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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to improving the infant formula supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. STEFANIK introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to improving the infant formula supply chain, 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 ''Babies Need More Formula Now Act of 2022''.

SEC. 2. DEFINITION.

In this Act, the term ''infant formula'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

SEC. 3. IMPORTATION OF INFANT FORMULA.

(a) WAIVER OF LABELING REQUIREMENTS FOR IMPORTS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by adding at the end the following:

''(j) WAIVER OF LABELING REQUIREMENTS FOR IMPORTS.—

''(1) IN GENERAL.—The Secretary may waive any labeling requirement under this Act applicable to—

''(A) the importation of infant formula from any country that is determined by the Secretary to be implementing and enforcing requirements for infant formula that provide a similar assurance of safety as the regulatory requirements of this Act; or

''(B) the distribution and sale of such imported infant formula.

''(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to limit the authority of the Secretary to require a recall of, or otherwise impose restrictions and requirements under this

Act with respect to, infant formula that is subject to a waiver under paragraph (1).''.

(b) HARMONIZATION.—The Secretary of Health and Human Services shall, when appropriate, enter into arrangements with other nations for the purpose of harmonizing the regulatory requirements of the United States for infant formula, including with respect to inspections, nutritional requirements, and common international labeling, with the corresponding regulatory requirements of such other nations.

(c) SUPPORT FOR THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.—Section 803(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383(c)(2)) is amended by striking ''foods'' and inserting ''foods (including infant formula)''.

(d) STUDY.—The Secretary of Health and Human Services shall enter into an arrangement with the National Academy of Medicine (or, if the National Academy declines to enter into such arrangement, another appropriate entity) under which the National Academy (or other appropriate entity) agrees to—

(1) conduct a study comparing infant formula in the United States and infant formula in the European Union, including with respect to nutritional

content and applicable labeling and other regulatory requirements; and

(2) not later than 1 year after the date of enactment of this Act, complete such study and submit a report on the results of such study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

SEC. 4. TRANSPARENCY TO SUPPORT INFANT FORMULA INNOVATION.

(a) ANNUAL REPORT TO CONGRESS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by section 3(a) of this Act, is further amended by adding at the end the following:

''(k) ANNUAL REPORT TO CONGRESS.—Not later than March 30 of each year, the Secretary shall submit a report to the Congress containing, with respect to the preceding calendar year, the following information:

''(1) The number of submissions received by the Secretary under subsection (d).

''(2) For each such submission—

''(A) the amount of time taken by the Secretary to respond;

''(B) the number of times the Secretary requested additional information from the person making such submission; and

''(C) whether such submission included any new ingredients that were not included in any infant formula already on the market.

''(3) The number of inspections conducted by the Food and Drug Administration or any agent thereof to evaluate compliance with subsection (b)(2).

''(4) The time between any inspection referred to in paragraph (3) and any necessary reinspection to evaluate compliance with subsection (b)(2).''.

(b) MARKETING SUBMISSIONS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by subsection (a), is further amended by adding at the end the following:

''(l) MARKETING SUBMISSIONS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall respond to a submission under subsection (d) for infant formula not later than 90 days after receiving such notification.

''(2) EXPEDITED RESPONSE.—The Secretary shall respond to a submission under subsection (d)

for infant formula not later than 75 days after receiving such notification if it—

"(A) is submitted by a manufacturer that is not already marketing infant formula in the United States; or

"(B) is for infant formula containing one or more ingredients that are not contained in infant formula that is already being marketed in the United States.

"(3) NOTIFICATION TO CONGRESS.—Whenever the Secretary fails to respond to a submission under subsection (d) by the deadline applicable under paragraph (1) or (2), the Secretary shall give notice of such failure to the Congress, including an explanation of the reasons for failing to meet the deadline.".

(c) TECHNICAL CORRECTION.—Section 412(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(B)) is amended by striking "subsection (c)(1)" and inserting "subsection (d)(1)".

SEC. 5. REDUCING BARRIERS TO INFANT FORMULA COMPETITION.

Not later than 180 days 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 guidance on which types of changes, if any, in the ingredients of infant formula may not require a new growth study to meet the requirements of section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a).

SEC. 6. COORDINATION OF EFFORTS TO MITIGATE SHORTAGES OF INFANT FORMULA.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall require appropriate staff of the Office of Nutrition and Food Labeling, and the Office of Compliance, of the Center for Food Safety and Applied Nutrition, to meet at least biweekly to discuss, with respect to infant formula, pending inspections, the findings of pending and concluded inspections, and any need for additional inspections.

SEC. 7. IMPORTATION FOR PERSONAL USE.

(a) IN GENERAL.—During the period of 90 days following the date of enactment of this Act, a person may, without prior notice to the Food and Drug Administration, import up to a three-month supply of infant formula for personal use from Canada, the European Union, or any country that is determined by the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to have safety standards for infant formula similar to such standards applicable under the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) LIMITATIONS.—Infant formula may be imported pursuant to subsection (a) only if the infant formula—

(1) is exclusively for personal use and will not be commercialized or promoted; and

(2) does not present an unreasonable risk to human health.

(c) REPORTING OF ADVERSE EVENTS.—If a health care provider becomes aware of any adverse event which the health care provider reasonably suspects to be associated with infant formula imported pursuant to subsection (a), the health care provider shall report such adverse event to the Food and Drug Administration.

(d) PUBLIC NOTICE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall post on the public website of the Food and Drug Administration notice that—

(1) infant formula imported pursuant to subsection (a) may not have been manufactured in a facility that has been inspected by the Food and Drug Administration;

(2) the labeling of such infant formula may not meet the standards and other requirements applicable with respect to infant formula under the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(3) the nutritional content of the infant formula may vary from that of infant formula meeting such standards and other requirements.

(e) SENSE OF CONGRESS.—It is the sense of Congress that persons considering the personal importation of infant formula should consult with their pediatrician about such importation.

SEC. 8. CONSIDERATION OF SUPPLY EFFECTS PRIOR TO RECOMMENDING OR REQUIRING A RECALL.

(a) IN GENERAL.—Section 412(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(f)(2)) is amended by adding at the end the following:

''(4) Before recommending or requiring any recall of infant formula due exclusively to labeling deficiencies, the Secretary shall ensure that the supply of infant formula in the United States will not be negatively affected by such recall.''.

(b) REGULATIONS.—Not later than 3 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 or update such regulations as may be necessary to implement paragraph (4) of section

412(f) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

SEC. 9. CONGRESSIONAL NOTIFICATION.

(a) IN GENERAL.—Not later than 24 hours after the initiation of a recall of infant formula, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Congress a notification of such recall.

(b) CONTENTS.—A notification under subsection (a) shall include the following:

(1) If the recall is required by the Food and Drug Administration, a summary of the determination of a case of adulterated or misbranded infant formula that presents a risk to human health.

(2) If the recall is voluntarily initiated by the manufacturer, a summary of the information provided to the Food and Drug Administration by the manufacturer regarding infant formula that has left the control of the manufacturer that may be adulterated or misbranded.

(3) Specification of when the Food and Drug Administration was first made aware of the instance or circumstances surrounding the recall.

(4) An initial estimate of the disruption in domestic production that may result from the recall.

SEC. 10. REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than 14 days after the initiation of a recall of infant formula, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit a report to the Congress regarding such recall.

(b) CONTENTS.—A report under subsection (a) shall include the following:

(1) A plan (including an estimated timeline) of actions the Food and Drug Administration and the manufacturer will take—

(A) to identify and address any cause of adulteration or misbranding; and

(B) to restore operation of the impacted facilities to meet production levels in place prior to the recall.

(2) The current domestic supply of infant formula, including—

(A) a breakdown of the specific types of formula involved; and

(B) an estimate of how long current supplies will last.

(3) In the case that a recall and subsequent actions to respond to the recall impact over 10 percent of the domestic production of infant formula, a plan to backfill supplies if the current domestic supply of

infant formula has or is expected to fall below the level demanded during the disruption in domestic production, which plan shall include—

(A) actions to work with the impacted manufacturer or other manufacturers to increase production; and

(B) specification of—

(i) any additional authorities needed regarding production or importation to fill a supply gap; and

(ii) any supplemental funding necessary to address the shortage.

SEC. 11. COORDINATION WITH MANUFACTURER ON RESTORING PRODUCTION.

(a) IN GENERAL.— Upon completing an inspection of an infant formula manufacturing facility impacted by a recall, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide the manufacturer involved a list of any actions necessary—

(1) to address deficiencies contributing to the potential adulteration or misbranding of product at the facility; and

(2) to safely restart production at the facility.

(b) RESPONSE TO MANUFACTURER.—Not later than 7 days after receiving a written communication from a manufacturer of infant formula regarding safely restoring production following a recall of such product, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide a substantive response to such communication, including any necessary next steps.