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114TH CONGRESS
1ST SESSION

H. R. 2415

To amend the Federal Food, Drug, and Cosmetic Act to provide for establishment of a streamlined data review program.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. BURGESS (for himself and Mr. ENGEL) 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 provide for establishment of a streamlined data review program.

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

SECTION 1. STREAMLINED DATA REVIEW PROGRAM.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355f) the following:

"SEC. 505F. STREAMLINED DATA REVIEW PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a streamlined data review program under which a holder of an approved application submitted under section

505(b)(1) or under section 351(a) of the Public Health Service Act may, to support the approval or licensure (as applicable) of the use of the drug that is the subject of such approved application for a new qualified indication, submit qualified data summaries.

''(b) ELIGIBILITY.—In carrying out the streamlined data review program under subsection (a), the Secretary may authorize the holder of the approved application to include one or more qualified data summaries described in subsection (a) in a supplemental application if—

''(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

''(2) the supplemental application is for approval or licensure (as applicable) under such section 505(c) or 351(a) of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

''(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

''(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

''(5) the full data sets used to develop the qualified data summaries are submitted, unless the Secretary determines that the full data sets are not required.

''(c) PUBLIC AVAILABILITY OF INFORMATION ON PROGRAM.—The Secretary shall post on the public website of the Food and Drug Administration and update annually—

''(1) the number of applications reviewed under the streamlined data review program;

''(2) the average time for completion of review under the streamlined data review program versus other review of applications for new indications; and

''(3) the number of applications reviewed under the streamlined data review program for which the Food and Drug Administration made use of full data sets in addition to the qualified data summary.

''(d) DEFINITIONS.—In this section:

''(1) The term 'qualified indication' means—

''(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

''(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

''(2) The term 'qualified data summary' means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.''.

(b) SENSE OF CONGRESS.—It is the sense of Congress that the streamlined data review program under section 505F of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), should enable the Food and Drug Administration to make approval decisions for certain supplemental applications based on qualified data summaries (as defined in such section 505F).

(c) GUIDANCE; REGULATIONS.—The Commissioner of Food and Drugs—

(1) shall—

(A) issue final guidance for implementation of the streamlined data review program established under section 505F of the Federal Food, Drug, and Cosmetic Act, as added by sub-

section (a), not later than 24 months after the date of enactment of this Act; and

(B) include in such guidance the process for expanding the types of indications to be subject to the streamlined data review program, as authorized by section 505F(c)(1)(B) of such Act; and

(2) in addition to issuing guidance under paragraph (1), may issue such regulations as may be necessary for implementation of the program.

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