DEPARTMENT OF HEALTH & HUMAN SERVICES | Public Health Service

Food and Drug Administration
Rockville MD 20857

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WARNING LETTER

VIA EXPRESS MAIL/RETURN RECEIPT
& FAX TO 1-888-715-6337

Robert Howard
Shipping Manager
CanaRx Services, Inc.
P.O. Box 44650
Detroit, MI 48244-0650

Dear Mr. Howard:

The Food and Drug Administration (FDA) has learned that you are assisting United States consumers in obtaining prescription drugs from Canada, through a drug purchasing arrangement that involves entities other than licensed Canadian pharmacies and that does not reliably use good shipping practices to assure drug safety and effectiveness. Specifically, you are running an Internet and U.S. mail operation that sends U.S. prescriptions, credit card information, and paperwork (including "Release and Limited Power of Attorney" agreements, "Enrollment Forms," "Conformation & Representations," and U.S. mailed or faxed "Patient Information" forms, all available on your Internet website) to a U.S. mail Post Office box in Detroit, MI. According to information provided by you, the prescription and forms are retrieved by fax or from your Detroit P.O. Box and transported into Canada by yourself or by one of your employees. A prescription is then obtained from a medical doctor in Canada, and Canadian drugs are dispensed by Eastown Pharmacy, located in the Canadian province of Ontario, to your firm for mailing directly to the U.S. consumer. For drugs requiring refrigeration, you or your employees transport the drugs, using Express Mail through the U.S. Postal Service or other common carriers directly to U.S. residents. As discussed in greater detail below, your actions violate the Federal Food, Drug and Cosmetic Act (FD&C Act or the Act), 21 U.S.C. § 301 et seq. Your actions also present a significant risk to public health, and you mislead the public about the safety of the drugs obtained through CanaRx Services, Inc. ("CanaRx").

FDA is taking this action against you and your firm because you should not be continuing to profit through illegal actions that put the health of the American public at risk.

Safety Concerns

FDA is concerned about your activities because of the inherent risk in buying prescription drugs from long-distance, unregulated sources, as well as claims implying that your drugs are just as safe as or equivalent to FDA-approved drugs. Unapproved foreign drugs do not have

the same assurance of safety as drugs subject to FDA oversight. Unapproved drugs have been found to be contaminated, counterfeit, contain different amounts of active ingredients, or contain different ingredients altogether. For drugs that are regulated by FDA, FDA protections include rigorous scientific standards for prescription drug approval and label review for accuracy and completeness; manufacturing procedures and testing performed under closely controlled conditions at FDA- registered and inspected facilities; and licensing by the states of pharmacists and wholesalers who sell or distribute prescription drugs in the U.S. Without regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labeling, and, therefore, may not be safe and effective.

In the case of CanaRx, for example, an FDA investigator that filled prescriptions through your company ordered and received insulin, a product that should generally be stored under refrigerated conditions. But the product was not shipped in a manner that ensures adherence with storage conditions specified in FDA approved labeling, potentially compromising its safety and effectiveness. Moreover, it appears that CanaRx is not a licensed Canadian pharmacy subject to regulatory oversight, and so may place patients at additional risk.

Legal Violations

Virtually every shipment of prescription drugs from Canadian pharmacies to consumers in the U.S. violates the Act. Even if a prescription drug is approved in the U.S., if the drug is also originally manufactured in the U.S., it is a violation of the Act for anyone other than the U.S. manufacturer to import the drug into the United States (21 U.S.C. § 381(d)(1)). We believe that virtually all drugs imported into the U.S. from Canada by or for individual U.S. consumers also violate U.S. law for other reasons. Generally, such drugs are 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).

The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that 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 U.S. 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 usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved. 21 U.S.C. § 355.

In order to ensure compliance with the Act when they are involved in shipping prescription drugs from abroad to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the 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, including that it bears the FDA-approved labeling. 21 C.F.R. § 201.100(c)(2). The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

Practically speaking, it is extremely unlikely that a pharmacy could ensure that all of the applicable legal requirements are met. Consequently, almost every time an individual or business ships a prescription drug from Canada or brings that drug illegally into the United States for overnight shipment to a U.S. consumer, the individual or business shipping the drug violates the FD&C Act. Moreover, individuals and businesses, such as CanaRx Services, 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...").

The CanaRx web site, www.canarx.com, misleadingly states, "Is there a quantity limited per prescription? Yes. The U.S. government and the F.D.A. limit the import of medication for personal use only to a maximum supply of three months.... " This is not correct. Under FDA's Personal Importation policy, as a matter of enforcement discretion in certain defined circumstances, FDA allows consumers to import otherwise illegal drugs. However, contrary to your statements, this policy is not intended to allow importation of foreign versions of drugs of which there is a FDA-approved version. This is especially true when the foreign versions of such drugs are being "commercialized" to U.S. citizens through operations such as yours.

Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

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

CanaRx's web site also makes misleading assurances to consumers about the safety of the drugs purchased through CanaRx. For example, the web site states that "there is no difference" between drugs purchased from the U.S. and from Canada. Such statements are not correct. 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. Foreign dispensers of drugs to American citizens 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 you are soliciting United States 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 our 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. To reiterate, 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.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps 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, MD 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,

David J. Horowitz, Esq.
Director
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Food and Drug Administration

Identical letters sent to:

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