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HOUSE BILL NO. 2596

Offered January 9, 2019

A BILL to amend and reenact § 54.1-3462 of the Code of Virginia, relating to misbranded devices; menstrual products.

Patron—Kory

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3462 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3462. Misbranded drug or device.

A drug or device shall be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.

2. If its package does not bear a label containing the name and place of business of the manufacturer, packer, or distributor. However, all prescription drugs intended for human use and devices shall bear a label containing the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Reasonable variations shall be permitted, and exemptions for small packages shall be allowed in accordance with regulations of the Board.

3. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed with such conspicuousness, as compared with other words, statements, designs or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

4. If it is for use by man and contains any quantity of the narcotic or hypnotic substances alpha-eucaine, barbituric acid, beta-eucaine, bromal, carbromal, chloral, coca, cocaine, codeine, morphine, opium, paraldehyde, or sulfonmethane, or any chemical derivative of such substances, which derivative, after investigation has been found to be and designated as, habit forming, by regulations issued by the Board under this chapter, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning — May Be Habit Forming."

5. If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula, the established name of the drug, and in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, shall apply only to prescription drugs. Any prescription drug shall have the established name of the drug or ingredient printed on its label prominently and in type at least half as large as that used for any proprietary name or designation for such drug or ingredient. Exemptions may be allowed under regulations of the Board.

As used in this subdivision, the term "established name," with respect to a drug or ingredient, means the applicable official name designated pursuant to § 508 of the federal act, or if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title in such compendium or if neither exists, then the common or usual name, if any, of such drug or of such ingredient. Whenever, an article is recognized in the United States Pharmacopoeia National Formulary and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia National Formulary shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

6. Unless its labeling bears adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. The Board shall promulgate regulations exempting such drug or device from such requirements when these requirements are not necessary to protect the public health and the articles are also exempted under regulations issued under § 502(f) of the federal act.

7. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed. The method of packing may be modified with the consent of the Board, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States Pharmacopoeia National Formulary and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia National Formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia National Formulary. However, in the event of inconsistency between the requirements of this subdivision and those of subdivision 5 as to the name by which the drug or its ingredients shall be designated, the requirements of subdivision 5 shall prevail.

8. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling or advertising.

9. If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless it is from a batch for which a certificate or release has been issued pursuant to § 506 of the federal act, and such certificate or release is in effect with respect to such drug.

10. If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative, unless it is from a batch, for which a certificate or release has been issued pursuant to § 507 of the federal act, and such certificate or release is in effect for such drug. This subdivision shall not apply to any drug or class of drugs exempted by regulations promulgated under § 507(c) or (d) of the federal law.

For the purpose of this subdivision the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution, including, the chemically synthesized equivalent of any such substance.

11. If it is a color additive, the intended use of which in or on drugs is for coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of the federal act.

12. In the case of any prescription drug distributed or offered for sale in this Commonwealth, unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter a true statement of (i) the established name, as defined in this section, printed prominently and in type at least half as large as that used for any trade or brand name, (ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under this section, and (iii) such other information in brief summary relating to side effects, contraindications, and effectiveness as are required in regulations issued under the federal act.

13. If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

14. If it is a menstrual device, unless its packaging and labeling prominently indicates whether the product contains any of the following ingredients or components and, if so, the amount of each such ingredient or component: (i) synthetic fibers, including viscose rayon, polycrylate rayon, polyester, and carboxymethylcellulose; (ii) dioxin; or (iii) bisphenol A. For the purpose of this subdivision, "menstrual device" means any menstrual cup described in 21 C.F.R. 884.5400, scented or scented deodorized menstrual pad described in 21 C.F.R. 884.5425, unscented menstrual pad described in 21 C.F.R. 884.5435, scented or scented deodorized menstrual tampon described in 21 C.F.R. 884.5460, unscented menstrual tampon described in 21 C.F.R. 884.5470, or therapeutic vaginal douche apparatus described in 21 C.F.R. 884.5900.

Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this chapter if such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the Board.