


S.L.C.AMENDMENT NO. 1 Calendar No. _____

Purpose: To waive certain requirements for importation of specialty infant formula.

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 Mr. Markowski + Dr. Cassidy

Viz:

1 In section 910, at the end add the following:

2 (k) SPECIALTY INFANT FORMULA FOR IMPORTA-
3 TION.—Section 412 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 350a), as amended by subsection
5 (f)(2), is further amended by adding at the end the fol-
6 lowing:

7 “(m) WAIVER OF REQUIREMENTS FOR IMPORTATION
8 OF SPECIALTY INFANT FORMULA.—

9 “(1) IN GENERAL.—The Secretary may, during
10 a shortage of specialty infant formula as determined
11 by the Secretary, waive any requirement under this

1 Act applicable to facilitate the importation of spe-
2 cialty infant formula. Such a waiver may be applica-
3 ble to—

4 “(A) the importation of specialty infant
5 formula from any country that is determined by
6 the Secretary to be implementing and enforcing
7 requirements for infant formula that provide a
8 similar assurance of safety as the regulatory re-
9 quirements of this Act; or

10 “(B) the distribution and sale of such im-
11 ported specialty infant formula.

12 “(2) RULE OF CONSTRUCTION.—Nothing in
13 paragraph (1) shall be construed to limit the author-
14 ity of the Secretary to require a recall of, or other-
15 wise impose restrictions and requirements under this
16 Act with respect to, specialty infant formula that is
17 subject to a waiver under paragraph (1).

18 “(3) DEFINITION OF SPECIALTY INFANT FOR-
19 MULA.—In this section, the term ‘specialty infant
20 formula’ means infant formula, including amino
21 acid-based formula, intended for use by individuals
22 who have inborn errors of metabolism or low birth
23 weight, or who otherwise have unusual medical or di-
24 etary problems.”.