

BLUMENTHAL

AMENDMENT 1

KER12290

Richard Blumenthal
S.L.C.

AMENDMENT NO. _____ Calendar No. _____

Purpose: To provide civil monetary penalties for the failure to provide the Secretary with a required notification regarding the discontinuance or interruption of the manufacture of certain drugs.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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. BLUMENTHAL

Viz:

1 On page 273, between lines 14 and 15, insert the following:
2

3 (b) CIVIL PENALTIES FOR FAILURE TO SUBMIT NOTIFICATION.—Section 303 (21 U.S.C. 333) is amended—
4

5 (1) in subsection (f)(5), by inserting “or subsection (h)” after “or (9)” each place such term appears; and
6
7

8 (2) by adding at the end the following:

1 “(h)(1) Any manufacturer that knowingly fails to
2 submit a notification in violation of section 506C(a) shall
3 be subject to a civil money penalty not to exceed \$10,000
4 for each day on which the violation continues, and not to
5 exceed \$1,800,000 for all such violations adjudicated in
6 a single proceeding.

7 “(2) Not later than 180 days after the date of enact-
8 ment of the Food and Drug Administration Safety and
9 Innovation Act, the Secretary shall, subject to paragraph
10 (1), promulgate final regulations establishing a schedule
11 of civil monetary penalties for violations of section
12 506C(a).”.