

106TH CONGRESS  
1ST SESSION

# S. 1191

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by the Food and Drug Administration, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JUNE 9, 1999

Mr. DORGAN (for himself, Mr. WELLSTONE, Ms. SNOWE, and Mr. JOHNSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by 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 “International Prescrip-  
5 tion Drug Parity Act”.

1 **SEC. 2. FACILITATION OF IMPORTATION OF DRUGS AP-**  
2 **PROVED BY FOOD AND DRUG ADMINISTRA-**  
3 **TION.**

4 (a) IN GENERAL.—Section 801(d) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is  
6 amended—

7 (1) by redesignating paragraphs (3) and (4) as  
8 paragraphs (4) and (5), respectively; and

9 (2) by striking “(d)(1)” and all that follows  
10 through the end of paragraph (2) and inserting the  
11 following:

12 “(d)(1) If a covered drug is domestically approved  
13 and is manufactured in a State and exported, or such drug  
14 is domestically approved and is for commercial distribu-  
15 tion and is manufactured in a foreign establishment reg-  
16 istered under section 510(i), the manufacturer shall, as  
17 a condition of maintaining the domestic approval of the  
18 drug, comply with the following:

19 “(A) Without regard to whether a shipment of  
20 such drug is intended for importation into the  
21 United States, for each shipment of such drug, the  
22 manufacturer shall—

23 “(i) maintain a record that identifies the  
24 shipment of such drug;

25 “(ii) maintain a record that details how  
26 such shipment of such drug complies with cur-

1           rent good manufacturing practice and section  
2           501; and

3           “(iii) provide the labeling required for any  
4           such drug pursuant to section 502 and pursu-  
5           ant to the application for domestic approval.

6           “(B) Upon the request of a person who intends  
7           to import into the United States drugs from such  
8           shipment (and who meets applicable legal require-  
9           ments to be an importer of covered drugs), the man-  
10          ufacturer shall provide to the person a copy of each  
11          of the records maintained under subparagraph (A)  
12          with respect to the shipment.

13          “(2) For the purpose of facilitating the importation  
14          into the United States of covered drugs, the Secretary  
15          shall promulgate by regulation the following:

16               “(A) Criteria regarding the records described in  
17               paragraph (1) and use of the records to demonstrate  
18               domestic approval of the drugs and compliance with  
19               sections 501 and 502.

20               “(B) Criteria regarding labeling requirements  
21               for the drugs that the Secretary determines to be  
22               appropriate.

23               “(C) Criteria regarding the amount of charges  
24               that may be imposed by manufacturers of the drugs

1 for maintaining and providing the records specified  
2 in subparagraph (A).

3 “(3) In this subsection:

4 “(A) The term ‘covered drug’ means a drug  
5 that is described in section 503(b)(1) or is composed  
6 wholly or partly of insulin.

7 “(B) The term ‘domestically approved’, with re-  
8 spect to a drug, means a drug for which an applica-  
9 tion is approved under section 505, or as applicable,  
10 under section 351 of the Public Health Service Act  
11 (42 U.S.C. 262). The term ‘domestic approval’, with  
12 respect to a drug, means approval of an application  
13 for a drug under such a section.”.

14 (b) CONFORMING AMENDMENTS.—

15 (1) Section 801(d) of the Federal Food, Drug,  
16 and Cosmetic Act (21 U.S.C. 381(d)) is amended in  
17 paragraph (5) (as redesignated by subsection (a)(1))  
18 by striking “paragraph (3)” each place such term  
19 appears and inserting “paragraph (4)”.

20 (2) Section 301(w) of the Federal Food, Drug,  
21 and Cosmetic Act (21 U.S.C. 331(w)) is amended—

22 (A) by striking “801(d)(3)” each place it  
23 appears and inserting “801(d)(4)”;

24 (B) by striking “801(d)(3)(A)” and insert-  
25 ing “801(d)(4)(A)”;

1 (C) by striking “801(d)(3)(B)” and insert-  
2 ing “801(d)(4)(B)”.

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