



**BY FEDERAL EXPRESS**  
**& FAXED to (866)705-5512**

SEP 10 2003

Mr. Terry Fraiser, Owner  
Smart Med Pharmasave  
SmartMeds.ca  
227 Mains St. NW  
Roblin, MB R0L 1P0 Canada

Dear Mr. Fraiser:

The Food and Drug Administration (FDA) has learned that, through the website [www.smartmed.ca](http://www.smartmed.ca), you are selling "Accutane" to United States (U.S.) consumers. Accutane is the trade name for a prescription drug approved for marketing in the United States under an approved new drug application by Roche Pharmaceuticals, Nutley, New Jersey. Even though the Smartmed.ca order forms state that the product offered for sale is "Accutane," the label of the actual product shipped states that it is "Accutane Roche 40." "Accutane Roche 40" does not have an approved new drug application and may not be legally marketed in the United States.

The "Accutane Roche 40" orders from your website are sent to American consumers from a Canadian pharmacy. The customer must print the prescription order form, the Smart Med Pharmacy Limited Power of Attorney & Release Form, and the Smart Med Pharmacy Patient Information Form. All the forms, signed by the patient, along with a copy of the written prescription, must be faxed to (866)705-5512. As discussed in greater detail below, your actions violate the Federal Food, Drug and Cosmetic Act (FD&C Act or Act), 21 United States Code (U.S.C.) § 301 et seq.

"The Accutane Roche 40" product sold through your websites is labeled as containing 40 mg of Isotretinoin and is packaged in an opened side fold out box with 30 individually wrapped capsules in a punch out card labeled in part, "\*\*\*\*Accutane\*\*\*\* Roche\*\*\*\*40 Isotretinoin capsules Roche Standard\*\*\*\*40 mg\*\*\*\* Nodular/inflammatory and Conglobate Acne Therapy\*\*\*Smart Med 227 Main St. NW Roblin, MB \*\*\*Pharmasave #448 \*\*\*Rx: \*\*\* Dr. Silagy, Stewart\*\*\* 09-Jun-2003 60 CAP Isotretinoin 40 mg \*\*\*30 Capsules\*\*\* Take 1 capsule twice a day with meals\*\*\*(L) B1051 EXP FE 2005\*\*\*Information for the Consumer\*\*\*Avoid pregnancy. Read information before taking\*\*\*Information for the Consumer\*\*\*Hoffmann-La Roche Limited/Limitee Mississauga, ON L5N 6L7."

Accutane (isotretinoin) is a systemically administered retinoid approved in 1982 to treat severe recalcitrant nodular acne. Isotretinoin carries significant potential risks, including that it may cause severe birth defects. The approved Accutane labeling states in part, "Accutane must not be used by females who are pregnant...must be prescribed under the System to Manage Accutane Related Teratogenicity (S.M.A.R.T.), a yellow Accutane Qualification Sticker must be on each prescription," (meaning special training has been given to the prescribing licensed practitioner and the patient) "and no telephone or computerized prescriptions are permitted."

Because it has serious known risks, isotretinoin is available in the U.S. only under specially created safety controls. These safety controls are bypassed when this drug is purchased from foreign sources or over the Internet, placing patients who use this imported drug at higher risk. Your website does not comply with the S.M.A.R.T. program.

The isotretinoin dispensed through your website is a "new drug" as defined by section 201(p) of the Act. Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. The continued distribution of this product into the U.S. without an approved NDA is a prohibited act as set forth in Section 301(d) of the Act.

This letter is not intended to identify all of the ways in which your activities might be in violation of United States law. For example, in addition to isotretinoin, your pharmacy also offers for sale and shipment to U.S. consumers numerous other prescription drugs. FDA believes that virtually all shipments of prescription drugs imported from non-U.S. pharmacies will violate the Act. It is your responsibility to ensure that all drug products dispensed, and distributed by you and your website in the United States are in compliance with applicable legal requirements.

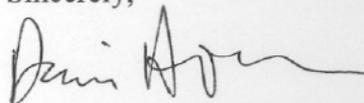
The agency has taken steps to warn our residents that drugs promoted and sold via the Internet, from foreign sources, may not be approved for marketing in this country, and may not be legally imported. With copies of this letter, we are advising the regulatory officials of Canada of these potential violations. In addition, we are advising the Bureau of Customs and Border Protection through an Import Alert that all shipments offered for importation into the U.S. as a result of your activities may be detained and subject to refusal of entry.

Page 3 – Accutane Letter

You are instructed to cease these practices, and you are requested within fifteen (15) days of your receipt of this letter, to describe to FDA in writing the actions you are taking to assure that your operations are in full compliance with United States law. Please address your correspondence to Mr. Melvin F. Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-314, 5600 Fishers Lane, Rockville, MD 20857

You should be aware that violations of the FD&C Act could result in seizure, injunction, and/or prosecution without further notice.

Sincerely,

A handwritten signature in black ink, appearing to read "David J. Horowitz", with a long horizontal flourish extending to the right.

David J. Horowitz

Director

Office of Compliance

Center for Drug Evaluation and Research

cc: Mr. Bruce Westman  
Administrator of [www.smartmeds.ca](http://www.smartmeds.ca)  
JAG Communications, Inc.  
1455 Lakeshore Rd., Suite 205s  
Burlington ON L7S 2J1 Canada  
Fax (905)681-6603

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

George Abercrombie,  
President, North America  
Roche Pharmaceutical  
Roche Laboratories, Inc.  
340 Kinsland Street  
Nutley, NJ 07110-1199