| (Original Signature of Member) |  |
|--------------------------------|--|
|                                |  |

117TH CONGRESS 2D SESSION

## H.R.

To provide for the expedited and duty-free importation of infant formula that may be lawfully marketed in the European Union, Canada, Japan, or the United Kingdom, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

| Mr. Sherman introduced | the following | bill; which was | referred to the |
|------------------------|---------------|-----------------|-----------------|
| Committee on _         |               |                 |                 |
|                        |               |                 |                 |

## A BILL

To provide for the expedited and duty-free importation of infant formula that may be lawfully marketed in the European Union, Canada, Japan, or the United Kingdom, 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,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Emergency Infant For-
- 5 mula Act".
- 6 SEC. 2. EXPEDITED IMPORTATION OF INFANT FORMULA.
- 7 (a) AUTHORIZATION FOR IMPORTATION AND SALE.—

| 1  | (1) Declaration of Shortage.—The Presi-                |
|----|--|
| 2  | dent may declare, in consultation with the Commis-     |
| 3  | sioner of Food and Drugs and through Executive         |
| 4  | Order, that a shortage exists in the United States of  |
| 5  | infant formula with respect to any period specified    |
| 6  | in such Order.   |
| 7  | (2) Authorization for importation and                  |
| 8  | SALE.—The President, in consultation with the          |
| 9  | Commissioner of Food and Drugs, may authorize          |
| 10 | the importation, distribution, and sale of any cov-    |
| 11 | ered infant formula, notwithstanding the provisions    |
| 12 | of the Federal Food, Drug, and Cosmetic Act (21        |
| 13 | U.S.C. 201 et seq.), if the applicable brand, manu-    |
| 14 | facturer, or manufacturing plant, or the specific in-  |
| 15 | fant formula product, is included in the Executive     |
| 16 | Order promulgated pursuant to the authority pro-       |
| 17 | vided by paragraph (1). Such Executive Order may       |
| 18 | further specify, with respect to such authorized       |
| 19 | products, specific requirements with respect to the    |
| 20 | labeling or usage guidance to be eligible for importa- |
| 21 | tion, distribution, and sale pursuant to the authority |
| 22 | provided by this paragraph.                            |
| 23 | (3) Labeling requirements.—                            |
| 24 | (A) Exemption from united states la-                   |
| 25 | BELING REQUIREMENTS.—Any provision of the              |

| 1  | Federal Food, Drug, and Cosmetic Act (21          |
|----|---|
| 2  | U.S.C. 201 et seq.) relating to labeling require- |
| 3  | ments for infant formula products imported        |
| 4  | into the United States shall not apply with re-   |
| 5  | spect to such products imported pursuant to       |
| 6  | the authority provided by paragraph (2).          |
| 7  | (B) REQUIREMENT WITH RESPECT TO                   |
| 8  | FOREIGN MARKETING ELIGIBILITY.—Notwith-           |
| 9  | standing subparagraph (A), the Commissioner       |
| 10 | of Food and Drugs shall require any retailer of   |
| 11 | covered infant formula imported subject to the    |
| 12 | authority provided by paragraph (2), including    |
| 13 | an online retailer, to include in an appropriate  |
| 14 | and conspicuous place next to the product or      |
| 15 | description of the product, as applicable, a      |
| 16 | label—  |
| 17 | (i) that indicates that such product              |
| 18 | has not been approved for importation, dis-       |
| 19 | tribution, or sale by the Commissioner of         |
| 20 | Food and Drugs and is authorized for sale         |
| 21 | only subject to the provisions of this Act;       |
| 22 | and   |
| 23 | (ii) that may additionally indicate the           |
| 24 | foreign country or countries where such           |
| 25 | product may be lawfully marketed.                 |

| 1  | (4) Termination of Shortage.—The Presi-                     |
|----|---|
| 2  | dent may, upon determining that a shortage no               |
| 3  | longer exists in the United States of infant formula,       |
| 4  | terminate a declaration described in paragraph (1).         |
| 5  | (b) Duty-free Treatment.—Notwithstanding any                |
| 6  | other provision of law, the President may, during any pe-   |
| 7  | riod in which an infant formula shortage is declared in     |
| 8  | accordance with subsection (a)(1), reduce or suspend any    |
| 9  | duties imposed—   |
| 10 | (1) with respect to the importation of covered              |
| 11 | infant formula; or  |
| 12 | (2) with respect to any other article used in the           |
| 13 | production of infant formula that the importer cer-         |
| 14 | tifies is being imported for such production.               |
| 15 | (c) Priority Handling of Entries.—During any                |
| 16 | period in which an infant formula shortage is declared in   |
| 17 | accordance with subsection (a)(1), the Commissioner of      |
| 18 | U.S. Customs and Border Patrol shall give the highest pri-  |
| 19 | ority and take any steps as may be necessary to expedite    |
| 20 | the processing of all entries of covered infant formula and |
| 21 | articles used in the production of infant formula (as de-   |
| 22 | scribed in subsection $(b)(2)$ .                            |
| 23 | (d) DEFINITIONS.—In this Act:                               |
| 24 | (1) Covered infant formula.—                                |

| 1  | (A) In general.—Subject to subpara-                 |
|----|---|
| 2  | graph (B), the term "covered infant formula"        |
| 3  | means any infant formula that is lawfully mar-      |
| 4  | keted in the European Union, Canada, Japan,         |
| 5  | the United Kingdom, or any country the Presi-       |
| 6  | dent determines to have sufficient health and       |
| 7  | safety standards with respect to infant formula.    |
| 8  | (B) Exception.—The President may ex-                |
| 9  | clude from the definition of the term "covered      |
| 10 | infant formula" products whose label—               |
| 11 | (i) is not in English or another lan-               |
| 12 | guage specified by the President;                   |
| 13 | (ii) does not include instructions for              |
| 14 | the use of the product which incorporate            |
| 15 | the imperial system of measurement; or              |
| 16 | (iii) does not identify all potential al-           |
| 17 | lergens that are contained in the product           |
| 18 | and appear on a list of potential allergens         |
| 19 | identified by the President.                        |
| 20 | (2) Infant formula.—In paragraph (1), the           |
| 21 | term "infant formula" has the meaning given to      |
| 22 | such term in section 201 of the Federal Food, Drug, |
| 23 | and Cosmetic Act (21 U.S.C. 201).                   |

- 1 (e) Sunset.—This Act shall cease to be effective on
- 2 the date that is 5 years after the date of enactment of
- 3 this Act.