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112TH CONGRESS
2D SESSION

H. R. 4972

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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 27, 2012

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.

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 Identification Act of 2012''.

SEC. 2. LABELING OF SOURCE OF HUMAN DRUG INGREDIENTS CONSTITUTING OR DERIVED FROM A GRAIN OR STARCH-CONTAINING INGREDIENT.

(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:

''(aa) If it is a drug—

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

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

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

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

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