DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 22 2004

WARNING LETTER

VIA FEDERAL EXPRESS & FACSIMILE

Mr. Noel Thomas Curb, R.Ph.
Expedite-Rx
SPC Global Technologies, Ltd.
2801 West Avenue T
Temple, TX 76504
Fax number: 1-800-810-3519

Mr. Tom Lanham
Expedite-RX
Employer Health Options Inc.
2801 West Avenue T
Temple, Texas 76504

Mr. Mike Strickland, President
Employer Health Options, Inc.
2801 West Avenue T
Temple, TX 76504

Mr. Mike Strickland, President
Employer Health Options, Inc.
201 Lonnie E. Crawford Blvd
Scottsboro, AL 35769
Fax number: 1-800-522-3335

Dear Messrs. Curb, Lanham, and Strickland:

The Food and Drug Administration (FDA) has learned that you are assisting United States (U.S.) consumers in obtaining prescription drugs from Canada through Expedite-Rx, SPC Global Technologies, Ltd., and Employer Health Options, Inc. Specifically, you are running a program that facilitates the importation of prescription drugs from Canada for U.S. consumers. Consumers who are members of your program send paperwork, including the "Initial Prescription Order Form," "Medical History Form," "Customer Agreement Form," and a U.S. prescription to Expedite-Rx by mail or facsimile. Expedite-Rx then sends the prescription to a Canadian pharmacy. This Canadian pharmacy arranges for a corresponding prescription from a medical doctor in Canada and then fills the prescription and sends the drug 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 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 that are obtained through your program.

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 U.S. (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).

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 the drugs sold: (1) are FDA-approved; (2) if manufactured in the U.S., are imported only by the manufacturer; and (3) comply with an 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. The businesses and individuals 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).

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 U.S. 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 Expedite-Rx, SPC Global Technologies, Ltd, and Employer Health Options, Inc., and their 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 Expedite-Rx web site, www.expedite-rx.com, misleadingly states, "In a published statement a FDA spokesman said that the federal government 'has not enforced any existing laws affecting such importation in years', and that it has instead taken 'a compassionate approach (to enforcement) (that is) intended to help people with serious health problems'." This is misleading. 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, this policy is not intended to

allow importation of foreign versions of drugs for 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 U.S. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

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

Expedite-Rx's web site also makes misleading assurances to consumers about the safety of the drugs purchased through the program. For example, on your website's page, Why Canada?, you make the claim that "Canada's patient-protective drug controls are most like those in the U.S." In addition, on your website's page, "Don't Be Intimidated?," you claim "[v]irtually all the drug brands are of common manufacture . . . ."

These statements could give the impression to consumers that drugs obtained through this program are the same as those approved in the U.S., and therefore, they present no safety risks. However, 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 U.S. 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 U.S. consumers to buy are indicated for serious medical conditions.

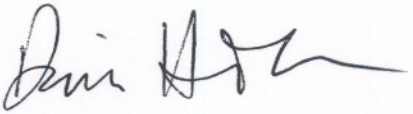
FDA is also very concerned about the importation of prescription drugs from Canada and other foreign countries because, in our experience, many drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Recent examples 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 U.S. 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 U.S. 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
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

cc:

Mayor Bobby Bright
City of Montgomery
P.O. Box 1111
Montgomery, Alabama 36101

Mark Hutzell
President
Independent Lifestyle Association, Inc.
1210 E. Main Street, P.O. Box 35 Panora
Lake Panorama, IA 50216

Dave Robertson
Cross Border Pharmacy/ Total Care Pharmacy
2912 Memorial Drive SE
Suite 100
Calgary, Alberta T2A 7R9
Canada

Gay Dodson, R.Ph.
Executive Director, Secretary
Texas State Board of Pharmacy
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street, Box 21
Austin, Texas 78701

Lowell Keig, Esq.
State of Texas
Office of the Attorney General
300 West 15th Street
Austin, Texas 78701

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

Merv Blair
Deputy Registrar
Alberta College of Pharmacists
Suite 1200-10303 Jasper Avenue
Edmonton, Alberta T5J 3N6