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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

March 21, 2003

Via Fax and Federal Express
Harry Lee Jones
Store Manager
Rx Depot, Inc.
200 S. Bloomington
Suite E 1
Lowell, AR 72745

Dear Mr. Jones:

The Food and Drug Administration (FDA) has learned that you are assisting United States consumers in obtaining prescription drugs from Canada. Specifically, you are running a storefront operation that sends U.S. prescriptions, credit card information, and paperwork (including a "Patient Profile" and "Release & Limited Power of Attorney") to a Canadian pharmacy. According to information provided by you and your store, a prescription is then obtained from a medical doctor in Canada, and Canadian drugs are shipped by a pharmacy in the Canadian province of Manitoba directly to the U.S. consumer. As discussed in greater detail below, your actions violate the Federal Food, Drug and Cosmetic Act (FD&C Act or 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 Rx Depot.

Legal Violations

Your actions violate the FD&C Act because 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. § 353(b)(2)), 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 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 to a U.S. consumer, the individual or business shipping the drug violates the FD&C Act. Moreover, individuals and businesses, such as Rx Depot, Inc. ("Rx Depot") 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...").

Rx Depot's web site, www.rxdepot.com, misleadingly claims that, "United States FDA policy allows importation of approved products for personal use in quantities not to exceed 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 statement, this policy is not intended to allow importation of foreign versions of drugs of which there is an 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

Rx Depot's web site and documents make misleading assurances to consumers about the safety of the drugs purchased through Rx Depot. For example, flyers provided at your storefront claim that these drugs are "FDA approved" and "[a]ll meet FDA standards." Rx Depot's web site claims that the products purchased through Rx Depot, "are all

approved for use by the United States government and are exactly the same as if purchased in the United States."

None of these statements is 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. Because the medications are not subject to 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 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.[1] At least one of them presents risks that FDA has determined warrant special patient labeling.[2]

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. 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.

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,

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[1] For example, Rx Depot's web site offers prescription drugs indicated for use in treating cancer (tamoxifen), HIV (abacavir sulfate), and hypertension (irbesartan).

[2] Rx Depot's web site offers abacavir sulfate (Ziagen), a carbocylic nucleoside reverse transcriptase inhibitor indicated for the treatment of HIV.

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,

/s/

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

cc Carl Moore
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