116TH CONGRESS
1ST SESSION

S. _____

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

Mr. BLUMENTHAL introduced the following bill; which was read twice and referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Gluten in Medicine Disclosure Act of 2019''.

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

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

''(ee) If it is a drug—

''(1) that is intended for human use;

''(2) that contains an ingredient that is derived directly or indirectly from a gluten-containing grain (including wheat, barley, rye, and crossbred hybrids of such grains); and

''(3) whose label fails—

''(A) to state that the drug contains such an ingredient; and

''(B) to identify each such ingredient and the type of gluten-containing grain from which it is derived.''.

(b) APPLICABILITY.—Section 502(ee) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section, shall apply beginning on the earlier of—

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

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