

117TH CONGRESS
2D SESSION

H. R. 6996

To amend the Federal Food, Drug, and Cosmetic Act with respect to the accelerated approval of a product for a serious or life-threatening disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 2022

Mrs. RODGERS of Washington 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 with respect to the accelerated approval of a product for a serious or life-threatening disease or condition, and for other purposes.

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 “Accelerating Access
5 for Patients Act of 2022”.

1 **SEC. 2. ACCELERATED APPROVAL.**

2 (a) IN GENERAL.—Subsection (c) of section 506 of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 356) is amended to read as follows:

5 “(c) ACCELERATED APPROVAL OF A DRUG FOR A SE-
6 RIOUS OR LIFE-THREATENING DISEASE OR CONDITION,
7 INCLUDING A FAST TRACK PRODUCT.—

8 “(1) IN GENERAL.—

9 “(A) ACCELERATED APPROVAL.—The Sec-
10 retary may approve an application for approval
11 of a product for a serious or life-threatening
12 disease or condition, including a fast track
13 product, under section 505(c) of this Act or sec-
14 tion 351(a) of the Public Health Service Act
15 upon a determination—

16 “(i) that the product has an effect on
17 a surrogate endpoint that is reasonably
18 likely to predict clinical benefit, or on a
19 clinical endpoint that can be measured ear-
20 lier than irreversible morbidity or mor-
21 tality, that is reasonably likely to predict
22 an effect on irreversible morbidity or mor-
23 tality or other clinical benefit, taking into
24 account the severity, rarity, or prevalence
25 of the disease or condition and the avail-
26 ability or lack of alternative treatments; or

1 “(ii) of the safety and effectiveness of
2 the product based on the known benefit-
3 risk profile of such product in the intended
4 population, taking into account the sever-
5 ity, rarity, or prevalence of the disease or
6 condition and the availability or lack of al-
7 ternative treatments.

8 “(B) COMPREHENSIVE CLINICAL DEVEL-
9 OPMENT PLAN.—The Secretary shall establish
10 procedures by which a sponsor of a product
11 seeking approval described in subparagraph (A)
12 may meet with appropriate officials of the Food
13 and Drug Administration to develop a plan to
14 provide clarity and certainty for the sponsor re-
15 garding the applicability of the requirements of
16 this subsection. Such a plan shall include—

17 “(i) a determination as to whether the
18 product subject to such approval is in-
19 tended to treat an unmet medical need;

20 “(ii) an agreement on the surrogate
21 or intermediate clinical endpoint to be as-
22 sessed, if applicable;

23 “(iii) an agreement on the design of
24 the studies to be conducted to support the
25 approval;

1 “(iv) a plan for a postapproval study
2 to satisfy paragraph (2)(A), if required, in-
3 cluding a plan for reaching agreement on
4 the design of any such study;

5 “(v) a plan for reaching agreement on
6 the types of developmental milestones to be
7 met; and

8 “(vi) a strategy for the inclusion of di-
9 verse populations.

10 “(C) EVIDENCE.—The evidence to support
11 that an endpoint is reasonably likely to predict
12 clinical benefit under subparagraph (A)(i) may
13 include epidemiological, pathophysiological,
14 therapeutic, pharmacologic, or other evidence
15 developed using biomarkers, for example, or
16 other scientific methods or tools.

17 “(D) REFERENCES.—In this section, ap-
18 proval described in subparagraph (A) is re-
19 ferred to as ‘accelerated approval’.

20 “(2) LIMITATION.—Approval of a product
21 under this subsection may be subject to 1 or both
22 of the following requirements:

23 “(A) That the sponsor conduct appropriate
24 postapproval studies (which may include clinical
25 evidence, patient registries, or other sources of

1 real world evidence) to verify and describe the
2 predicted effect on irreversible morbidity or
3 mortality or other clinical benefit.

4 “(B) That the sponsor submit copies of all
5 promotional materials related to the product
6 during the preapproval review period and, fol-
7 lowing approval and for such period thereafter
8 as the Secretary determines to be appropriate,
9 at least 30 days prior to dissemination of the
10 materials.

11 “(3) GUIDANCE.—The Secretary shall issue—

12 “(A) guidance describing criteria, proc-
13 esses, and other general considerations for dem-
14 onstrating the safety and effectiveness of drugs
15 submitted for approval described in paragraph
16 (1)(A)(ii); and

17 “(B) guidance on the use of novel clinical
18 trial designs that may be used to conduct ap-
19 propriate postapproval studies as may be re-
20 quired under paragraph (2)(A).

21 “(4) APPROVAL OF STUDY PROTOCOL.—Not
22 later than 60 calendar days after the submission by
23 the sponsor of a product of a proposed protocol for
24 a postapproval study required under paragraph
25 (2)(A), the Secretary shall—

1 “(A) approve the protocol; or

2 “(B) specify changes to the protocol that
3 would enable such approval.

4 “(5) EXPEDITED WITHDRAWAL OF AP-
5 PROVAL.—The Secretary may withdraw approval of
6 a product approved under accelerated approval using
7 expedited procedures (as prescribed by the Secretary
8 in regulations which shall include an opportunity for
9 an informal hearing) if—

10 “(A) the sponsor fails to conduct any re-
11 quired postapproval study of the product with
12 due diligence;

13 “(B) a study required to verify and de-
14 scribe the predicted effect on irreversible mor-
15 bidity or mortality or other clinical benefit of
16 the product fails to verify and describe such ef-
17 fect or benefit;

18 “(C) other evidence demonstrates that the
19 product is not safe or effective under the condi-
20 tions of use; or

21 “(D) the sponsor disseminates false or
22 misleading promotional materials with respect
23 to the product.

24 “(6) REPORTING.—Not later than 180 days
25 after the date of enactment of the Accelerating Ac-

1 cess for Patients Act of 2022, and annually there-
2 after, the Secretary shall submit to the Committee
3 on Energy and Commerce of the House of Rep-
4 resentatives and the Committee on Health, Edu-
5 cation, Labor, and Pensions of the Senate a report
6 describing—

7 “(A) the circumstances and number of ap-
8 plications submitted for approval described in
9 paragraph (1)(A) for which real world evidence
10 was deemed appropriate to support or fulfill
11 postapproval studies required under this sub-
12 section; and

13 “(B) the circumstances and number of ap-
14 plications submitted for approval described in
15 paragraph (1)(A) for which real world evidence
16 was submitted for such postapproval studies.”.

17 (b) INITIAL GUIDANCE.—The Secretary of Health
18 and Human Services, acting through the Commissioner of
19 Food and Drugs—

20 (1) shall issue draft guidance pursuant to sec-
21 tion 506(c)(3) of the Federal Food, Drug, and Cos-
22 metic Act, as amended by subsection (a), not later
23 than 18 months after the date of enactment of this
24 Act;

1 (2) shall promulgate final guidance pursuant to
2 such section 506(c)(3) not later than 18 months
3 after the close of the public comment period on such
4 draft guidance; and

5 (3) may approve products as described in sec-
6 tion 506(c)(1)(A) of the Federal Food, Drug, and
7 Cosmetic Act, as amended by subsection (a), prior to
8 issuing initial draft or final guidance under this sub-
9 section.

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