To provide for the importation of drugs into the United States from Canada and Mexico, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2003

Mr. CROWLEY (for himself, Mr. SANDERS, Mr. CASE, Mr. HINCHNEY, and Mrs. MALONEY) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To provide for the importation of drugs into the United States from Canada and Mexico, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “New Aid for Trustworthy, Affordable Drugs Act (NAFTA Drugs Act)”. 
SEC. 2. HARMONIZATION OF DRUG LAWS REGARDING IMPORTATION INTO NAFTA COUNTRIES FROM OTHER NAFTA COUNTRIES.

Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended by adding at the end the following subsection:

“(d)(1) Consistent with the North American Free Trade Agreement approved by the Congress under section 101(a) of Public Law 103–182 (referred to in this subsection as ‘NAFTA’), the United States Trade Representative shall seek to enter into agreements with other NAFTA countries to harmonize regulatory requirements for drugs such that drugs approved for commercial distribution in any NAFTA country may be imported or exported from any NAFTA country into any NAFTA country.

“(2) The United States Trade Representative shall carry out this subsection in consultation with the Secretary and the Commissioner of Food and Drugs.

“(3) The United States Trade Representative may enter into a harmonization agreement under paragraph (1) only if such Representative determines as follows:

“(A) That the proposed agreement provides for regulatory standards for drugs that are consistent with the requirements of this Act.
“(B) That the proposed agreement provides for—

“(i) the display of a seal on the labeling of the drugs involved, whose purpose is to indicate that the drugs meet the standards of the harmonization agreement and may be imported as provided in paragraph (1);

“(ii) uniform standards applicable to the display of such a seal in any NAFTA country; and

“(iii) approval of such a seal by the appropriate health authority in any NAFTA country before the display of the seal in that country, for the purpose of ensuring that the seal complies with the uniform standards described in clause (ii).

“(C) That the proposed agreement provides that a drug may not be imported into a NAFTA country from another NAFTA country unless the labeling of the drug bears a seal described in subparagraph (B).

“(D) That the proposed agreement provides for a system of unique tracking numbers to indicate—
“(i) the manufacturer of the drug involved, the NAFTA country of origin, and the wholesale distributors of the drug; and

“(ii) in the case of a prescription drug, the pharmacy that dispenses the drug.

“(E) That the proposed agreement provides for—

“(i) the placement of a seal described in subparagraph (B) on the labeling of a drug only by a pharmacy registered in accordance with this subparagraph;

“(ii) registration of pharmacies in each NAFTA country by the appropriate health authority in each such country for the purpose of authorizing such pharmacies to place a seal described in subparagraph (B) on the labeling of drugs; and

“(iii) uniform standards applicable to such registration.

“(F) That the proposed agreement—

“(i) requires drug manufacturers to reimburse the Secretary of Health and Human Services for benefits derived by such manufacturers from research performed by the National Institutes of Health; and
“(ii) authorizes use of such reimbursement to pay the expenses incurred by the Food and Drug Administration in approving seals under subparagraph (B) and registering pharmacies under subparagraph (E).

“(G) That the proposed agreement prohibits any discrimination by any person in the manufacture, distribution, or sale of any drug that bears a seal described in subparagraph (B), on the basis of a prospective customer’s citizenship or residency in a NAFTA country, or on the basis of a request for shipment of the drug to any NAFTA country.

“(4) The authority of the United States Trade Representative to enter a harmonization agreement under paragraph (1) terminates one year after the date of the enactment of New Aid for Trustworthy, Affordable Drugs Act (NAFTA Drugs Act).

“(5) For purposes of this subsection, the term ‘NAFTA country’ means each of the United States, Canada, and the United Mexican States—

“(A) for such time as NAFTA is in force with respect to such country; and
“(B) in the case of each of Canada and the United Mexican States, for such time as the United States applies NAFTA to such country.”