A bill to be entitled

An act relating to the sale of products containing ephedrine or ephedra; 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, for which there are penalties; providing rulemaking authority; providing an effective date.

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

Section 1. Section 499.033, Florida Statutes, is 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 without a prescription any product that contains any quantity of ephedrine or ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine. Any product that contains any quantity of ephedrine or ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe medicinal drugs.

(2) A 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 product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular 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.

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

Section 2. This act shall take effect July 1, 2004.