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114TH CONGRESS
1ST SESSION

H. R. 2547

To amend the Federal Food, Drug, and Cosmetic Act to provide for the development of accelerated approval development plans for investigational drugs and biological products.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2015

Mrs. MCMORRIS RODGERS 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 the development of accelerated approval development plans for investigational drugs and biological products.

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 ''Surrogate Endpoint Improvement and Utilization Act of 2015''.

SEC. 2. ACCELERATED APPROVAL DEVELOPMENT PLAN.

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

''(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—

''(1) IN GENERAL.—In the case of a drug determined to be eligible for accelerated approval under subsection (c), at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, the sponsor of such drug may voluntarily request agreement by the Secretary to an accelerated approval development plan with respect to a surrogate endpoint to be used to study the drug.

''(2) PLAN.—A plan described in paragraph (1) shall include agreement on—

''(A) the surrogate endpoint to be assessed under the plan;

''(B) the design of the study that will utilize the surrogate endpoint; and

''(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient

to form the primary basis of a claim that the drug is effective.

''(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

''(A) the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug involved; or

''(B) the drug is no longer eligible for accelerated approval under subsection (c).

''(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

''(5) DEFINITION.—In this section, the term 'accelerated approval development plan' means a development plan agreed upon by the Secretary and the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint that—

"(A) is reasonably likely to predict clinical benefit; and

"(B) is intended to be the basis of the accelerated approval of a drug under subsection (e).".

(b) TECHNICAL AMENDMENTS.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by striking "(f) AWARENESS EFFORTS" and inserting "(e) AWARENESS EFFORTS"; and

(2) by striking "(e) CONSTRUCTION" and inserting "(f) CONSTRUCTION".

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