SEC. ____. TABLE OF CONTENTS.

The table of contents of this file is as follows:

TITLE IX—DRUG SHORTAGES

SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

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

"SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining; or

''(C) intended for use in the prevention of a debilitating disease or condition;

''(2) for which an application has been approved under section 505(b) or 505(j); and

''(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product;

shall notify the Secretary of a discontinuance of the manufacture of the drug, or an interruption of the manufacture of the drug that is likely to produce a drug shortage, in accordance with subsection (b).

''(b) TIMING.—A notice required by subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation or interruption of the manufacture of the drugs described in subsection (a) to appropriate physician and patient organizations, as described in section 506D.''.

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, after issuing a notice of proposed rule and holding a public hearing, shall promulgate final regulations that implement the amendment made by subsection (a).

(2) CONTENTS.—Such regulations shall—

(A) include a list of the drugs that are subject to the requirements of section 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)), as amended by subsection (a), if the manufacture of such drug is to be discontinued, or an interruption of the manufacture of the drug that is likely to produce a drug shortage; and

(B) define the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention of a debilitating disease or condition'' for purposes of section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c).

SEC. 902. DRUG SHORTAGE LIST.

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

''SEC. 506D. DRUG SHORTAGE LIST.

''(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are verified to be in shortage in the United States.

''(b) CONTENTS.—For each drug on such list, the Secretary shall include the following information:

''(1) The name of the drug in shortage.

''(2) The name of each manufacturer of such drug.

''(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

''(A) Requirements related to complying with good manufacturing practices.

''(B) Regulatory delay.

''(C) Shortage of an active ingredient.

''(D) Shortage of a non-active pharmaceutical ingredient component.

''(E) Discontinuation of the manufacture of the drug.

''(F) Delay in shipping of the drug.

''(G) Demand increase for the drug.

''(4) The anticipated duration of the shortage, as determined by the Secretary.

''(c) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

''(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or

amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

''(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publically available under paragraph (1) if the Secretary determines that disclosure of such information would adversely affect the public health.''.

SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

''(A) complete review of such request; and

''(B) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein.

''(2) A request is described in this paragraph if—

''(A) the request pertains to a controlled substance on the list of drugs in shortage maintained

under section 506D of the Federal Food, Drug, and Cosmetic Act;

''(B) the request is submitted by the manufacturer of the controlled substance; and

''(C) the controlled substance is in schedule II.''.

SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING CHANGES FOR POTENTIAL AND VERIFIED SHORTAGES OF DRUGS THAT ARE LIFE THREATENING, LIFE SUSTAINING, OR INTENDED FOR USE IN THE TREATMENT OR PREVENTION OF A DEBILITATING DISEASE OR CONDITION.

Subsection (c) of section 506A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356a) is amended by adding at the end the following new paragraph:

''(3) CHANGES ADDRESSING A DRUG SHORTAGE.—

''(A) CERTIFICATION.—

''(i) DESCRIPTION.—A certification is described in this subparagraph if the holder of the approved application or license for the drug involved certifies (in such certification) that the major manufacturing change for which approval is being sought

may prevent or alleviate a verified or anticipated shortage of a drug described in section 506C(a)(1).

''(ii) BAD FAITH EXCEPTION.—Subparagraphs (B) and (C) do not apply in the case of a certification which the Secretary determines to be made in bad faith.

''(B) EXPEDITED REVIEW.—If a certification described in subparagraph (A) is submitted in connection with a supplemental application for a major manufacturing change, the Secretary shall—

''(i) expedite any technical review or inspection necessary for consideration of the supplemental application;

''(ii) provide any technical assistance necessary to facilitate approval of the supplemental application; and

''(iii) not later than 60 days after receipt of the certification, complete review of the supplemental application.

''(C) GOOD MANUFACTURING PRACTICE.—In approving a major manufacturing change for which a certification described in subparagraph (A) is submitted, the Secretary may, for the

purpose of preventing or alleviating the shortage addressed by the certification, deem the change to be in compliance with the requirements of this Act for current good manufacturing practice (within the meaning of section 501(a)(1)(B)) if the manufacturing facilities involved—

''(i) have a plan to achieve full compliance with such requirements, as in effect at the time of the Secretary's determination;

''(ii) have sufficient resources to achieve, and demonstrate adequate progress in achieving, such full compliance; and

''(iii) are implementing adequate interim controls, as determined by the Secretary, in order to ensure the quality of the drug.

''(D) INTERIM CONTROLS.—The interim controls required by subparagraph (C)(iii) for a drug shall include additional testing, such as in-process or release testing of the drug or its active ingredients, excipients, or components.''.

SEC. 905. STUDY ON DRUG SHORTAGES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study to examine the cause of drug shortages and formulate recommendations on how to prevent or alleviate such shortages.

(b) CONSIDERATION.—In conducting the study under this section, the Comptroller General shall consider the following questions:

(1) What are the dominant characteristics of drugs that have gone into actual shortage over the preceding three years?

(2) Are there systemic high-risk factors that have led to the concentration of drug shortages in certain drug products that have made such products vulnerable to drug shortages?

(3) Is there a reason why drug shortages have occurred primarily in the sterile injectable market and in certain therapeutic areas?

(4) How have regulations, guidance documents, regulatory practices, and other actions of Federal departments and agencies affected drug shortages?

(5) How does hoarding affect drug shortages?

(6) How would incentives alleviate or prevent drug shortages?

(c) CONSULTATION WITH STAKEHOLDERS.—In conducting the study under this section, the Comptroller Gen-

eral shall consult with relevant stakeholders, including physicians, pharmacists, hospitals, patients, and drug manufacturers.

(d) REPORT.—Note later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the results of the study under this section.

SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.

Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on drug shortages that—

(1) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(2) describes the Food and Drug Administration's efforts to expedite the review of new manufacturing sites, new suppliers, and specification changes to prevent or alleviate a drug shortage;

(3) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(4) identifies the number of, and describes the, instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(5) identifies the number of instances in which the Food and Drug Administration asked firms to increase production to prevent or alleviate a shortage;

(6) identifies the number of notifications submitted to the Secretary under section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by section 901 of this Act, including the percentage of such notifications for a drug that is a sterile injectable;

(7) describes the Food and Drug Administration's implementation of section 506D of the Federal Food, Drug, and Cosmetic Act (relating to a

drug shortage list), as added by section 902 of this Act, and identifies—

(A) the name of each drug on the list under such section 506D at any point during the period covered by the report;

(B) the name of each manufacturer of each such drug;

(C) the reason for the shortage of each such drug; and

(D) the anticipated or, if known, actual duration of the shortage of each such drug;

(8) identifies whether, and how, the Food and Drug Administration expedited the review of regulatory submissions to prevent or alleviate shortages, including how the Administration utilized the authority in section 506A(c)(3) of the Federal Food, Drug, and Cosmetic Act, as added by section 904 of this Act;

(9) identifies the number of certifications submitted under such section 506A(c)(3) and, for each such certification, whether the Food and Drug Administration completed expedited review within 60 days as required by subparagraph (B) of such section 506A(c)(3);

(10) specifies—

(A) the number of waivers and reductions for human drug applications and supplements requested under section 736(e) of the Federal Food, Drug, and Cosmetic Act, as added by section [103] of this Act, and the number of such waivers and reductions granted; and

(B) the number of waivers and reductions for abbreviated new drug applications and prior approval supplements requested under section 744A(o) of the Federal Food, Drug, and Cosmetic Act, as added by section [302] of this Act, and the number of such waivers and reductions granted; and

(11) describes the Secretary's public engagement on drug shortages with stakeholders, including physicians, pharmacists, patients, hospitals, and drug manufacturers; and

(12) contains the Secretary's plan for addressing drug shortages in the upcoming year, including with respect to the issues described in paragraphs (1) through (11).