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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements for postapproval studies for drugs approved using accelerated approval, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. PALLONE introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements for postapproval studies for drugs approved using accelerated approval, 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 “Accelerated Approval
5 Integrity Act of 2022”.

1 **SEC. 2. POSTAPPROVAL STUDIES REQUIRED FOR ACCELER-**
2 **ATED APPROVAL DRUGS.**

3 (a) IN GENERAL.—Section 506(c) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is
5 amended—

6 (1) in paragraph (2)—

7 (A) in the matter preceding subparagraph
8 (A), by striking “may be subject to 1 or both
9 of” and inserting “shall be subject to” ;

10 (B) by amending subparagraph (A) to read
11 as follows:

12 “(A) POSTAPPROVAL STUDIES.—

13 “(i) IN GENERAL.—The sponsor of a
14 product approved under accelerated ap-
15 proval shall—

16 “(I) conduct appropriate, ade-
17 quate, and well-controlled post-
18 approval studies to verify and describe
19 the predicted effect on irreversible
20 morbidity or mortality or other clin-
21 ical benefit; and

22 “(II) submit reports on such
23 studies in accordance with section
24 506B.

25 “(ii) AGREEMENT.—The Secretary
26 and the sponsor shall enter into an agree-

1 ment regarding the required conduct of
2 such studies prior to the Secretary approv-
3 ing a product under accelerated approval.
4 Such agreement may include requirements
5 regarding enrollment targets, study pro-
6 tocol, and milestones, including the target
7 date of study completion.

8 “(iii) STUDIES BEGUN BEFORE AP-
9 PROVAL.—The Secretary may—

10 “(I) require such studies to be
11 underway prior to approval; and

12 “(II) refuse to approve a product
13 under accelerated approval until such
14 studies are underway.”; and

15 (C) in subparagraph (B), by striking “(B)
16 That the sponsor” and inserting the following:

17 “(B) PROMOTIONAL MATERIALS.—The
18 sponsor of a product approved under acceler-
19 ated approval shall”; and

20 (2) by striking paragraph (3) and inserting the
21 following:

22 “(3) EXPEDITED WITHDRAWAL OF AP-
23 PROVAL.—

24 “(A) IN GENERAL.—The Secretary may
25 withdraw approval of a product approved under

1 accelerated approval using expedited procedures
2 described in subparagraph (B), if—

3 “(i) the sponsor fails to conduct any
4 required postapproval study of the product
5 with due diligence;

6 “(ii) the sponsor fails to achieve
7 agreed upon enrollment targets, mile-
8 stones, or timely study completion;

9 “(iii) the sponsor fails to submit re-
10 ports in accordance with section 506B;

11 “(iv) a study required to verify and
12 describe the predicted effect on irreversible
13 morbidity or mortality or other clinical
14 benefit of the product fails to verify and
15 describe such effect or benefit;

16 “(v) other evidence demonstrates that
17 the product is not shown to be safe or ef-
18 fective under the conditions of use; or

19 “(vi) the sponsor disseminates false or
20 misleading promotional materials with re-
21 spect to the product.

22 “(B) EXPEDITED PROCEDURES DE-
23 SCRIBED.—Expedited procedures described in
24 this subparagraph—

25 “(i) shall consist of—

1 “(I) providing the sponsor due
2 notice and an opportunity for written
3 appeal to the Commissioner of Food
4 and Drugs; and

5 “(II) an opportunity for public
6 comment on the notice proposing to
7 withdraw approval; and

8 “(ii) may include, at the Secretary’s
9 discretion, convening and consulting an ad-
10 visory committee.

11 “(C) AUTOMATIC EXPIRATION.—The ap-
12 proval of a product approved under accelerated
13 approval after the date of enactment of the Ac-
14 celerated Approval Integrity Act of 2022 shall
15 automatically expire 1 year after any target
16 date of study completion included in an agree-
17 ment described in clause (ii) of paragraph
18 (2)(A), and in no case later than 5 years after
19 the date on which the product is approved, un-
20 less—

21 “(i) a study required to verify and de-
22 scribe the predicted effect on irreversible
23 morbidity or mortality or other clinical
24 benefit of the product has verified that
25 predicted effect; or

1 “(ii) the Secretary has determined
2 that adequate progress has been made on
3 completion of postapproval studies required
4 under paragraph (2)(A).

5 “(4) LABELING.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), the label for a product approved
8 under accelerated approval shall include—

9 “(i) a statement indicating that the
10 product was approved under accelerated
11 approval;

12 “(ii) a statement indicating that con-
13 tinued approval of the product is subject to
14 postmarketing studies to verify clinical
15 benefit;

16 “(iii) identification of the clinical end-
17 point that is under study and any known
18 limitations of that surrogate or inter-
19 mediate endpoint in determining clinical
20 benefit;

21 “(iv) a succinct description of the
22 product and any uncertainty about antici-
23 pated clinical benefit and a discussion of
24 available evidence with respect to such clin-
25 ical benefit; and

1 “(v) any other information required
2 by the Secretary in the order approving the
3 product.

4 “(B) APPLICABILITY.—The labeling re-
5 quirements of subparagraph (A) shall apply
6 only to products approved under accelerated ap-
7 proval for which the predicted effect on irre-
8 versible morbidity or mortality or other clinical
9 benefit has not been verified.”.

10 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
11 tion 506B(a) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 356b(a)) is amended—

13 (1) by redesignating paragraph (2) as para-
14 graph (3); and

15 (2) by inserting after paragraph (1) the fol-
16 lowing:

17 “(2) ACCELERATED APPROVAL.—Notwith-
18 standing paragraph (1), a sponsor of a drug ap-
19 proved under accelerated approval shall submit to
20 the Secretary a report of the progress of any study
21 required under section 506(c), including progress to-
22 ward any agreed upon enrollment targets, mile-
23 stones, and other information as required by the
24 Secretary, not later than 90 days after the approval
25 of such drug and not less frequently than every 90

1 days thereafter, until the study is completed or ter-
2 minated. ”.

3 (c) ENFORCEMENT.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
5 ed by inserting after paragraph (eee) the following:

6 “(fff) The failure of a sponsor of a product approved
7 under accelerated approval pursuant to section 506(c)—

8 “(1) to conduct with due diligence any post-
9 approval study required under section 506(c) with
10 respect to such product; or

11 “(2) to submit timely reports with respect to
12 such product in accordance with section
13 506B(a)(2).”.