

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

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.

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 “Surrogate Endpoint
5 Improvement and Utilization Act of 2015”.

1 **SEC. 2. ACCELERATED APPROVAL DEVELOPMENT PLAN.**

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

5 “(g) ACCELERATED APPROVAL DEVELOPMENT
6 PLAN.—

7 “(1) IN GENERAL.—In the case of a drug deter-
8 mined to be eligible for accelerated approval under
9 subsection (c), at any time after the submission of
10 an application for the investigation of the drug
11 under section 505(i) of this Act or section 351(a)(3)
12 of the Public Health Service Act, the sponsor of
13 such drug may voluntarily request agreement by the
14 Secretary to an accelerated approval development
15 plan with respect to a surrogate endpoint to be used
16 to study the drug.

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

19 “(A) the surrogate endpoint to be assessed
20 under the plan;

21 “(B) the design of the study that will uti-
22 lize the surrogate endpoint; and

23 “(C) the magnitude of the effect of the
24 drug on the surrogate endpoint that is the sub-
25 ject of the agreement that would be sufficient

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

3 “(3) MODIFICATION; TERMINATION.—The Sec-
4 retary may require the sponsor of a drug that is the
5 subject of an accelerated approval development plan
6 to modify or terminate the plan if additional data or
7 information indicates that—

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

11 “(B) the drug is no longer eligible for ac-
12 celerated approval under subsection (c).

13 “(4) SPONSOR CONSULTATION.—If the Sec-
14 retary requires the modification or termination of an
15 accelerated approval development plan under para-
16 graph (3), the sponsor shall be granted a request for
17 a meeting to discuss the basis of the Secretary’s de-
18 cision before the effective date of the modification or
19 termination.

20 “(5) DEFINITION.—In this section, the term
21 ‘accelerated approval development plan’ means a de-
22 velopment plan agreed upon by the Secretary and
23 the sponsor submitting the plan that contains study
24 parameters for the use of a surrogate endpoint
25 that—

1 “(A) is reasonably likely to predict clinical
2 benefit; and

3 “(B) is intended to be the basis of the ac-
4 celerated approval of a drug under subsection
5 (c).”.

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

9 (1) by striking “(f) AWARENESS EFFORTS” and
10 inserting “(e) AWARENESS EFFORTS”; and

11 (2) by striking “(e) CONSTRUCTION” and in-
12 serting “(f) CONSTRUCTION”.

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