

116TH CONGRESS
1ST SESSION

H. R. 478

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 10, 2019

Ms. PINGREE (for herself and Ms. HERRERA BEUTLER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada.

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 “Safe and Affordable
5 Drugs from Canada Act of 2019”.

6 **SEC. 2. SAFE AND AFFORDABLE DRUGS FROM CANADA.**

7 Chapter VIII of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 381 et seq.) is amended by adding
9 at the end the following:

1 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**
2 **TION DRUGS FROM CANADA.**

3 “(a) IN GENERAL.—Notwithstanding any other pro-
4 vision of this Act, not later than 180 days after the date
5 of enactment of this section, the Secretary shall promul-
6 gate regulations permitting individuals to safely import
7 into the United States a prescription drug described in
8 subsection (b).

9 “(b) PRESCRIPTION DRUG.—A prescription drug de-
10 scribed in this subsection—

11 “(1) is a prescription drug that—

12 “(A) is purchased from an approved Cana-
13 dian pharmacy;

14 “(B) is dispensed by a pharmacist licensed
15 to practice pharmacy and dispense prescription
16 drugs in Canada;

17 “(C) is purchased for personal use by the
18 individual, not for resale, in quantities that do
19 not exceed a 90-day supply;

20 “(D) is filled using a valid prescription
21 issued by a physician licensed to practice in a
22 State in the United States; and

23 “(E) has the same active ingredient or in-
24 gredients, route of administration, dosage form,
25 and strength as a prescription drug approved
26 by the Secretary under chapter V; and

1 “(2) does not include—

2 “(A) a controlled substance (as defined in
3 section 102 of the Controlled Substances Act
4 (21 U.S.C. 802));

5 “(B) a biological product (as defined in
6 section 351 of the Public Health Service Act
7 (42 U.S.C. 262));

8 “(C) an infused drug (including a peri-
9 toneal dialysis solution);

10 “(D) an intravenously injected drug;

11 “(E) a drug that is inhaled during surgery;

12 “(F) a parenteral drug;

13 “(G) a drug manufactured through one or
14 more biotechnology processes, including—

15 “(i) a therapeutic DNA plasmid prod-
16 uct;

17 “(ii) a therapeutic synthetic peptide
18 product of not more than 40 amino acids;

19 “(iii) a monoclonal antibody product
20 for in vivo use; and

21 “(iv) a therapeutic recombinant DNA-
22 derived product;

23 “(H) a drug required to be refrigerated at
24 any time during manufacturing, packing, proc-
25 essing, or holding; or

1 “(I) a photoreactive drug.

2 “(c) APPROVED CANADIAN PHARMACY.—

3 “(1) IN GENERAL.—In this section, an ap-
4 proved Canadian pharmacy is a pharmacy that—

5 “(A) is located in Canada; and

6 “(B) that the Secretary certifies—

7 “(i) is licensed to operate and dis-
8 pense prescription drugs to individuals in
9 Canada; and

10 “(ii) meets the criteria under para-
11 graph (3).

12 “(2) PUBLICATION OF APPROVED CANADIAN
13 PHARMACIES.—The Secretary shall publish on the
14 internet website of the Food and Drug Administra-
15 tion a list of approved Canadian pharmacies, includ-
16 ing the internet website address of each such ap-
17 proved Canadian pharmacy, from which individuals
18 may purchase prescription drugs in accordance with
19 subsection (a).

20 “(3) ADDITIONAL CRITERIA.—To be an ap-
21 proved Canadian pharmacy, the Secretary shall cer-
22 tify that the pharmacy—

23 “(A) has been in existence for a period of
24 at least 5 years preceding the date of such cer-
25 tification and has a purpose other than to par-

1 participate in the program established under this
2 section;

3 “(B) operates in accordance with phar-
4 macy standards set forth by the provincial
5 pharmacy rules and regulations enacted in Can-
6 ada;

7 “(C) has processes established by the phar-
8 macy, or participates in another established
9 process, to certify that the physical premises
10 and data reporting procedures and licenses are
11 in compliance with all applicable laws and regu-
12 lations, and has implemented policies designed
13 to monitor ongoing compliance with such laws
14 and regulations;

15 “(D) conducts or commits to participate in
16 ongoing and comprehensive quality assurance
17 programs and implements such quality assur-
18 ance measures, including blind testing, to en-
19 sure the veracity and reliability of the findings
20 of the quality assurance program;

21 “(E) agrees that laboratories approved by
22 the Secretary shall be used to conduct product
23 testing to determine the safety and efficacy of
24 sample pharmaceutical products;

1 “(F) has established, or will establish or
2 participate in, a process for resolving grievances
3 and will be held accountable for violations of es-
4 tablished guidelines and rules;

5 “(G) does not resell products from online
6 pharmacies located outside Canada to cus-
7 tomers in the United States; and

8 “(H) meets any other criteria established
9 by the Secretary.”.

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