

111TH CONGRESS
1ST SESSION

S. 1477

To establish a user fee for follow-up reinspections under the Federal Food,
Drug, and Cosmetic Act.

IN THE SENATE OF THE UNITED STATES

JULY 21, 2009

Mr. FEINGOLD introduced the following bill; which was read twice and
referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a user fee for follow-up reinspections under
the Federal Food, Drug, and Cosmetic Act.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. ESTABLISHMENT OF USER FEE FOR FOLLOW-**
4 **UP REINSPECTIONS.**

5 (a) IN GENERAL.—The Secretary shall assess and
6 collect a user fee from each facility registered under sec-
7 tion 415 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 350d), establishment registered under section
9 510 of such Act (21 U.S.C. 360), and facility described
10 in section 351(a)(1)(C) of the Public Health Service Act

1 (42 U.S.C. 262(1)(C)) for which a follow-up reinspection
2 is required to ensure correction of a violation found by
3 the Secretary during initial inspection of the facility or
4 establishment of a good manufacturing practices require-
5 ment under the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 301 et seq.).

7 (b) PAYMENT OF FEE.—The user fee required under
8 subsection (a) shall be due from a facility or establishment
9 described in such subsection upon the reinspection of such
10 facility or establishment, as described in subsection (a).

11 (c) AMOUNT OF USER FEE.—The amount of the user
12 fee required under subsection (a) shall be established by
13 the Secretary.

14 (d) DEFINITIONS.—For purposes of this section—

15 (1) the terms “animal drug”, “device”, “drug”,
16 and “food” have the meanings given those terms in
17 section 201 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 321);

19 (2) the term “biological product” has the mean-
20 ing given the term in section 351 of the Public
21 Health Service Act (42 U.S.C. 262); and

22 (3) the term “Secretary” means the Secretary
23 of Health and Human Services.

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