I

117TH CONGRESS
2D SESSION

H. R. 6963

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

MARCH 7, 2022

Mr. PALLONE 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 strengthen requirements for postapproval studies for drugs approved using accelerated approval, and for other purposes.

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 ''Accelerated Approval Integrity Act of 2022''.

SEC. 2. POSTAPPROVAL STUDIES REQUIRED FOR ACCELERATED APPROVAL DRUGS.

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

(1) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking ''may be subject to 1 or both of'' and inserting ''shall be subject to'';

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

''(A) POSTAPPROVAL STUDIES.—

''(i) IN GENERAL.—The sponsor of a product approved under accelerated approval shall—

''(I) conduct appropriate, adequate, and well-controlled postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit; and

''(II) submit reports on such studies in accordance with section 506B.

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

ment regarding the required conduct of such studies prior to the Secretary approving a product under accelerated approval. Such agreement may include requirements regarding enrollment targets, study protocol, and milestones, including the target date of study completion.

''(iii) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may—

''(I) require such studies to be underway prior to approval; and

''(II) refuse to approve a product under accelerated approval until such studies are underway.''; and

(C) in subparagraph (B), by striking ''(B) That the sponsor'' and inserting the following:

''(B) PROMOTIONAL MATERIALS.—The sponsor of a product approved under accelerated approval shall''; and

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

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—

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

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

"(i) the sponsor fails to conduct any required postapproval study of the product with due diligence;

"(ii) the sponsor fails to achieve agreed upon enrollment targets, milestones, or timely study completion;

"(iii) the sponsor fails to submit reports in accordance with section 506B;

"(iv) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(v) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

"(vi) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(B) EXPEDITED PROCEDURES DESCRIBED.—Expedited procedures described in this subparagraph—

"(i) shall consist of—

"(I) providing the sponsor due notice and an opportunity for written appeal to the Commissioner of Food and Drugs; and

"(II) an opportunity for public comment on the notice proposing to withdraw approval; and

"(ii) may include, at the Secretary's discretion, convening and consulting an advisory committee.

"(C) AUTOMATIC EXPIRATION.—The approval of a product approved under accelerated approval after the date of enactment of the Accelerated Approval Integrity Act of 2022 shall automatically expire 1 year after any target date of study completion included in an agreement described in clause (ii) of paragraph (2)(A), and in no case later than 5 years after the date on which the product is approved, unless—

"(i) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product has verified that predicted effect; or

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

''(4) LABELING.—

''(A) IN GENERAL.—Subject to subparagraph (B), the label for a product approved under accelerated approval shall include—

''(i) a statement indicating that the product was approved under accelerated approval;

''(ii) a statement indicating that continued approval of the product is subject to postmarketing studies to verify clinical benefit;

''(iii) identification of the clinical endpoint that is under study and any known limitations of that surrogate or intermediate endpoint in determining clinical benefit;

''(iv) a succinct description of the product and any uncertainty about anticipated clinical benefit and a discussion of available evidence with respect to such clinical benefit; and

"(v) any other information required by the Secretary in the order approving the product.

"(B) APPLICABILITY.—The labeling requirements of subparagraph (A) shall apply only to products approved under accelerated approval for which the predicted effect on irreversible morbidity or mortality or other clinical benefit has not been verified.".

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

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following:

"(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved under accelerated approval shall submit to the Secretary a report of the progress of any study required under section 506(c), including progress toward any agreed upon enrollment targets, milestones, and other information as required by the Secretary, not later than 90 days after the approval of such drug and not less frequently than every 90

days thereafter, until the study is completed or terminated.''.

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

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

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

''(2) to submit timely reports with respect to such product in accordance with section 506B(a)(2).''.

○