

Mr. Romney
Amendment #1

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require congressional notification 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)

Viz:

- 1 On page 482, between lines 6 and 7, insert the fol-
- 2 lowing:
- 3 (1) CONGRESSIONAL NOTIFICATION OF RE-
- 4 CALL.—
- 5 (A) IN GENERAL.—Not later than 24
- 6 hours after the initiation of a recall of infant
- 7 formula as described in section 412(e) of the
- 8 Federal Food, Drug, and Cosmetic Act (21
- 9 U.S.C. 350e(e)), the Secretary of Health and
- 10 Human Services, acting through the Commis-

1 sioner of Food and Drugs, shall submit to Con-
2 gress a notification of such recall.

3 (B) CONTENTS.—A notification under sub-
4 paragraph (A) shall include the following:

5 (i) If the recall is required by the
6 Food and Drug Administration, a sum-
7 mary of the determination of a case of
8 adulterated or misbranded infant formula
9 that presents a risk to human health.

10 (ii) If the recall is voluntarily initiated
11 by the manufacturer, a summary of the in-
12 formation provided to the Food and Drug
13 Administration by the manufacturer re-
14 garding infant formula that has left the
15 control of the manufacturer that may be
16 adulterated or misbranded.

17 (iii) Specification of when the Food
18 and Drug Administration was first made
19 aware of the instance or circumstances
20 surrounding the recall.

21 (iv) An initial estimate of the disrup-
22 tion in domestic production that may re-
23 sult from the recall.