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Food and Drug Administration
Rockville MD 20857WARNING LETTER

BY FEDERAL EXPRESS
& FAXED to (775) 414-9344
& (0870)139-8938

SEP 9 2003

Mr. Eric Kaiser
Registrant
Edrugnet.com,
laccutane.com
Accutane-acne-treatments-medication.com,
3508 Van Teylingen Dr.
Apt. D
Colorado Springs, CO 80917

Dear Mr. Kaiser:

The Food and Drug Administration (FDA) has learned that, through the websites Edrugnet.com, Accutane-acne-treatments-medication.com and laccutane.com, 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 Edrugnet.com, Accutane-acne-treatments-medication.com and laccutane.com order forms state that the product offered for sale is "Accutane (brand) Roaccutane," the label of the actual product shipped states that it is "Roaccutane Isotretinoin 10 mg Capsules." "Roaccutane" does not have an approved new drug application and may not be legally marketed in the United States.

You sell "Roaccutane" from your website without a prescription, and these orders are sent to the American consumers from a pharmacy in Thailand. The customer may order on-line over the Internet, or print the order form, then fax it to (775)414-9344 (U.S.A. number) or 0870139-8938 (U.K. number). 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.

The Roaccutane product sold through your websites contains 10 mg of Isotretinoin which is packaged in a box containing 3 strips of 10 individually wrapped capsules labeled in part, "Roaccutane*** Isotretinoin 10 mg. ***Roche***Attention: Adhere strictly to precautions! Pregnancy forbidden! Risk of malformation!***". The box containing the three strips was labeled in part, "Roaccutane***Isotretinoin 10 mg

Attention ***Roche *** 30 capsulesinsert *** Thai Reg. No. 1C 230/41 ***
Made under license from F. Hoffmann-La Roche Ltd, Basel, Switzerland by R.P. Scherer
GmbH, Eberbach, Germany.”

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.

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.

The isotretinoin dispensed through Edrugnet.com, Accutane-acne-treatments-medication.com and Iaccutane.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).

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

False statements are being made by you on www.edrugnet.com that are aimed at and accessible to American consumers stating in part, “***Order legally***offering a huge selection of medications based on brand name and generic name which are approved by FDA ***.” False statements again, are being made by you on www.accutane-acne-treatments-medication.com and www.Iaccutane.com that are aimed at and accessible to

American consumers stating, "FDA Approved Products" are available on your website. The product was then packaged and mailed in Thailand. Inside the package was a U.S. Customs Declaration stating in part, "****I am United States Citizen *** None of these Medication enclosed pose any risk to the Public's Health and/or Well being***These Medications which I must have access to are for treating a life threatening or debilitating condition***." These false and misleading statements on your Internet site and packaging labeling cause 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, through numerous different websites you offer 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 through you and your website (s) 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 the regulatory officials of the State of Colorado, The United Kingdom and Thailand 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.

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,



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