



Mitt Romney.
Amendment #4

AMENDMENT NO. _____

Calendar No. _____

Purpose: To improve the bill with respect to dietary supplement requirements.

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

Viz:

1 On page 143, strike lines 10 and 11.

2 On page 146, strike lines 11 through 20 and insert
3 the following:

4 “(5) ADDITIONAL INFORMATION.—The respon-
5 sible person shall provide, upon written request from
6 the Secretary, including justification for the request,
7 within 10 calendar days of such request, as applica-
8 ble in accordance with such request—

9 “(A) the full business name and physical
10 and mailing address from which the responsible

1 person receives a dietary ingredient or combina-
2 tion of dietary ingredients that the responsible
3 person uses in the manufacture of the dietary
4 supplement or, if applicable, from which the re-
5 sponsible person receives the dietary supple-
6 ment; or

7 “(B) the amount per serving of dietary in-
8 gredients within a proprietary blend.”.

9 On page 148, on lines 3 and 4, strike “subparagraph
10 (D) or (E)(iv) of subsection (b)(1)” and insert “subsection
11 (b)(1)(D) or (b)(5)”.

12 On page 150, strike lines 5 through 8.