

114TH CONGRESS  
1ST SESSION

# H. R. 3648

To amend the Federal Food, Drug, and Cosmetic Act to require the label of drugs intended for human use to contain a parenthetical statement identifying the source of any ingredient constituting or derived from a grain or starch-containing ingredient.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2015

Mr. RYAN of Ohio (for himself and Mrs. LOWEY) 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 require the label of drugs intended for human use to contain a parenthetical statement identifying the source of any ingredient constituting or derived from a grain or starch-containing ingredient.

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 2015”.

1 **SEC. 2. LABELING OF SOURCE OF HUMAN DRUG INGREDI-**  
2 **ENTS CONSTITUTING OR DERIVED FROM A**  
3 **GRAIN OR STARCH-CONTAINING INGRE-**  
4 **DIENT.**

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

8 “(dd) If it is a drug—

9 (1) that is intended for human use;

10 (2) that contains an ingredient (other than a  
11 polyol) that constitutes or is derived from a grain or  
12 starch-containing ingredient; and

13 (3) whose label fails to include a parenthetical  
14 statement identifying the source of the ingredient so  
15 constituted or derived.”.

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

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

22 (2) the date that is 2 years after the date of the  
23 enactment of this Act.

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