

117TH CONGRESS
2D SESSION

H. R. 8010

To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to act upon pending submissions for new infant formula, to increase regulatory flexibility in the event of an infant formula shortage, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 9, 2022

Mr. GUTHRIE (for himself, Mr. GRIFFITH, Mr. MCKINLEY, Mr. ARMSTRONG, Mr. JOYCE of Pennsylvania, Mr. BUCSHON, Mr. DUNN, Mr. CARTER of Georgia, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to act upon pending submissions for new infant formula, to increase regulatory flexibility in the event of an infant formula shortage, 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 “More Options for In-
5 fants and Parents Act of 2022”.

1 **SEC. 2. PENDING SUBMISSIONS FOR NEW INFANT FOR-**
2 **MULA.**

3 Not later than 14 days after the date of enactment
4 of this Act, the Secretary of Health and Human Services,
5 acting through the Commissioner of Food and Drugs,
6 shall act upon any pending submissions from domestic
7 manufacturers for new infant formula under section
8 412(c) of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 350a(c)).

10 **SEC. 3. REGULATORY FLEXIBILITY IN THE EVENT OF AN IN-**
11 **FANT FORMULA SHORTAGE.**

12 Section 412 of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 350a) is amended by adding at the end
14 the following:

15 “(j) REGULATORY FLEXIBILITY IN THE EVENT OF
16 A SHORTAGE.—

17 “(1) LIST OF PRODUCTS FOR SUBSTITUTION
18 DURING A SHORTAGE.—The Secretary shall publish
19 and keep up-to-date a list on the internet website of
20 the Food and Drug Administration detailing which
21 infant formula products may be appropriate sub-
22 stitutes for infant formula products—

23 “(A) which the Secretary has determined
24 to be in shortage or at risk of being in short-
25 age; and

1 “(B) that are relied upon by infants and
2 individuals with amino-acid and metabolic con-
3 ditions.

4 “(2) FLEXIBILITIES.—The Secretary—

5 “(A) shall consider whether any infant for-
6 mula products may be substituted for those in
7 shortage; and

8 “(B) may waive any applicable require-
9 ments under section 412 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 350a) re-
11 garding labeling and nutrient content to facili-
12 tate such substitutions.”.

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