction of such person under
104 this section has become final, such person commits ~~is guilty of~~
105 a misdemeanor of the first degree, punishable as provided in s.
106 775.082 or s. 775.083.

107 Section 4. Weight Loss and Athletic Performance Dietary
108 Supplement Review Committee.--

109 (1) The Weight Loss and Athletic Performance Dietary
110 Supplement Review Committee is created for the purpose of
111 evaluating the safety of ingredients contained in dietary
112 supplements that are sold in Florida and that claim to promote
113 weight loss and athletic performance. The committee shall be
114 established by August 1, 2004, and its evaluation process shall
115 include reviewing scientific research and adverse incident
116 reports relating to weight loss and athletic performance dietary
117 supplements. The committee shall draft a report that summarizes
118 its findings and provides recommendations for future legislative
119 and executive branch action that may be taken to protect the
120 public from dangerous weight loss and athletic performance
121 dietary supplements. This report shall be submitted to the
122 President of the Senate and the Speaker of the House of
123 Representatives by August 1, 2005.

124 (2) The committee shall consist of:

125 (a) The Commissioner of Agriculture, or his or her
126 designee.

127 (b) The Secretary of Health, or his or her designee.

128 (c) Two members who are health care practitioners, as
129 defined in s. 456.001, Florida Statutes, or scientists, who
130 possess expertise in the area of weight loss and athletic
131 performance dietary supplements, to be appointed by the
132 Secretary of Health.

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133 (d) Two members who possess expertise in the area of
134 dietary supplement regulation, to be appointed by the
135 Commissioner of Agriculture.

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

139 (3) There is appropriated \$10,000 from general revenue for
140 fiscal year 2004-2005 for use in payment of costs associated
141 with meeting attendance for appointees to the committee.
142 Additional administrative support shall be provided by the
143 Department of Agriculture and Consumer Services.

144 Section 5. Section 501.0583, Florida Statutes, as created
145 by section 1 of chapter 2003-24, Laws of Florida, is repealed.

146 Section 6. This act shall take effect July 1, 2004.