**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**PUBLIC HEALTH SERVICE**
**FOOD AND DRUG ADMINISTRATION**
**CENTER_FOR DRUG EVALUATION AND RESEARCH**

7520 Standish Place
Rockville, Maryland 20855
USA

Date: January 21, 2000 Ref. No. 00-HFD-310I-001

Hamada Dayateknindo, P.T
JL.. SAKTI II No. 15
JAKARTA, JAWA 12270
ID

Dear Hamada Dayateknindo:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.VIAGRAGOGO.COM and that the drug VIAGRA ® being offered for sale isa prescription drug in the United States (U.S.). FDA is unable to determine that the VIAGRA ® marketed by your firm has been made in accordance with the U.S. specifications and is the same product marketed legally in the United States. Therefore, the sale and distribution of this product 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 ordered from your web site is the same product 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 from foreign sources via the Internet may not be approved for marketing in this country. With copies of this letter, we are advising the regulatory drug officials in the countries from which you operate of these potential violations. We are also 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. The Viagra ® ordered from your web site does not meet the criteria in FDA's personal use policy.

Please notify this office in writing what you plan to do about these potential violations. Your response may be sent electronically (E-mail) to Mr. William Nychis at the following address: Nychis@CDER.FDA.GOV. You may also provide written response via fax at (301) 594-0165 or hard copy letter to the letterhead address. Mr. Nychis may be reached by telephone at (301) 594-0063.

Sincerely yours,
/s/
Bradford W. Williams
Director
Division of Labeling and
Non-prescription Drug Compliance (HFD-310)