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112TH CONGRESS
1ST SESSION

H. R. 338

To amend the Federal Food, Drug, and Cosmetic Act to ensure accurate, intelligible information on dosage delivery devices packaged with liquid over-the-counter medications.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 2011

Mr. ISRAEL introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure accurate, intelligible information on dosage delivery devices packaged with liquid over-the-counter medications.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Protecting Our Kids' Medicine Act''.

SEC. 2. REQUIREMENT OF ACCURATE DOSAGE DELIVERY DEVICES FOR LIQUID OTC DRUGS.

(a) CLARIFICATION OF TREATMENT OF DOSAGE DELIVERY DEVICES.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following new subsection:

''(aa) If it is a liquid formulation of a drug that is not subject to section 503(b) and—

''(1) it is not packaged with a dosage delivery device; or

''(2) it is packaged with a dosage delivery device and—

''(A) the calibrated units of measure marked on the dosage delivery device (such as 'teaspoon', 'tablespoon', or 'milliliter') are not the same as the units of measure specified in the dosage directions—

''(i) on the outside packaging or bottle for the drug; or

''(ii) contained in any other written instructions that are included in the labeling of the drug;

''(B) if any units of measure on the dosage delivery device are abbreviated on the dosage delivery device and—

''(i) the abbreviation used on the dosage delivery device is not the same as the abbreviation used in the dosage directions described under subparagraph (A);

''(ii) international or national standards for abbreviations for units of measure are not used on the dosage delivery device;

''(iii) nonstandard or uncommon abbreviations for units of measure are used on the dosage delivery device; or

''(iv) the abbreviations for units of measure that are used on the dosage delivery device are not defined on such device or in the dosage directions described under subparagraph (B);

''(C) decimals or fractions on the dosage delivery device are not printed clearly (as determined by the Secretary);

''(D) leading zeros are not used before decimal points printed on the dosage delivery device for purposes of avoiding tenfold dosing errors;

''(E) smaller font sizes are not used for numerals in fractions printed on dosage delivery

devices, as compared to the size of the font used for numerals not in fractions;

''(F) the dosage delivery device contains extraneous or unnecessary markings (as determined by the Secretary) that may be confusing to consumers; or

''(G) the markings on the dosage delivery device are not clearly visible or are obscured when the drug is added to the device.

For purposes of this paragraph, the term 'dosage delivery device' means an object that is designed to measure the dosage of a drug in liquid form and deliver that drug to an individual and includes calibrated cups, droppers, syringes, and spoons.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect at the end of the one-year period beginning on the date of the enactment of this Act.

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