

106TH CONGRESS
1ST SESSION

H. R. 3240

To amend the Federal Food, Drug, and Cosmetic Act to clarify certain responsibilities of the Food and Drug Administration with respect to the importation of drugs into the United States.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 5, 1999

Mr. GUTKNECHT (for himself, Mr. FOLEY, Mr. COBURN, and Mr. PAUL) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify certain responsibilities of the Food and Drug Administration with respect to the importation of drugs into the United States.

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 “Drug Import Fairness
5 Act of 1999”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Pharmacists, patients, and other persons
2 sometimes have reason to import into the United
3 States drugs that have been approved by the Food
4 and Drug Administration (“FDA”).

5 (2) There have been circumstances in which—

6 (A) a person seeking to import such a drug
7 has received a notice from FDA that importing
8 the drug violates or may violate the Federal
9 Food, Drug, and Cosmetic Act; and

10 (B) the notice failed to inform the person
11 of the reasons underlying the decision to send
12 the notice.

13 (3) FDA should not send a warning notice re-
14 garding the importation of a drug without providing
15 to the person involved a statement of the underlying
16 reasons for the notice.

17 **SEC. 3. CLARIFICATION OF CERTAIN RESPONSIBILITIES OF**
18 **FOOD AND DRUG ADMINISTRATION WITH RE-**
19 **SPECT TO IMPORTATION OF DRUGS INTO**
20 **UNITED STATES.**

21 Section 801 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 381) is amended by adding at the end the
23 following subsection:

24 “(g)(1) With respect to a drug being imported or of-
25 fered for import into the United States, the Secretary may

1 not send a warning notice to a person (including a phar-
2 macist or wholesale importer) unless the following condi-
3 tions are met:

4 “(A) The notice specifies, as applicable to the
5 importation of the drug, that the Secretary has
6 made a determination that—

7 “(i) importation is in violation of section
8 801(a) because the drug is or appears to be
9 adulterated, misbranded, or in violation of sec-
10 tion 505;

11 “(ii) importation is in violation of section
12 801(a) because the drug is forbidden or re-
13 stricted in sale in the country in which it was
14 produced or from which it was exported;

15 “(iii) importation by any person other than
16 the manufacturer of the drug is in violation of
17 section 801(d); or

18 “(iv) importation is otherwise in violation
19 of Federal law.

20 “(B) The notice does not specify any provision
21 described in subparagraph (A) that is not applicable
22 to the importation of the drug.

23 “(C) The notice states the reasons underlying
24 such determination by the Secretary, including a
25 brief application to the principal facts involved of the

1 provision of law described in subparagraph (A) that
2 is the basis of the determination by the Secretary.

3 “(2) The term ‘warning notice’, with respect to the
4 importation of a drug, means a communication from the
5 Secretary (written or otherwise) notifying a person, or
6 clearly suggesting to the person, that importing the drug
7 is, or appears to be, a violation of this Act.”.

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