

Paul Amdt. #2

S.L.C.


AMENDMENT NO. 2 Calendar No. _____

Purpose: To establish criteria for issuing regulations for food additives.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

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 At the appropriate place, add the following:

2 **SEC. ____ . FOOD ADDITIVES.**

3 Section 409(a) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 348(a)) is amended—

5 (1) in paragraph (2), by striking “; or” and in-
6 serting “;”;

7 (2) in paragraph (3)(B), by striking the period
8 and inserting “; or”; and

9 (3) by inserting after paragraph (3) the fol-
10 lowing:

1 “(4) there is in effect a regulation, approval, or
2 other determination issued by one or more developed
3 countries, including a country in the European
4 Union, prescribing the conditions under which such
5 additive may be safely used, and the additive and its
6 use or intended use are in conformity with such reg-
7 ulation, approval, or other determination, unless the
8 Secretary by regulation determines—

9 “(A) the additive is unsafe in its intended
10 use under the conditions prescribed in such reg-
11 ulation, approval, or other determination; or

12 “(B) the regulation, approval, or other de-
13 termination process in a particular country is
14 not capable of prescribing the conditions under
15 which an additive may be safely used.”.