

113TH CONGRESS
2D SESSION

H. R. 4918

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

JUNE 19, 2014

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

A BILL

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

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 “Speeding Access to
5 Already Approved Pharmaceuticals Act of 2014”.

6 **SEC. 2. EXPEDITED REVIEW OF EU-APPROVED PHARMA-**
7 **CEUTICALS.**

8 (a) IN GENERAL.—Section 506 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by
10 adding at the end the following:

1 “(g) EU-APPROVED PHARMACEUTICALS.—

2 “(1) EXPEDITED REVIEW.—Beginning not later
3 than 90 days after a new pharmaceutical is ap-
4 proved for marketing in the European Union, the
5 Secretary shall, at the request of the sponsor of the
6 pharmaceutical, facilitate the development and expe-
7 dite the review of such new pharmaceutical under
8 section 505 or 515 of this Act or section 351 of the
9 Public Health Service Act, as appropriate.

10 “(2) DEFINITION.—In this subsection, the term
11 ‘pharmaceutical’ means a drug (including a biologi-
12 cal product) or a device.”.

13 (b) TECHNICAL CORRECTION.—Subsection (f) (relat-
14 ing to awareness efforts) of section 506 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 356) is hereby
16 moved so as to follow subsection (e) (relating to construc-
17 tion) of such section 506.

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