



DEPARTMENT OF HEALTH & HUMAN SERVICES

94535d
Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 18 2004

WARNING LETTER

VIA FEDERAL EXPRESS
& FAX TO 1-304-366-8343

Ms. Carole Becker
President
Discount Prescriptions from Canada, Inc.
709 Benoni Ave.
Fairmont, WV 26554

Dear Ms. Becker:

The Food and Drug Administration (FDA) has learned that you operate a commercial business that helps United States (U.S.) consumers to obtain prescription drugs from Canada. Specifically, you are running an operation that sends U.S. prescriptions, credit card information, and paperwork including "Customer Purchasing Agreements," "New Account Forms," "Medical History Forms," and "Physician Info Forms" to CanAmerica Drugs, Inc. (CanAm), located in Manitoba, Canada. Alternatively, you submit the same information on your customer's behalf to CanAm via its website, www.canamericadrugs.com. CanAm then arranges for a corresponding prescription from a Canadian doctor and then fills the prescription and sends the drugs directly to the U.S. consumer. As discussed in greater detail below, your actions violate the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. §§ 301-397. Your actions also present a significant risk to public health, and you mislead the public about the safety of the drugs obtained through CanAm.

Legal Violations

Virtually every shipment of prescription drugs from Canadian pharmacies to U.S. consumers violates the Act. Even if a prescription drug is approved in the U.S., it is a violation of the Act for anyone other than its original manufacturer to import the drug back into the U.S. if that drug was originally manufactured in the United States before it was sent abroad. 21 U.S.C. § 381(d)(1). Moreover, drugs shipped into the U.S. from Canadian pharmacies are generally unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. § 352), and/or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Thus, their shipment into the U.S. from Canada violates the Act. *See, e.g.*, 21 U.S.C. 331(a), (d), (t).

Canadian and other foreign versions of FDA-approved drugs are generally considered unapproved in the United States because FDA approvals are manufacturer-specific, 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. 21 C.F.R. § 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, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is unapproved in this country. 21 U.S.C. § 355.

In order to ensure compliance with the Act when they ship prescription drugs to U.S. consumers, businesses and individuals must ensure, among other things, that the drugs sold: (1) are FDA-approved; (2) if manufactured in the U.S., are imported only by the manufacturer; and (3) comply with the applicable FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. They must also ensure that each drug meets all U.S. labeling requirements. 21 U.S.C. § 352. The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

It is extremely unlikely that any pharmacy located in Canada could ensure that all of the applicable legal requirements are met. Consequently, almost every time that an individual or business ships a prescription drug from Canada, the individual or business violates the Act. Moreover, individuals and businesses, such as Discount Prescriptions from Canada, Inc. and its responsible personnel, that cause those shipments also violate the Act. 21 U.S.C. § 331 (“The following acts and the causing thereof are hereby prohibited . . .”).

You state and CanAm states on the web site www.canamericadrugs.com that a U.S. consumer can legally import as much as a 90-day supply of a prescription drug. This is misleading. FDA's Personal Importation Policy is our statement of enforcement policy and it assists the Agency in exercising its enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows 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 may not be available domestically. FDA has followed this approach with products that do not present an unreasonable risk and for which there is no known commercialization and promotion to U.S. residents. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

However, the Personal Importation Policy is not intended to allow importation of drugs which are commercialized and promoted to U.S. residents by operations such as yours. The Policy is also not intended to apply to foreign versions of U.S.-approved drugs. Finally, while the Personal Importation Policy describes the Agency's enforcement priorities, it does not change the law.

FDA's Public Health Concerns and Your Misleading Statements about Drug Safety

Your store-front operation and the CanAm website mislead U.S. consumers to believe that drugs from Canada are as safe as domestically dispensed prescription drugs. You tell your customers: "the prescription drugs from Canada are identical to the prescription I would get filled at my local pharmacy except that they are packaged differently in blister packaging. That is the only difference from the approved U.S. version." That is a false and misleading statement. Prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because drugs from foreign countries have been manufactured, shipped, held and/or repackaged outside of FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to Americans may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products that you are soliciting U.S. consumers to buy are indicated for serious medical conditions.

FDA is also very concerned about the importation of prescription drugs from Canada and other foreign countries because, in the Agency's experience, many drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Recent examples of counterfeit products entering the U.S. marketplace also raise substantial safety questions about drugs from foreign countries. Moreover, there is a possibility that drugs, which come to U.S. consumers through Canada, or purport to be from Canada, may not actually be Canadian drugs. In short, drugs delivered to the American public from foreign countries may be very different from products approved by FDA and may not be safe and effective. For all of these reasons, FDA believes that operations such as yours expose the public to significant potential health risks.

Action Needed

This letter is not intended to identify all of the ways in which your activities violate United States law. It is your responsibility to ensure that you are in compliance with applicable legal requirements.

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Please notify this office in writing within fifteen working days of your receipt of this letter of the specific steps that you will take to assure that your operations are in full compliance with United States law. Please address your correspondence to Mr. Melvin Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 5600 Fishers Lane, Rockville, Maryland 20857. If you do not promptly correct your violations, FDA may take legal action without further notice. Possible actions include seizure and/or injunction. Further, federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Sincerely

/S/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc:



Adeline Saria
Licensed Pharmacist
CanAmerica Drugs, Inc.
7- 1391 St. James St.
Winnipeg, Manitoba R3H 0Z1
Canada
Fax (866)982-9542

Canamerica Drugs [different name from first paragraph of letter]
Registrant of www.canamericadrugs.com
12 Carina Cove
Winnipeg, Manitoba R2V 4N8
Canada
Fax (306)933-4987

William T. Douglass, Jr.
Executive Director
State of West Virginia Board of Pharmacy
232 Capital Street
Charleston, WV 25301
Fax (304)558-0572

Daniele Dionne
Inspectorate Health Canada
Health Products and Food Branch
11 Holland Ave.
Ottawa, Ontario K1A 0K9 Canada
Fax (613)957-2991

Ronald Guse
Registrar
The Manitoba Pharmaceutical Association
187 St. Mary's Road
Winnipeg, Manitoba
R2H 1J2 Canada
Fax (204)237-3468