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115TH CONGRESS
1ST SESSION

H. R. 2113

To require the Food and Drug Administration to expedite review of pharmaceuticals that are approved for marketing in the European Union.

IN THE HOUSE OF REPRESENTATIVES

APRIL 20, 2017

Mr. STIVERS (for himself and Mr. RYAN of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Food and Drug Administration to expedite review of pharmaceuticals that are approved for marketing in the European Union.

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 ''Speeding Access to Already Approved Pharmaceuticals Act of 2017''.

SEC. 2. EXPEDITED REVIEW OF EU-APPROVED PHARMACEUTICALS.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

''(i) EU-APPROVED PHARMACEUTICALS.—

''(1) EXPEDITED REVIEW.—Beginning not later than 90 days after a new pharmaceutical is approved for marketing in the European Union, the Secretary shall, at the request of the sponsor of the pharmaceutical, facilitate the development and expedite the review of such new pharmaceutical under section 505 or 515 of this Act or section 351 of the Public Health Service Act, as appropriate.

''(2) DEFINITION.—In this subsection, the term 'pharmaceutical' means a drug (including a biological product) or a device.''.

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