


S.L.C.AMENDMENT NO. 2 Calendar No. _____

Purpose: To temporarily allow importation of infant formula
from certain countries for personal use.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to
revise and extend the user-fee programs for prescription
drugs, medical devices, generic drugs, and biosimilar
biological products, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. Mikawski

Viz:

- 1 In section 910, at the end add the following:
- 2 (k) IMPORTATION FOR PERSONAL USE.—
- 3 (1) IN GENERAL.—Notwithstanding any other
- 4 provision of law, during the 90-day period beginning
- 5 on the date of enactment of this Act, a person may,
- 6 without prior notice to the Food and Drug Adminis-
- 7 tration, import up to a 3-month supply of infant for-
- 8 mula for personal use from—
- 9 (A) Canada;
- 10 (B) any country in the European Union; or

1 (C) any other country that is determined
2 by the Secretary of Health and Human Serv-
3 ices, acting through the Commissioner of Food
4 and Drugs, to have safety standards for infant
5 formula similar to such standards applicable
6 under the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 301 et seq.).

8 (2) LIMITATIONS.—Infant formula may be im-
9 ported pursuant to paragraph (1) only if the infant
10 formula—

11 (A) is exclusively for personal use and will
12 not be commercialized or promoted; and

13 (B) does not present an unreasonable risk
14 to human health.

15 (3) REPORTING OF ADVERSE EVENTS.—If a
16 health care provider becomes aware of any adverse
17 event which the health care provider reasonably sus-
18 pects to be associated with infant formula imported
19 pursuant to paragraph (1), the health care provider
20 shall report such adverse event to the Commissioner
21 of Food and Drugs.

22 (4) PUBLIC NOTICE.—The Secretary of Health
23 and Human Services, acting through the Commis-
24 sioner of Food and Drugs, shall post on the public

1 website of the Food and Drug Administration notice
2 that—

3 (A) infant formula imported pursuant to
4 paragraph (1) may not have been manufactured
5 in a facility that has been inspected by the
6 Food and Drug Administration;

7 (B) the labeling of such infant formula
8 may not meet the standards and other require-
9 ments applicable with respect to infant formula
10 under the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 301 et seq.); and

12 (C) the nutritional content of the infant
13 formula may vary from that of infant formula
14 meeting such standards and other require-
15 ments.

16 (5) SENSE OF CONGRESS.—It is the sense of
17 Congress that persons considering the personal im-
18 portation of infant formula should consult with their
19 pediatrician about such importation.

20 (6) DEFINITION.—In this subsection, the term
21 “infant formula” has the meaning given such term
22 in section 201 of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 321).