

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Limit Ongoing Short-
3 ages and Stabilize Supply Act of 2020” or the “LOSS
4 Act of 2020”.

5 **SEC. 2. RISK ASSESSMENTS AND RISK MITIGATION PLANS**
6 **FOR DRUGS.**

7 (a) IN GENERAL.—The Federal Food, Drug, and
8 Cosmetic Act is amended by inserting after section 506C—
9 1 of such Act (21 U.S.C. 356c–1) the following new sec-
10 tion:

11 **“SEC. 506C–2. RISK ASSESSMENTS AND RISK MITIGATION**
12 **PLANS FOR DRUGS.**

13 “(a) COVERED DRUG DEFINED.—In this section, the
14 term ‘covered drug’—

15 “(1) means a drug that—

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

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

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

25 “(b) REQUIREMENT.—The manufacturer of a covered
26 drug shall—

1 “(1) conduct a risk assessment that identifies
2 and evaluates risks to the supply of the drug, includ-
3 ing vulnerabilities that would likely lead to a mean-
4 ingful disruption in the supply of the drug in the
5 United States;

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

9 “(3) implement such plan during such a short-
10 age.

11 “(c) CONFIDENTIALITY.—The Secretary shall—

12 “(1) maintain the confidentiality of any risk as-
13 sessment, and any risk mitigation plan, under this
14 section; and

15 “(2) limit the use by the Secretary of informa-
16 tion in such an assessment or plan to preventing,
17 mitigating, or responding to a drug shortage.

18 “(d) GUIDANCE.—The Secretary shall publish guid-
19 ance on—

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

23 “(2) the elements of a risk mitigation plan
24 under this section; and

1 “(3) the form and manner of developing and
2 maintaining such plan.

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

6 “(f) EXPEDITED INSPECTIONS AND REVIEWS.—The
7 Secretary may conduct an expedited inspection or review
8 as described in section 506C(g) for the purpose of facili-
9 tating the implementation of a risk management plan de-
10 veloped pursuant to this section.”.

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

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

17 (c) APPLICABILITY.—The amendments made by this
18 section apply beginning on the date that is 24 months
19 after the date of enactment of this Act, except that the
20 Secretary of Health and Human Services, acting through
21 the Commissioner of Food and Drugs, shall have discre-
22 tion to allow persons subject to such amendments addi-
23 tional time to comply with such amendments as the Sec-
24 retary determines necessary.

1 **SEC. 3. DISCONTINUANCE OR INTERRUPTION IN PRODUC-**
2 **TION.**

3 (a) ACTIVE PHARMACEUTICAL INGREDIENTS.—

4 (1) ACTIVE PHARMACEUTICAL INGREDIENTS.—

5 Section 506C of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 356c) is amended by adding
7 at the end the following:

8 “(j) APPLICABILITY WITH RESPECT TO ACTIVE
9 PHARMACEUTICAL INGREDIENTS.—This section shall
10 apply with respect to an active pharmaceutical ingredient
11 in a drug described in subsection (a) in the same manner
12 and to the same extent as this section applies with respect
13 to a drug described in subsection (a), except that sub-
14 section (i) shall not apply with respect to active pharma-
15 ceutical ingredients.”.

16 (2) GUIDANCE.—

17 (A) ISSUANCE.—Not later than 24 months
18 after the date of enactment of this Act, the Sec-
19 retary of Health and Human Services, acting
20 through the Commissioner of Food and Drugs,
21 shall issue final guidance on implementing the
22 amendment made by paragraph (1).

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

1 (i) the form and manner of the disclo-
2 sures required by the amendment made by
3 paragraph (1); and

4 (ii) the details that need to be in-
5 cluded in such disclosures.

6 (b) PROHIBITED ACTS WITH RESPECT TO DRUGS
7 AND ACTIVE PHARMACEUTICAL INGREDIENTS.—Section
8 301 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 331), as amended by section 2(b), is further
10 amended by adding at the end the following:

11 “(ggg) The failure of a manufacturer of a drug de-
12 scribed in section 506C(a) or an active pharmaceutical in-
13 gredient of such a drug, without a reasonable basis as de-
14 termined by the Secretary, to notify the Secretary of a
15 permanent discontinuance or an interruption, and the rea-
16 sons for such discontinuance or interruption, as required
17 by section 506C.”.

18 (c) APPLICABILITY.—The amendments made by sub-
19 sections (a) and (b) apply beginning on the date that is
20 180 days after the date of enactment of this Act.

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