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

303-2226-04

A bill to be entitled

An act relating to the sale of products containing ephedrine or ephedra; amending s. 499.0121, F.S.; providing recordkeeping requirements relating to the storage and handling of prescription drugs which affiliated groups must fulfill; amending s. 499.033, F.S.; prohibiting the sale or delivery of products containing ephedrine or ephedra over the counter without a prescription, subject to certain exceptions; amending s. 500.04, F.S.; prohibiting the sale or delivery of dietary supplements or other foods containing ephedrine or ephedra; creating the Weight Loss and Athletic Performance Dietary Supplement Review Committee; providing an appropriations; repealing s. 501.0583, F.S., relating to the sale of weight-loss pills containing ephedrine or ephedra products to minors; providing an effective date.

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

Section 1. Paragraph (h) is added to subsection (6) of section 499.0121, Florida Statutes, to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of

prescription drugs and for the establishment and maintenance of prescription drug distribution records.

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

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

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

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

b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are

stored, if the prescription drugs were distributed in or into this state.

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

a. The repackager must:

(I) In lieu of the written statement required by paragraph (d) or paragraph (e), for all repackaged prescription drugs distributed in or into this state, issue the following written statement under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";

(II) Purchase all prescription drugs it repackages:

(A) Directly from the manufacturer; or

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

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

b. In addition, all members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of

the location where the records are stored or where the repackager is located.

4. This paragraph expires July 1, 2006.

Section 2. 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 promotion of the drug product; the duration, scope, health significance, and societal cost of abuse of the particular drug product; the need to provide

medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.

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

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

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

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

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

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

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

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

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

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

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

Section 3. Subsection (12) is added to section 500.04, Florida Statutes, to read:

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

(12) The sale or delivery of any dietary supplement or any other food that contains any quantity of ephedrine, a salt of epherdrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine, including any part of the plant genus ephedra or the plant genus sida cordifolia, and any species thereof.

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

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

(2) The committee shall consist of:

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

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

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

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

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

(3) The sum of $10,000 is appropriated from the General Revenue Fund for fiscal year 2004-2005 for use in payment of costs associated with meeting attendance for appointees of this committee. Additional administrative support shall be provided by the Department of Agriculture and Consumer Services.

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

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

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
CS/CS Senate Bill 446

CS for CS for CS for SB 446 is different from CS for CS SB 446 in that it:

1. Changes recordkeeping requirements for affiliated groups concerning the storage and handling of prescription drugs;

2. Prohibits the sale or delivery of dietary supplements or foods containing ephedrine or ephedra;

3. Appropriates $10,000 to the Department of Agriculture and Consumer Services from General Revenue for fiscal year 2004-2005 for costs associated with the Weight Loss and Athletic Performance Dietary Supplement Review Committee.