

AMENDMENT NO. 4

Calendar No. _____

Purpose: To facilitate substitutions for infant formulas during shortages.

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 _____

Viz:

1 Strike subsection (d) of section 910 and insert the
2 following:

3 (d) INFANT FORMULA FLEXIBILITIES.—

4 (1) SUBSTITUTION LIST FOR CERTAIN INDIVID-
5 UALS.—The Secretary shall publish a list on the
6 website of the Food and Drug Administration detail-
7 ing which infant formula products may be appro-
8 priate substitutes for infant formula products in
9 shortage that are relied upon by infants and other
10 individuals with amino-acid and metabolic condi-
11 tions.

1 (2) FACILITATING SUBSTITUTIONS.—The Sec-
2 retary—

3 (A) shall consider whether any products
4 may be substituted for infant formulas in short-
5 age; and

6 (B) may waive any applicable requirements
7 under section 412 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 350a) regarding
9 labeling and nutrient content to facilitate such
10 substitutions during such shortage.