

109TH CONGRESS
2D SESSION

S. 3981

To amend the Federal Food, Drug, and Cosmetic Act to establish requirements for certain petitions submitted to the Food and Drug Administration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2006

Mr. KOHL (for himself and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish requirements for certain petitions submitted to the Food and Drug Administration, and for other purposes.

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. SHORT TITLE.**

4 This Act may be cited as the “Citizen Petition Fair-
5 ness and Accuracy Act of 2006”.

1 **SEC. 2. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**
2 **AGENCY ACTION.**

3 Section 505(j)(5) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355(j)(5)) is amended by adding
5 at the end the following:

6 “(G)(i) Notwithstanding any other provision of law,
7 any petition submitted under section 10.30 or section
8 10.35 of title 21, Code of Federal Regulations (or any suc-
9 cessor regulation), shall include a statement that to the
10 petitioner’s best knowledge and belief, the petition—

11 “(I) includes all information and views on which
12 the petitioner relies, including all representative data
13 and information known to the petitioner that is fa-
14 vorable or unfavorable to the petition;

15 “(II) is well grounded in fact and is warranted
16 by law;

17 “(III) is not submitted for an improper pur-
18 pose, such as to harass or cause unnecessary delay
19 (including unnecessary delay of competition or agen-
20 cy action); and

21 “(IV) does not contain a materially false, mis-
22 leading, or fraudulent statement.

23 “(ii) The Secretary shall investigate, on receipt of a
24 complaint, a request under clause (vi), or on its own initia-
25 tive, any petition submitted under such section 10.30 or
26 section 10.35 (or any successor regulation), that—

1 “(I) does not comply with the requirements of
2 clause (i);

3 “(II) may have been submitted for an improper
4 purpose as described in clause (i)(III); or

5 “(III) may contain a materially false, mis-
6 leading, or fraudulent statement as described in
7 clause (i)(IV).

8 “(iii) If the Secretary finds that the petitioner has
9 knowingly and willingly submitted the petition for an im-
10 proper purpose as described in clause (i)(III), or which
11 contains a materially false, misleading, or fraudulent
12 statement as described in clause (i)(IV), the Secretary
13 may—

14 “(I) impose a civil penalty of not more than
15 \$1,000,000, plus attorneys fees and costs of review-
16 ing the petition and any related proceedings;

17 “(II) suspend the authority of the petitioner to
18 submit a petition under such section 10.30 or sec-
19 tion 10.35 (or any successor regulation), for a period
20 of not more than 10 years;

21 “(III) revoke permanently the authority of the
22 petitioner to submit a petition under such section
23 10.30 or section 10.35 (or any successor regulation);
24 or

1 “(IV) dismiss the petition at issue in its en-
2 tirety.

3 “(iv) If the Secretary takes an enforcement action de-
4 scribed in subclause (I), (II), (III), or (IV) of clause (iii)
5 with respect to a petition, the Secretary shall refer that
6 petition to the Federal Trade Commission for further ac-
7 tion as the Federal Trade Commission finds appropriate.

8 “(v) In determining whether to take an enforcement
9 action described in subclause (I), (II), (III), or (IV) of
10 clause (iii) with respect to a petition, and in determining
11 the amount of any civil penalty or the length of any sus-
12 pension imposed under that clause, the Secretary shall
13 consider the specific circumstances of the situation, such
14 as the gravity and seriousness of the violation involved,
15 the amount of resources expended in reviewing the petition
16 at issue, the effect on marketing of competing drugs of
17 the pendency of the improperly submitted petition, includ-
18 ing whether the timing of the submission of the petition
19 appears to have been calculated to cause delay in the mar-
20 keting of any drug awaiting approval, and whether the pe-
21 titioner has a history of submitting petitions in violation
22 of this subparagraph.

23 “(vi)(I) Any person aggrieved by a petition filed
24 under such section 10.30 or section 10.35 (or any suc-
25 cessor regulation), including a person filing an application

1 under subsection (b)(2) or (j) of this section to which such
2 petition relates, may request that the Secretary initiate
3 an investigation described under clause (ii) for an enforce-
4 ment action described under clause (iii).

5 “(II) The aggrieved person shall specify the basis for
6 its belief that the petition at issue is false, misleading,
7 fraudulent, or submitted for an improper purpose. The ag-
8 grieved person shall certify that the request is submitted
9 in good faith, is well grounded in fact, and not submitted
10 for any improper purpose. Any aggrieved person who
11 knowingly and intentionally violates the preceding sen-
12 tence shall be subject to the civil penalty described under
13 clause (iii)(I).

14 “(vii) The Secretary shall take final agency action
15 with respect to a petition filed under such section 10.30
16 or section 10.35 (or any successor regulation) within 6
17 months of receipt of such petition. The Secretary shall not
18 extend such 6-month review period, even with consent of
19 the petitioner, for any reason, including based upon the
20 submission of comments relating to a petition or supple-
21 mental information supplied by the petitioner. If the Sec-
22 retary has not taken final agency action on a petition by
23 the date that is 6 months after the date of receipt of the
24 petition, such petition shall be deemed to have been denied
25 on such date.

1 “(viii) The Secretary may promulgate regulations to
2 carry out this subparagraph, including to determine
3 whether petitions filed under such section 10.30 or section
4 10.35 (or any successor regulation) merit enforcement ac-
5 tion by the Secretary under this subparagraph.”.

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