

118TH CONGRESS  
1ST SESSION

# H. R. 4263

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

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2023

Mr. PHILLIPS (for himself, Mr. LAWLER, Ms. SHERRILL, and Mr. GALLAGHER) 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 a drug intended for human use to identify each ingredient in such drug that is, or is derived directly or indirectly from, a major food allergen or a gluten-containing grain, 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 “Allergen Disclosure  
5 In Non-food Articles Act” or the “ADINA Act”.

1 **SEC. 2. LABELING OF DRUGS WITH AN INGREDIENT THAT**  
2 **IS A MAJOR FOOD ALLERGEN OR IS MADE**  
3 **FROM A GLUTEN-CONTAINING GRAIN.**

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

7 “(hh) If it is a drug—

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

9 “(2) that contains an ingredient that is, or is  
10 derived directly or indirectly from—

11 “(A) a major food allergen; or

12 “(B) a gluten-containing grain (including  
13 wheat, barley, rye, and their crossbred hybrids);  
14 and

15 “(3) whose label fails—

16 “(A) to state that the drug contains such  
17 an ingredient; and

18 “(B) to identify each such ingredient and,  
19 as applicable, the type of gluten-containing  
20 grain.”.

21 (b) APPLICABILITY.—Section 502(hh) of the Federal  
22 Food, Drug, and Cosmetic Act, as added by subsection  
23 (a), shall apply beginning on the earlier of—

24 (1) a date to be determined by the Secretary of  
25 Health and Human Services; or

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

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