

S.J.C.

 Amendment #2

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require FDA to coordinate with the applicable manufacturer in the event of a recall of 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. ROMNEY (for
 himself, ~~and~~ Mr. MARSHALL) *and Mr. Cassidy*

Viz:

1 On page 487, between lines 23 and 24, insert the fol-
 2 lowing:

3 (1) IN GENERAL.—

4 (A) COMMUNICATION FOLLOWING INSPEC-
 5 TION.—Upon completing an inspection of an in-
 6 fant formula manufacturing facility impacted
 7 by a recall, the Secretary of Health and Human
 8 Services, acting through the Commissioner of
 9 Food and Drugs, shall provide the manufac-

1 turer involved a list of any actions necessary
2 to—

3 (i) address deficiencies contributing to
4 the potential adulteration or misbranding
5 of product at the facility; and

6 (ii) safely restart production at the fa-
7 cility.

8 (B) RESPONSE TO MANUFACTURER.—Not
9 later than 7 days after receiving a written com-
10 munication from a manufacturer of infant for-
11 mula regarding safely restoring production fol-
12 lowing a recall of such product, the Secretary of
13 Health and Human Services, acting through the
14 Commissioner of Food and Drugs, shall provide
15 a substantive response to such communication,
16 including any necessary next steps.