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

October 31, 2001

Ref. No. 01-HFD-310I-127

Mr. Fernando Benavides
Farmamondo
Via Volta 2
Chiasso
Switzerland

Dear Mr. Benavides:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.farmamondo.com and has determined that the drug product ciprofloxacin and numerous other medicines being offered for sale at your web site 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 adequate assurance to the American public that the drug products ordered from your web site are the same products approved by FDA. In addition, federal law prohibits dispensing 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 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.

The ciprofloxacin offered for sale from your web site does not meet the criteria in FDA's personal use policy, at least in part, because an approved version (Cipro) is available in the U.S. Moreover, unwarranted prescribing and inappropriate use of Cipro in the absence of suspected or confirmed exposure to an infectious agent, such as *Bacillus anthracis*, could pose serious risks to the public health.

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