

HB 1471

2012

1                                   A bill to be entitled  
 2           An act relating to prescription drugs; amending s.  
 3           499.033, F.S.; requiring products containing ephedrine  
 4           or a related compound to be dispensed by prescription  
 5           only; providing a definition; providing rulemaking  
 6           authority; repealing s. 893.1495, F.S., relating to  
 7           the retail sale of ephedrine and related compounds;  
 8           providing an effective date.

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

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

14           499.033   Ephedrine and related compounds; prescription  
 15   required. ~~Ephedrine is declared to be a prescription drug.~~

16           (1) ~~Except as provided in subsection (2),~~ Any product that  
 17   contains any quantity of ephedrine or a related compound, ~~a salt~~  
 18   ~~of ephedrine, an optical isomer of ephedrine, or a salt of an~~  
 19   ~~optical isomer of ephedrine~~ may be dispensed only upon the  
 20   prescription of a duly licensed practitioner authorized by the  
 21   laws of the state to prescribe prescription drugs. As used in  
 22   this section, the term "ephedrine or a related compound" means  
 23   ephedrine, pseudoephedrine, phenylpropanolamine, or any of their  
 24   salts, optical isomers, or salts of optical isomers.

25           ~~(2) A product containing ephedrine described in paragraphs~~  
 26   ~~(a)-(e) is exempt from subsection (1) if it may lawfully be sold~~  
 27   ~~over the counter without a prescription under the federal act;~~  
 28   ~~is labeled and marketed in a manner consistent with the~~

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29 ~~pertinent United States Food and Drug Administration Over the~~  
30 ~~Counter Tentative Final or Final Monograph; and is manufactured~~  
31 ~~and distributed for legitimate medicinal use in a manner that~~  
32 ~~reduces or eliminates the likelihood of abuse, when considered~~  
33 ~~in the context with: the package sizes and the manner of~~  
34 ~~packaging of the drug product; the name and labeling of the~~  
35 ~~product; the manner of distribution, advertising, and promotion~~  
36 ~~of the product; the duration, scope, health significance, and~~  
37 ~~societal cost of abuse of the particular product; the need to~~  
38 ~~provide medically important ephedrine-containing therapies to~~  
39 ~~the public for United States Food and Drug Administration~~  
40 ~~approved indications on an unrestricted, over the counter basis;~~  
41 ~~and other facts as may be relevant to and consistent with public~~  
42 ~~health and safety.~~

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

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

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

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

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

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

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

56 ~~2. Phenylephrine (not greater than 5mg), ephedrine (not~~

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57 ~~greater than 5mg), chlorpheniramine (not greater than 2mg),~~  
 58 ~~dextromethorphan (not greater than 10mg), ammonium chloride (not~~  
 59 ~~greater than 40mg), ipecac fluid extract (not greater than~~  
 60 ~~0.005ml).~~

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

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

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

68 (2)(3) The department may implement this section by rule.

69 Section 2. Section 893.1495, Florida Statutes, is  
 70 repealed.

71 Section 3. This act shall take effect July 1, 2012.