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116TH CONGRESS
2D SESSION

H. R. 6660

To amend the Federal Food, Drug, and Cosmetic Act to require the holders of approved applications for drugs to conduct a risk assessment to identify and evaluate risks to their supply chain and develop, maintain, and implement risk mitigation plans to address such risks, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 1, 2020

Ms. BLUNT ROCHESTER (for herself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require the holders of approved applications for drugs to conduct a risk assessment to identify and evaluate risks to their supply chain and develop, maintain, and implement risk mitigation plans to address such risks, 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 ''Limit Ongoing Shortages and Stabilize Supply Act of 2020'' or the ''LOSS Act of 2020''.

SEC. 2. RISK ASSESSMENTS AND RISK MITIGATION PLANS FOR DRUGS.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506C–1 of such Act (21 U.S.C. 356c–1) the following new section:

''SEC. 506C–2. RISK ASSESSMENTS AND RISK MITIGATION PLANS FOR DRUGS.

''(a) COVERED DRUG DEFINED.—In this section, the term 'covered drug'—

''(1) means a drug that—

''(A) is described in section 506C(a); or

''(B) is included, or was included at any point during the preceding 5 years, in the drug shortage list in effect under section 506E; and

''(2) includes any such drug that is not required to be approved pursuant to an application under subsection (b) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act to be lawfully marketed.

''(b) REQUIREMENT.—The manufacturer of a covered drug shall—

''(1) conduct a risk assessment that identifies and evaluates risks to the supply of the drug, including vulnerabilities that would likely lead to a meaningful disruption in the supply of the drug in the United States;

''(2) develop and maintain a risk mitigation plan to ensure the supply of the drug during such a shortage; and

''(3) implement such plan during such a shortage.

''(c) CONFIDENTIALITY.—The Secretary shall—

''(1) maintain the confidentiality of any risk assessment, and any risk mitigation plan, under this section; and

''(2) limit the use by the Secretary of information in such an assessment or plan to preventing, mitigating, or responding to a drug shortage.

''(d) GUIDANCE.—The Secretary shall publish guidance on—

''(1) how manufacturers should work with their supply chain partners in developing the required risk assessments and risk mitigation plans;

''(2) the elements of a risk mitigation plan under this section; and

''(3) the form and manner of developing and maintaining such plan.

''(e) INSPECTION.—A risk mitigation plan under this section shall be subject to inspection and copying by the Secretary under section 704.

''(f) EXPEDITED INSPECTIONS AND REVIEWS.—The Secretary may conduct an expedited inspection or review as described in section 506C(g) for the purpose of facilitating the implementation of a risk management plan developed pursuant to this section.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(fff) The failure to conduct a risk assessment, or to develop, maintain, and implement a risk mitigation plan, in accordance with section 506C–2.''.

(c) APPLICABILITY.—The amendments made by this section apply beginning on the date that is 24 months after the date of enactment of this Act, except that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall have discretion to allow persons subject to such amendments additional time to comply with such amendments as the Secretary determines necessary.

SEC. 3. DISCONTINUANCE OR INTERRUPTION IN PRODUCTION.

(a) ACTIVE PHARMACEUTICAL INGREDIENTS.—

(1) ACTIVE PHARMACEUTICAL INGREDIENTS.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended by adding at the end the following:

''(j) APPLICABILITY WITH RESPECT TO ACTIVE PHARMACEUTICAL INGREDIENTS.—This section shall apply with respect to an active pharmaceutical ingredient in a drug described in subsection (a) in the same manner and to the same extent as this section applies with respect to a drug described in subsection (a), except that subsection (i) shall not apply with respect to active pharmaceutical ingredients.''.

(2) GUIDANCE.—

(A) ISSUANCE.—Not later than 24 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance on implementing the amendment made by paragraph (1).

(B) CONTENTS.—The guidance required by subparagraph (A) shall specify—

(i) the form and manner of the disclosures required by the amendment made by paragraph (1); and

(ii) the details that need to be included in such disclosures.

(b) PROHIBITED ACTS WITH RESPECT TO DRUGS AND ACTIVE PHARMACEUTICAL INGREDIENTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 2(b), is further amended by adding at the end the following:

''(ggg) The failure of a manufacturer of a drug described in section 506C(a) or an active pharmaceutical ingredient of such a drug, without a reasonable basis as determined by the Secretary, to notify the Secretary of a permanent discontinuance or an interruption, and the reasons for such discontinuance or interruption, as required by section 506C.''.

(c) APPLICABILITY.—The amendments made by subsections (a) and (b) apply beginning on the date that is 180 days after the date of enactment of this Act.

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