

By Senator Margolis

35-88A-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; providing an effective date.

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

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 11           Section 1. Section 499.033, Florida Statutes, is  
 12   amended to read:

13           499.033 Ephedrine; prescription required.--Ephedrine  
 14   is declared to be a prescription drug.

15           (1) Except as provided in subsection (2), a person may  
 16   not sell or deliver over the counter without a prescription  
 17   any product that contains any quantity of ephedrine or  
 18   ephedra, a salt of ephedrine, an optical isomer of ephedrine,  
 19   or a salt of any optical isomer of ephedrine.Any product that  
 20   contains any quantity of ephedrine or ephedra, a salt of  
 21   ephedrine, an optical isomer of ephedrine, or a salt of an  
 22   optical isomer of ephedrine may be dispensed only upon the  
 23   prescription of a duly licensed practitioner authorized by the  
 24   laws of the state to prescribe medicinal drugs.

25           (2) A product containing ephedrine described in  
 26   paragraphs (a)-(e) is exempt from subsection (1) if it may  
 27   lawfully be sold over the counter without a prescription under  
 28   the federal act; is labeled and marketed in a manner  
 29   consistent with the pertinent United States Food and Drug  
 30   Administration Over-the-Counter Tentative Final or Final  
 31   Monograph; and is manufactured and distributed for legitimate

1 medicinal use in a manner that reduces or eliminates the  
2 likelihood of abuse, when considered in the context with: the  
3 package sizes and the manner of packaging of the drug product;  
4 the name and labeling of the product; the manner of  
5 distribution, advertising, and promotion of the product; the  
6 duration, scope, health significance, and societal cost of  
7 abuse of the particular product; the need to provide medically  
8 important ephedrine-containing therapies to the public for  
9 United States Food and Drug Administration approved  
10 indications on an unrestricted, over-the-counter basis; and  
11 other facts as may be relevant to and consistent with public  
12 health and safety.

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

21 (b) Liquid oral dosage forms that combine active  
22 ingredients in the following ranges for each (5ml) dose:  
23 1. Theophylline (not greater than 45mg), ephedrine  
24 (not greater than 36mg), guaifenesin (not greater than 100mg),  
25 phenobarbital (not greater than 12mg).  
26 2. Phenylephrine (not greater than 5mg), ephedrine  
27 (not greater than 5mg), chlorpheniramine (not greater than  
28 2mg), dextromethorphan (not greater than 10mg), ammonium  
29 chloride (not greater than 40mg), ipecac fluid extract (not  
30 greater than 0.005ml).

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- 1 (c) Anorectal preparations containing less than 5
- 2 percent ephedrine.
- 3 (d) Nasal decongestant compounds, mixtures, or
- 4 preparations containing 0.5 percent or less ephedrine.
- 5 (e) Any drug product containing ephedrine that is
- 6 marketed pursuant to an approved new drug application or legal
- 7 equivalent under the federal act.
- 8 (3) The department may administer ~~implement~~ this
- 9 section by rule.

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

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SENATE SUMMARY

Prohibits the sale or delivery of products containing ephedrine over the counter without a prescription.