



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 4 2004

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The Honorable Charlie Ryan  
Mayor, City of Springfield  
36 Court Street  
Springfield, MA 01103

Re: Docket No. 2003P-0479/CP1

Dear Mayor Ryan:

This responds to the citizen petition (Petition) submitted to the Food and Drug Administration (FDA) on October 15, 2003, by your predecessor, Mayor Michael Albano, on behalf of the City of Springfield, Massachusetts. The petition requests that FDA take the following actions:

- Use its enforcement discretion to allow importation of Canadian versions of drugs that are approved in the United States
- Provide a complete copy of all documents between FDA and Health Canada's Therapeutic Products Directorate (Canadian Directorate) regarding FDA's review of the Canadian Directorate to assess the safety, efficacy, and quality of prescription medicines being authorized for sale in Canada
- Verify that all drugs regulated by the Canadian Directorate pose no additional risk to the public's health and safety
- Immediately promulgate regulations as required by the Medicine Equity and Drug Safety Act of 2000 (MEDSA), 21 U.S.C. 384(a)
- Amend, suspend, revoke, or waive the Agency's interpretations of certain statutes (i.e., sections 301(a), (d), and (t); 503(b)(1) and (2); 505; and 801(d)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331(a), (d), and (t); 353(b)(1) and (2); 355; and 381(d)(1)) and regulations (21 CFR 201.100(c)(2) and 314.50), which have resulted or may result in administrative or legal action being taken
- Dismiss, suspend, or revoke all current legal and administrative actions that inhibit implementation of MEDSA

For the reasons stated below, the petition is denied. Regarding the request for copies of documents between FDA and the Canadian Directorate, if you wish to pursue the request,

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FDA's Division of Federal-State Relations in accordance with the Freedom of Information Act (FOIA), as discussed below.

## **I. BACKGROUND**

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. In examining imported drugs sent through the mail, FDA has identified so-called "foreign versions" of FDA-approved drugs, improperly labeled drugs, drugs that failed to meet special storage conditions, drugs requiring close physician monitoring, and drugs containing addictive controlled substances. Such findings show the serious risks posed by the illegal importation of prescription drugs. The Agency cannot provide adequate assurance that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA, or that they are safe and effective for their intended uses.

These concerns are reflected in the import provisions of the Act, which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

The Act provides the legal framework applicable to imports of prescription drugs. Virtually all drugs imported to the United States from Canada violate the Act because they are unapproved (section 505 of the Act), labeled incorrectly (sections 502 (21 U.S.C. 352) and 503 of the Act), or dispensed without a valid prescription (section 503(b)(1) of the Act). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the Act is prohibited under section 301(a) and/or (d) of the Act.

FDA drug approvals are manufacturer- and product-specific and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (§ 314.50). Frequently, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets may not meet all of the specific requirements of the U.S. approval, and thus it is considered to be unapproved (section 505 of the Act).

Furthermore, if a prescription drug is also originally manufactured in this country and exported, only the U.S. manufacturer may import the drug back into the United States (section 801(d)(1) of the Act). This is true even if that drug complies with the Act in all other respects. Importing a drug into the United States in violation of section 801(d)(1) is prohibited under section 301(t) of the Act.

Thus, to comply with the Act when shipping prescription drugs to consumers in the United States, businesses and individuals must ensure, among other things, that the drugs sold (1) are FDA-approved; (2) if manufactured in the United States, are imported back into the United States only by the manufacturer; and (3) comply with an applicable FDA approval in all respects. The businesses and individuals must also ensure that each drug meets all U.S. labeling requirements (section 502 of the Act). In addition, the drug must be dispensed by a pharmacist pursuant to a valid prescription (section 503(b)(1) of the Act).

Practically speaking, it is extremely unlikely that a foreign pharmacy could ensure that all of the applicable legal requirements for importation are met. Consequently, almost every time an individual or business ships a prescription drug from Canada or brings that drug into the United States for overnight shipment to a U.S. consumer, the individual or business shipping the drug violates the Act. Moreover, individuals and businesses, and their responsible personnel that *cause* those shipments also violate the Act (section 301 of the Act).

Consistent with this analysis, on November 6, 2003, Federal District Court Judge Claire V. Eagan issued a preliminary injunction against Rx Depot, Inc. to prevent it from causing the importation of unapproved and misbranded drugs into the United States from Canada. See *United States v. Rx Depot, Inc. and Rx of Canada LLC*, 2003 WL 22519473 (N.D. Okla.)

Rx Depot is a domestic "storefront pharmacy" that was engaged in the business of helping individuals procure prescription medications from pharmacies in Canada. Rx Depot would accept a prescription from a U.S. customer and then transmit that prescription and the customer's credit card number to a cooperating pharmacy in Canada. The Canadian pharmacy would then fill the prescription, bill the customer's credit card, and mail the prescription drugs directly to the U.S. citizen. Rx Depot typically received a 10-12 percent commission for each sale it facilitated.

Judge Eagan held that, although Rx Depot never took possession of the imported drugs, its facilitation of the transactions caused the importation of unapproved new drugs into the United States in violation of section 505 of the Act and also caused the importation of U.S.-manufactured drugs into the United States by someone other than their original manufacturer in violation of section 801(d)(1) of the Act. The Court explained that "unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration." *Id.* at 4. The Court also observed that, "[b]ecause the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States." *Id.*

## II. DISCUSSION

### A. Enforcement Discretion

The petition requests that FDA exercise its enforcement discretion to allow importation of Canadian versions of drugs that are approved in the United States (Petition at 1). According to the petition, FDA has taken administrative and legal action to “intimidate, coerce and threaten” companies and individuals who seek to help U.S. citizens obtain drugs from Canada (id. at 2). The petition also asks that FDA amend, suspend, revoke, or waive the Agency’s interpretations of the following statutes and regulations that have resulted or may result in any administrative or legal action being taken: sections 301(a), (d), and (t); 503(b)(1) and (2); 505; and 801(d)(1) of the Act and §§ 201.100(c)(2) and 314.50. For the following reasons, FDA denies these requests.

FDA has issued a Personal Importation Policy<sup>1</sup> that sets forth the Agency’s general enforcement priorities with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA may allow consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient’s treatment of a serious condition for which effective treatment is not available domestically. FDA has generally followed this approach for such products that do not present an unreasonable risk and for which there is no known commercialization and promotion to U.S. residents.

Although the Personal Importation Policy describes the Agency’s enforcement priorities, it does not change the law. The policy does not legalize importation of unapproved foreign versions of FDA-approved drugs that have been manufactured, shipped, and held outside of this country’s comprehensive system for assuring a drug’s safety from the point of manufacture, through distribution, and on to the pharmacy and patients. Nor does the policy legalize the importation of a U.S.-made drug by anyone other than the drug’s original manufacturer.

Rather, the Personal Importation Policy represents the agency’s current thinking on how to set its enforcement priorities in a way that most effectively implements the intent of Congress. The personal importation that our policy discusses is very different from importation by or from businesses that sell foreign versions of FDA-approved drugs to U.S. residents. To date, FDA has focused its limited enforcement resources on potentially dangerous drugs and those commercializing the practice of importing illegal drugs without regulatory oversight. Nevertheless, the petition requests that FDA ignore the will of Congress and sanction the complete and systematic violation of the statutory provisions that FDA was created to enforce. FDA cannot simply substitute its (or your) judgment over the judgment of Congress as expressed in the Act.

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<sup>1</sup> FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

As section I of this response explains, the drug importation provisions in the Act create a relatively closed system to help us maintain the integrity of the domestic drug supply. The restriction that new drugs cannot be sold in the United States until pre-approved by FDA is a cornerstone of federal drug regulation and has been the law in the United States since 1938. The restriction in section 801(d)(1) of the Act that prohibits persons other than a drug's original manufacturer from importing a U.S.-made drug back into the United States was enacted by Congress in 1988 as part of the Prescription Drug Marketing Act (PDMA) (Public Law 100-293). In section 2 of the PDMA, Congress found that "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Clearly, Congress enacted section 801(d)(1) with a specific public health objective in mind.

In light of this language, and in light of Judge Eagan's opinion in the Rx Depot case, we decline to interpret the law differently or, as the petition requests, to ignore it altogether.

We are also denying your request because the Department of Health and Human Services (the Department) is still studying the issue of importation pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the MMA). As you may know, section 1122 of the MMA directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department is currently working on the comprehensive report and has created an intergovernmental Task Force on Drug Importation (Task Force) to steer this effort to completion by the Congressional deadline this year. FDA is participating on the Task Force, and we believe it important that its study be completed and considered before advocating a position that would involve importation of drugs that have been dispensed outside of the United States.

The Agency's current objections to proposals that would legalize large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that the proposals will create substantial drug safety problems without clear, large-scale, long-term benefits. The principal concern is that such proposals would weaken our existing safety protections rather than providing the necessary resources and additional authorities that would be required to enable the Agency to assure drug safety and security. FDA has a statutory responsibility to protect the safety of the nation's drug supply. Therefore, the Agency has sent warning letters to certain companies that have facilitated the purchase of prescription drugs from foreign countries and put American consumers at risk by providing them with unapproved, illegal, and potentially risky foreign prescription drugs. The drug safety laws that FDA is charged with enforcing require that drugs be proven safe and effective to be legally introduced into interstate commerce. FDA will continue to do all that it can to make safe and affordable drugs available and is committed to enforcing the law against those who endanger Americans by importing illegal, unapproved, and possibly harmful medicines.

**B. MEDSA**

The petition asserts that FDA has not fulfilled its obligation under MEDSA to promulgate regulations permitting pharmacists and wholesalers to import drugs into the United States (Petition at 3). The petition states that this has cost U.S. consumers millions of dollars and prevented U.S. citizens from obtaining needed prescription drugs. Therefore, the petition requests that FDA dismiss, suspend, or revoke all legal and administrative actions that inhibit implementation of MEDSA (id. at 2). The Agency denies these requests for the reasons set forth below.

MEDSA established authority for the importation of drugs by pharmacists and wholesalers from foreign sources but provided that the program could not become effective unless the Secretary of Health and Human Services (HHS) (Secretary) certified that implementing the program would (1) pose no additional risk to public health and safety and (2) result in a significant reduction in the cost of drugs to the American consumer. Both Secretary Thompson and former Secretary Shalala have concluded (separately) in the past that such products may pose additional risks to safety and therefore should not be imported.

The Agency is well aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs without subjecting U.S. citizens to potentially dangerous unapproved drugs. These steps include (1) establishing new initiatives to accelerate approval of innovative medical procedures and drug therapies, (2) changing our regulations to reduce litigation that has been shown to delay access to more affordable generic drugs, and (3) proposing a plan to increase Agency resources for the review and approval of generic drugs – products that are often far less expensive than brand-name products and may in fact be less expensive in the United States than generic drugs sold abroad. The Administration also worked with Congress on landmark legislation in the MMA to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs under Medicare.

Section 1121 of the MMA retains the requirement that drug importation is to become effective only if the Secretary is first able to certify to Congress that implementing the program will pose no additional risk to public health and safety and will result in a significant reduction in the cost of drugs to the American consumer. The Department is working through the Task Force to determine how drug importation might be conducted safely and its potential impact, positive and negative, on the health of American patients, medical costs, and the development of new medicines.

FDA is also working diligently to respond to this mandate from Congress under MMA, and we will consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. The Task Force has begun a series of meetings with the various stakeholders in this important area so that it can advise Congress on how and whether to proceed in its deliberations on drug importation. When the study required by

section 1122 of the MMA is completed, FDA will be better able to assess whether the certification standard set forth in section 1121 can be met.

**C. Drugs Regulated by the Canadian Directorate**

The petition requests FDA to verify that all drugs regulated by the Canadian Directorate pose no additional risk to public health and safety (Petition at 2). The Act requires the Agency to assess the safety and effectiveness of drugs marketed in this country. This assessment is based, in part, on information obtained from companies that conform to U.S. current good manufacturing practice and labeling regulations. Drug products prepared by manufacturers that are not FDA-regulated and are located in other countries most likely do not meet these requirements. Currently, there is no mechanism in place to accept the safety and effectiveness recommendations provided by other countries or entities as the sole basis for FDA approval. Nevertheless, as stated above, the Agency and the Department are participating in the Task Force that will advise Congress on how and whether to proceed on drug importation. As part of that effort, FDA and the Department are attempting to assess certain material aspects of the Canadian drug regulatory system. The MMA gives the Department up to 12 months to complete its study.

**D. Document Request**

The petition asks for a complete copy of all documents between FDA and the Canadian Directorate regarding FDA's review of the Directorate to assess the safety, efficacy, and quality of prescription medicines before being authorized for sale in Canada (Petition at 1-2). If you still seek this information, you should submit a request under the FOIA to Carl I. Vassar, Division of Federal-State Relations, Food and Drug Administration, 5600 Fishers Lane, Room 12-07, Rockville, MD 20857, 301-827-6906.

**III. CONCLUSION**

FDA shares the concern expressed in the petition regarding the availability of safe, effective, and affordable prescription drugs for U.S. citizens. We understand the desire to lower drug costs for Americans, and we are doing all we can under the law to lower drug prices without opening our borders to unapproved pharmaceuticals. However, for the reasons stated above, the petition is denied. To obtain the requested copies of documents between FDA and the Canadian Directorate, you should contact FDA's Division of Federal-State Relations.

Sincerely yours,



William K. Hubbard  
Associate Commissioner  
for Policy and Planning