

114TH CONGRESS
2D SESSION

H. R. 6259

To amend the Federal Food, Drug, and Cosmetic Act to ensure that liquid over-the-counter medications are packaged with appropriate dosage delivery devices and, in the case of such medications labeled for pediatric use, appropriate flow restrictors, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2016

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 that liquid over-the-counter medications are packaged with appropriate dosage delivery devices and, in the case of such medications labeled for pediatric use, appropriate flow restrictors, and for other purposes.

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 of 2016”.

1 **SEC. 2. DOSAGE DELIVERY DEVICES FOR LIQUID OTC**
2 **DRUGS AND FLOW RESTRICTORS FOR SUCH**
3 **DRUGS LABELED FOR PEDIATRIC USE.**

4 (a) IN GENERAL.—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:

7 “(dd)(1) If it is a liquid formulation of a drug that
8 is not subject to section 503(b) and—

9 “(A) it is not packaged with a dosage delivery
10 device in accordance with specifications to be deter-
11 mined by the Secretary by regulation;

12 “(B) in the case of such a liquid formulation
13 that is labeled for pediatric use, it is not packaged
14 with a dosage delivery device, as described in sub-
15 paragraph (A), and—

16 “(i) a flow restrictor; or

17 “(ii) another mechanism to reduce the fre-
18 quency and volume of accidental ingestion that
19 provides a level of safety that is equivalent to
20 or greater than the level of safety that would be
21 provided by a flow restrictor, as determined by
22 the Secretary by regulation; or

23 “(C) its labeling is in violation of subparagraph
24 (2).

25 “(2) The Secretary shall require that any measure-
26 ment in the labeling of a liquid formulation of a drug that

1 is not subject to section 503(b), including any measure-
2 ment in the labeling of a dosage delivery device packaged
3 with the liquid formulation, be expressed exclusively in
4 metric units. The Secretary may waive the requirement
5 in the preceding sentence with respect to one or more liq-
6 uid formulations if the Secretary determines that, with re-
7 spect to such formulations, implementation of such re-
8 quirement would not benefit the public health.

9 “(3) In this paragraph:

10 “(A) The term ‘dosage delivery device’—

11 “(i) means an object that is designed to
12 measure the dosage of a drug in liquid form
13 and deliver that drug to an individual; and

14 “(ii) includes calibrated cups, droppers, sy-
15 ringes, and spoons.

16 “(B) The term ‘flow restrictor’ has such mean-
17 ing as the Secretary may prescribe by regulation.”.

18 (b) REGULATIONS.—Not later than 1 year after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services, acting through the Commissioner of
21 Food and Drugs, shall—

22 (1) promulgate a final rule implementing the
23 amendment made by subsection (a); and

24 (2) include in such rule a definition of the term
25 “flow restrictor”.

1 (c) APPLICABILITY.—The amendment made by sub-
2 section (a) applies beginning on the date that is 1 year
3 after the date of enactment of this Act.

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