110TH CONGRESS 1ST SESSION

S. 2192

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 18, 2007

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 manufacturer of a food, drug,
- 7 device, biological product, or animal drug for which a fol-
- 8 low-up reinspection is required to ensure correction of a
- 9 violation, found by the Secretary during initial inspection
- 10 of the manufacturer, of a Good Manufacturing Practices

- 1 requirement under the Federal Food, Drug, and Cosmetic
- 2 Act (21 U.S.C. 301 et seq.).
- 3 (b) Payment of Fee.—The user fee required by
- 4 subsection (a) shall be due from a manufacturer upon the
- 5 reinspection of the manufacturer as described in sub-
- 6 section (a).
- 7 (c) Amount of User Fee.—The amount of the user
- 8 fee required under subsection (a) shall be established by
- 9 the Secretary.
- 10 (d) Definitions.—For purposes of this section—
- 11 (1) the terms "animal drug", "device", "drug",
- and "food" have the meanings given those terms in
- section 201 of the Federal Food, Drug, and Cos-
- 14 metic Act (21 U.S.C. 321);
- 15 (2) the term "biological product" has the mean-
- ing given the term in section 351 of the Public
- Health Service Act (42 U.S.C. 262); and
- 18 (3) the term "Secretary" means the Secretary
- of Health and Human Services.

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