DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

VIA EXPRESS MAIL/RETURN RECEIPT
& FAXED to (775)924-4501

SEP 9 2003

Mr. David Anderson
2bBrands
P.O.Box 0798
Manhattan Beach, CA 90266

Dear Mr. Anderson:

The Food and Drug Administration (FDA) has learned that, through the websites www.2bbrands.com and www.mexican-drugstore.com, you are selling "Accutane topical gel" 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 submitted by Roche Pharmaceuticals, Nutley, New Jersey. The only approved Accutane products approved for marketing in the United States are capsules for oral ingestion. Even though the mexican-drugstore.com order form states that the product offered for sale is "Accutane topical gel," the label of the actual product shipped states that it is "ISOTREX ISOTRENINOINA GEL 0.05%." The labeling for this product is in Spanish. Neither "Accutane topical gel" nor "Isotrex" has an approved new drug application, and they may not be legally marketed in the United States.

You sell "Accutane topical gel" from your website without a prescription to American consumers from a Mexican pharmacy. As discussed in greater detail below, these actions violate the Federal Food, Drug and Cosmetic Act (FD&C Act or Act), 21 United States Code (U.S.C.) § 301 et seq.

When a U.S. resident logs onto the Internet site, www.2bbrands.com/drugstore they are automatically taken to www.mexican-drugstore.com that states in part, "***US Corporation enables you to purchase medicines from Mexico***Privately delivered to your address Medicines in Mexico are made from the same quality ingredients, made by the same companies *** in compliance with all U.S. and international laws***." Your firm packages the dispensed prescription and mails it directly to the resident in the United States.

The "Accutane" product sold through your web site is labeled in part, "ISOTREX ***ISOTRETINOINA GEL 0.05%***Tubo con 30 g Formila: Cada 100 g contiene: Isotretinoina 0.05g Excipiente c.b.p. 100 g. ***Hecho en Mexico por STIEFEL MEXICANA, S.A. DE C.V., Eje Norte Sur No. 11, Nuevo Parques Industrial, San Juan

del Rio Qro., C.P. 76809. Segun Formula y bajo licencia de: STIEFEL LABORATORIES, INC.,. Coral Gables, FL 33134 ***Lote. 130002F428 CAD. 15/JUN/2004***."

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." The approved Accutane is for oral ingestion. FDA has not approved a topical gel version of Accutane or any other isotretinoin drug.

Because it has serious 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.

The isotretinoin dispensed through mexican-drugstore.com 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.

The isotretinoin dispensed through mexican-drugstore.com is also misbranded under section 502(f)(1) of the Act because its labeling fails to bear adequate directions for the uses for which it is being offered and it is not exempt from this requirement (See 21 CFR § 201.115). The drug is also not allowed to bear the required information solely in Spanish because it is not distributed solely in the Commonwealth of Puerto Rico or in a U.S. Territory where the predominant language is Spanish (See 21 CFR § 201.15(c)).

This drug is also misbranded pursuant to section 503(b)(1) of the Act because it is dispensed without a prescription.

In addition, false statements are being made by you on www.2bbrands.com and www.mexican-drugstore.com, such as "All items are shipped *** in compliance with all U.S. and international laws." You are giving the incorrect impression that all the drugs sold on your website are FDA approved and/or legal to be sold and shipped to U.S. residents. This is a false and misleading statement on your Internet site causing the drugs you distribute to be misbranded pursuant to section 502(a) 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 into the United States are in compliance with applicable legal requirements.

The agency has taken steps to warn our residents that drugs 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 Mexican, New York, and California drug regulatory officials of these potential violations. In addition, we are advising the U.S. Custom's Bureau, through an Import Alert, that shipments offered for importation into the U.S. as a result of your activities may be detained and subject to refusal of entry.

You are instructed to cease these practices, and you are requested within fifteen (15) days of your receipt of this letter, to describe 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-310, 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,

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

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