

117TH CONGRESS
1ST SESSION

H. R. 2435

To amend the Federal Food, Drug, and Cosmetic Act to require the label of a drug that is intended for human use and contains an ingredient that is derived directly or indirectly from a gluten-containing grain to identify each such ingredient, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 8, 2021

Mr. RYAN (for himself and Mr. STIVERS) 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 require the label of a drug that is intended for human use and contains an ingredient that is derived directly or indirectly from a gluten-containing grain to identify each such ingredient, 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 “Gluten in Medicine
5 Disclosure Act of 2021”.

1 **SEC. 2. LABELING OF DRUGS WITH AN INGREDIENT MADE**
2 **FROM A GLUTEN-CONTAINING GRAIN.**

3 (a) MISBRANDING.—Section 502 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
5 ed by adding at the end the following:

6 “(gg) If it is a drug—

7 “(1) that is intended for human use;

8 “(2) that contains an ingredient that is derived
9 directly or indirectly from a gluten-containing grain
10 (including wheat, barley, rye, and their crossbred hy-
11 brids); and

12 “(3) whose label fails—

13 “(A) to state that the drug contains such
14 an ingredient; and

15 “(B) to identify each such ingredient and
16 the type of gluten-containing grain from which
17 it is derived.”.

18 (b) APPLICABILITY.—Section 502(gg) of the Federal
19 Food, Drug, and Cosmetic Act, as added by subsection
20 (a) of this section, shall apply beginning on the sooner
21 of—

22 (1) a date to be determined by the Secretary of
23 Health and Human Services; and

24 (2) the date that is 2 years after the date of the
25 enactment of this Act.