

116TH CONGRESS  
1ST SESSION

# S. 3021

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 SENATE OF THE UNITED STATES

DECEMBER 11, 2019

Mr. BLUMENTHAL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## 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 2019”.

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 “(ee) 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 crossbred hybrids  
 11 of such grains); 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(ee) of the Federal  
 19 Food, Drug, and Cosmetic Act, as added by subsection  
 20 (a) of this section, shall apply beginning on the earlier  
 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.