DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

BY FEDERAL EXPRESS
& FAXED to 011-66-2-946-7690

SEP 9 2003

Mr. S. Vincent
Registrant
Medicapharma.com
1455 Tallevast Road
Suite L1128
Sarasota, FL 34243

Dear Mr. Vincent:

The Food and Drug Administration (FDA) has learned that, through the website www.medicapharma.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. The only Accutane products approved for marketing in the United States are capsules for oral ingestion. Even though the medicapharma.com order form states the product for sale is "Accutane (Roaccutane)," the label of the actual product shipped states that it is "Roaccutane Isotretinoin 10 mg tablet." "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 Thai 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.

The "Roaccutane" product sold through your web site is 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 capsules***insert *** Thai Reg. No. 1C 230/41 *** Made under license from F. Hoffmann-La Roche Ltd, Basel, Switzerland by R.P. Scherer GmbH, Eberbach, Germany." The capsules are packaged in a box containing 3 strips of 10 individually wrapped capsules.

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 medicapharma.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 medicapharma.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.

In addition, false statements are being made by you on www.medicapharma.com such as, "Import of medicine for personal use is OK provided recipient has prescription. Copy of prescription should accompany shipment. Prescription drugs should be no more than 3 months' supply or 100 count [sic]." You are giving the incorrect impression that all the drugs sold on the web site are legal to be sold and shipped to U.S. residents. This false and misleading statement on your Internet site causes 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 in the United States are in compliance with applicable legal requirements.

For your information, Mr. Suthapintu Vut at P.O. Box 25, Klongkum, Bangkok, 10244 Thailand was issued a Cyber Letter by FDA on March 1, 2002 (See attachment) notifying him and medicapharma.com that various drugs including Accutane may be illegal in this country.

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 Thailand and Florida regulatory officials 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

Attachment: Cyber Letter 3/1/01

cc:

Florida Board of Pharmacy
Lucy Gee,
Interim Executive Director
4052 Bald Cypress Way, Bin Co4
Tallahassee, FL 32399-3254

Dr. Yuppadee Javroonrgit
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

7520 Standish Place-Room 254
Rockville, Maryland 20855
USA

March 1, 2001

Ref. No. 01-HFD-310I-086

Mr. Suthapintu Vut
PO Box 25
Khlongkum,
Bangkok 10244
Thailand

Dear Sir:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.medicapharma.com and has determined that the drug products, Accupril®, Adalat®, Accutane®, Actifed® and numerous other medicines being offered for sale are prescription drugs in the United States (U.S.). FDA is unable to determine that the drug products marketed by your firm have been made in accordance with the U.S. specifications and are the same products marketed legally in the United States. Therefore, the sale and distribution of these products on your Internet web site may be illegal in this country and may be in violation of Title 21 of the United States Code, Sections 331(a), 331(d), and 355(a).

Many prescription drugs available from foreign sources are either products for which there is no U.S. approved counterpart or foreign versions of FDA approved drugs. In either case, these products are not approved for use in the U.S. and therefore, it is illegal for a foreign source to ship these products into the U.S. In our experience, many drugs obtained from foreign sources that purport to be the same as U.S. approved prescription drugs have been of unknown quality. FDA approves a drug on the basis of scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide assurance to the American public that the drug products ordered from your web site are the same products approved by FDA and prescribed by the consumer's physician. In addition, federal law prohibits the sale of prescription drugs to U.S. citizens without a valid prescription, 21 U.S.C. Section 353(b).

The agency is taking steps to warn our citizens 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 drug officials in the countries from which you operate of these potential violations. In addition, we are advising the U.S. Customs Service through an Import Alert that all shipments offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

FDA would like to take this opportunity to clarify the agency's policy concerning the importation of pharmaceutical products for personal use. For many years, FDA has permitted individuals and their physicians to bring into the United States small quantities of drugs sold abroad, but not approved in the U.S. for a patient's treatment of a serious condition. This compassionate approach has been applied to products that do not represent an unreasonable risk and for which there is no known commercialization or promotion to persons residing in the U.S. A patient seeking to import such product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. Accupril®, Adalat®, Accutane®, Actifed® and the numerous other medicines ordered from your web site do not meet the criteria in FDA's personal use policy.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market to the United States. It is your responsibility to ensure that all products marketed by your firm are in compliance with applicable U.S. laws.

If you need additional information, or have questions concerning any products distributed through your web site, please contact FDA. You may reach FDA electronically (E-mail) Don Leggett at: Leggett@CDER.FDA.GOV. or you may provide written response via fax at (301) 594-2114 or hard copy letter to the letterhead address. You may reach FDA by telephone at (301) 594-0054.

Sincerely yours,
/s/
David J Horowitz , Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc: M & Co Co. , Ltd.
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