

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Protecting Our Kids’
5 Medicine Act”.

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

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

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

9 “(1) it is not packaged with a dosage delivery
10 device; or

11 “(2) it is packaged with a dosage delivery de-
12 vice and—

13 “(A) the calibrated units of measure
14 marked on the dosage delivery device (such as
15 ‘teaspoon’, ‘tablespoon’, or ‘milliliter’) are not
16 the same as the units of measure specified in
17 the dosage directions—

18 “(i) on the outside packaging or bottle
19 for the drug; or

20 “(ii) contained in any other written
21 instructions that are included in the label-
22 ing of the drug;

23 “(B) if any units of measure on the dosage
24 delivery device are abbreviated on the dosage
25 delivery device and—

1 “(i) the abbreviation used on the dos-
2 age delivery device is not the same as the
3 abbreviation used in the dosage directions
4 described under subparagraph (A);

5 “(ii) international or national stand-
6 ards for abbreviations for units of measure
7 are not used on the dosage delivery device;

8 “(iii) nonstandard or uncommon ab-
9 breviations for units of measure are used
10 on the dosage delivery device; or

11 “(iv) the abbreviations for units of
12 measure that are used on the dosage deliv-
13 ery device are not defined on such device
14 or in the dosage directions described under
15 subparagraph (B);

16 “(C) decimals or fractions on the dosage
17 delivery device are not printed clearly (as deter-
18 mined by the Secretary);

19 “(D) leading zeros are not used before dec-
20 imal points printed on the dosage delivery de-
21 vice for purposes of avoiding tenfold dosing er-
22 rors;

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

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

3 “(F) the dosage delivery device contains
4 extraneous or unnecessary markings (as deter-
5 mined by the Secretary) that may be confusing
6 to consumers; or

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

10 For purposes of this paragraph, the term ‘dosage
11 delivery device’ means an object that is designed to
12 measure the dosage of a drug in liquid form and de-
13 liver that drug to an individual and includes cali-
14 brated cups, droppers, syringes, and spoons.”.

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

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