TAM17983 S.L.C. Susan M. Collins

AMENDMENT NO. 1 Calendar No._____

Purpose: To improve the bill.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. COLLINS (for herself and Mr. FRANKEN)

Viz:

At the end, add the following:

TITLE IX—GENERIC DRUG ACCESS

Subtitle A—Removing Regulatory Barriers to Competition

SEC. 901. IMPROVING ACCESS TO GENERIC DRUGS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

"(11)(A) The Secretary shall prioritize the review of, and act within 240 calendar days of the date of the sub-

mission of, an original abbreviated new drug application submitted for review under this subsection, or on a supplement to such an application, that is for a drug—

"(i) for which there are not more than 3 approved drugs listed under paragraph (7), except that the review of an application submitted more than 30 months in advance of the last applicable expiration date for a patent for which a certification under paragraph (2)(A)(vii)(III) has been submitted, or of the expiration date for an applicable period of exclusivity under this Act, will not be expedited; or

"(ii) that has been included on the list under section 506E.

"(B) The Secretary shall require the applicant, not later than 60 days prior to the submission of an application described in subparagraph (A), to provide complete, accurate information regarding facilities involved in manufacturing processes and testing, including facilities in corresponding Type II active pharmaceutical ingredients drug master files submitted with an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, in order to make a determination regarding whether an inspection of an establishment is necessary.

"(C) The Secretary may expedite an inspection or re-inspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

"(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

"(12) The Secretary shall provide review status updates to applicants regarding applications under this subsection, as appropriate, including when the application is awaiting final regulatory action by the office charged with review.

"(13) The Secretary shall publish on the Internet website of the Food and Drug Administration a list of all drugs approved under subsection (b) for which all patents and periods of exclusivity under this Act have expired. Such list shall be updated at least once every 180 days.".

SEC. 902. REPORTING ON PENDING GENERIC DRUG APPLICATIONS, PRIORITY REVIEW APPLICATIONS, AND INSPECTIONS.

(a) IN GENERAL.—Not later than 180 calendar days after the date of enactment of this Act, and quarterly thereafter until October 1, 2022, the Secretary of Health and Human Services (referred to in this section as the

"Secretary") shall post on the Internet website of the Food and Drug Administration a report that provides—

(1) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the applicant, including such applications that were filed prior to October 1, 2014;

(2) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the Secretary, including such applications that were filed prior to October 1, 2014;

(3) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and prior approval supplements withdrawn in each month covered by the report;

(4) the mean and median approval and tentative approval times for applications covered by the report;

(5) the number of applications described in paragraphs (1), (2), and (3) that are subject to priority review; and

(6) the number of such applications on which the Secretary has taken action pursuant to section

506H(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 901.

(b) ANNUAL REPORT ON PRIORITY REVIEW APPLICATIONS.—

(1) IN GENERAL.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Special Committee on Aging of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report, not later than March 31 of each year, on the following:

(A) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and are awaiting action by the applicant.

(B) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and are awaiting action by the Secretary.

(C) The number of applications filed under section 505(j) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and have been approved by the Secretary.

(D) For each of subparagraphs (A) through (C), the number of such applications—

(i) for which there are not more than 3 approved drugs listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(ii) the number of such applications that are for a drug on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

(c) ANNUAL REPORT ON INSPECTIONS.—Not later than March 1 of each year, the Secretary shall post on the Internet website of the Food and Drug Administration—

(1) the average and median amount of time, following a request by staff of the Food and Drug Administration reviewing an application or report submitted under an applicable section described in subparagraph (A), (B), or (C), to schedule and complete inspections of facilities necessary for—

(A) approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) approval of a device under section 515 of such Act (21 U.S.C. 360e); and

(C) clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)); and

(2) the average and median amount of time to schedule and complete for-cause inspections of facilities of drugs and devices.

Subtitle B—Incentivizing Competition

SEC. 911. EXPEDITING GENERIC COMPETITION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506G the following:

"SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.

"(a) IN GENERAL.—The Secretary shall, at the request of an applicant, expedite the development and review of an application under subsection (j) of section 505 for a drug—

"(1) for which there are not more than 3 approved drug products listed under section 505(j)(7); or

"(2) that is included on the list under section 506E.

"(b) REQUEST FROM SPONSORS.—A request to expedite the development and review of an application under subsection (a) shall be submitted by the applicant prior to the submission of such application.

"(c) OTHER APPLICATIONS.—Nothing in this section shall prevent the Secretary from expediting the development and review of other applications as the Secretary determines appropriate.

"(d) ADDITIONAL COMMUNICATION.—The Secretary shall take such actions as are appropriate to expedite the development and review of the application for approval of a drug described in subsection (a), including, as appropriate—

"(1) holding meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application;

"(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the application to ensure that the collection of nonclinical and clinical data necessary for approval is as efficient as practicable;

"(3) in the case of a complex product, assigning a cross-disciplinary project lead for the review team

to facilitate an efficient review of the development program and application, including manufacturing inspections; and

"(4) in the case of a complex product, including drug-device combinations, involving senior managers and experienced review staff, as appropriate, in a collaborative, cross- disciplinary review.

"(e) REPORTING REQUIREMENT.—A sponsor of a drug expedited under this section shall report to the Secretary, one year following approval of an application under section 505(j), on whether the approved drug has been marketed in interstate commerce since approval.".

SEC. 912. LIST OF GENERIC DRUGS WITH LIMITED COMPETITION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506H, as added by section 911, the following:

"SEC. 506I. DRUG LISTING.

"(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The holder of an application approved under subsection (b) or (j) of section 505 shall notify the Secretary within 180 days of removing the drug that is the subject of such application from interstate commerce, withdrawing such approved application, or transferring such approved application, and a reason for such removal, withdrawal, or trans-

fer. If compliance with this subsection within such 180-day period is not practicable, then the holder shall comply as soon as practicable. The Secretary shall cross-reference information listed pursuant to section 506C where applicable to avoid duplicative reporting.

"(b) DRUGS WITH LIMITED COMPETITION.—

"(1) INFORMATION.—The Secretary shall—

"(A) maintain information with respect to applications approved under section 505(j); and

"(B) publish on the Internet website of the Food and Drug Administration such information under subparagraph (A) with respect to drugs for which there are 3 or fewer application holders; and

"(C) update the information published pursuant to subparagraph (B) every 180 days.

"(2) CONTENTS.—The public information maintained and published under paragraph (1)(B) shall include—

"(A) the name of the drug, name of the holder of the approved application, and the marketing status for each drug; and

"(B) an indication of whether the Secretary considers the drug to be for the treatment or prevention of a serious disease or med-

ical condition, for which there is no alternative drug that is judged by medical professionals to be an adequate substitute available in adequate supply.

"(c) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available if the Secretary determines that disclosure of such information would adversely affect the public health.

"(d) NOTIFICATION.—When the Secretary first publishes the information under subsection (b), the Secretary shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, that the information has been published and will be updated regularly.".

SEC. 913. SUITABILITY PETITIONS.

(a) IN GENERAL.—It is the sense of the Senate that the Food and Drug Administration shall meet the requirement under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(C)) and section 314.93(e) of title 21, Code of Federal Regulations, of responding to suitability petitions within 90 days of submission.

(b) REPORT.—The Secretary of Health and Human Services shall include in the annual reports under section 902(b)—

(1) the number of pending petitions under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(C)); and

(2) the number of such petitions pending a substantive response for more than 180 days from the date of receipt.

SEC. 914. INSPECTIONS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), as amended by section 901, is further amended by adding at the end the following:

"(14) If the Secretary issues feedback pursuant to section 704(b)(2) with respect to information submitted in response to a report under section 704(b)(1), and a report that was issued under section 704(b)(1) is the only obstacle to approval of an application under this subsection or the Secretary determines that the public health benefit of approving an application under this subsection outweighs any risk to public health, the Secretary shall, within 45 days of notification by the applicant that necessary changes have been made to the establishment to address any findings or deficiencies identified previously by the Secretary—

"(A) re-inspect the establishment with respect to which the report was issued; or

"(B) make a determination regarding the response to such report and review of such application.".