I

107TH CONGRESS
2D SESSION

H. R. 5186

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 23, 2002

Mr. KINGSTON (for himself, Mr. GUTKNECHT, Mr. THUNE, Mr. STUMP, Mrs. JO ANN DAVIS of Virginia, Mr. KOLBE, Mr. DAN MILLER of Florida, Mrs. NORTHUP, Mrs. EMERSON, Mr. CROWLEY, Mr. BARTLETT of Maryland, Mr. BALDACCI, Mr. PAUL, Mr. DUNCAN, Mr. SHAYS, Mr. TANCREDO, Mr. JONES of North Carolina, Mr. WAMP, Mr. POMEROY, and Mr. HOEKSTRA) 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 with respect to the importation of prescription drugs.

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 ''Drug Importation Act of 2002''.

SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS.

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

''(p) The Secretary may not prevent an individual who is not in the business of importing prescription drugs within the meaning of subsection (g) from importing a prescription drug that (1) appears to be approved by the Secretary; (2) does not appear to be a narcotic drug; and (3) appears to be manufactured, prepared, propagated, compounded, or processed in an establishment registered pursuant to section 510.''.

(b) PHARMACISTS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a) of this section, is amended by adding at the end the following subsection:

''(q)(1) The Secretary shall by regulation carry out a program under which covered pharmacists are authorized to import into the United States prescription drugs that meet the standards described in subsection (a) for the importation of drugs (including with respect to denying entry to drugs that are adulterated or misbranded, or are not approved under section 505, or are not manufactured, prepared, propagated, compounded, or processed in establishments registered under section 510), subject to

paragraphs (3) and (4) and subject to compliance with such procedures as the Secretary determines to be appropriate to facilitate determinations by the Secretary of whether the prescription drugs meet such standards.

''(2) Procedures under paragraph (1) may include requiring, as a condition of importing prescription drugs under such paragraph, that covered pharmacists register with the Secretary, and that the Secretary approve the chain of distribution of such drugs outside the United States.

''(3) A prescription drug may not be imported under paragraph (1) if such drug is a controlled substance in schedule I, II, or III under section 202(c) of the Controlled Substances Act or a biological product as defined in section 351 of the Public Health Service Act.

''(4) Regulations under paragraph (1) may authorize the use of alternative labeling for prescription drugs imported under such paragraph, which labeling for the drug involved meets the requirements of section 502 but is modified to the extent necessary to comply with applicable law regarding trademarks and copyrights. A prescription drug imported under paragraph (1) whose labeling is in accordance with such regulations may not be considered misbranded under section 502.

''(5) For purposes of this subsection:

''(A) The term 'covered pharmacist' means, with respect to the prescription drug involved, a pharmacist who lacks authority under subsection (d)(1) to import the drug into the United States.

''(B) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs. Such term includes pharmacies that are so licensed.

''(C) The term 'prescription drug' means a drug subject to section 503(b).''.

(2) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule for carrying out the program under section 801(q) of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1) of this subsection) and shall begin operation of such program.

○