



Food and Drug Administration  
7520 Standish Place-Room 254  
Rockville, MD 20855

December 7, 2000

Ref. No. 00-HFD-310I-066

Hamid Reza Makhmalchi  
SF2, Pearl Villa  
6<sup>th</sup> Cross  
Sultanpalaya  
Bangalore-560032 India

Dear Dr. Makhmalchi:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your "offer list & prices" obtained through your Internet address: [machdr@hotmail.com](mailto:machdr@hotmail.com) and has determined that the drugs being offered for sale are prescription drugs in the United States (U.S.). FDA is unable to determine that drugs such as mifepristone (RU 486), tramadol (Ultram), pentazocin injection, carisoprodol (similar to Soma), fluoxetine, diazepam (similar to Valium), ketamine, nandrolone and other prescription drugs 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 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 drugs 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. Custom's 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 and/or life-threatening condition. This compassionate approach has been applied to foreign drug 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. The RU 486, tramadol, pentazocin injection, and numerous other medicines ordered from [machdr@hotmail.com](mailto:machdr@hotmail.com) 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) at [Leggett@CDER.FDA.GOV](mailto:Leggett@CDER.FDA.GOV) or you may provide written response via fax at (301) 594-0165 or hard copy letter to the letterhead address. You may reach FDA by telephone at (301) 594-0063.

Sincerely yours,

/s/

David J. Horowitz, Esq.

Director

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration