

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 (301) 594-7363

October 4, 2002

Lex van Nes Health Care Inspectorate Regional Office South Holland Steenvoordelaan 370 P.O. Box 5837 2280 HV Rijswijk The Netherlands

Dear Mr. van Nes:

The U.S. Food and Drug Administration (FDA) has reviewed the web site http://www.de-sjamaan.nl operating within The Netherlands. The web site is marketing "Yellow Jacket," a street drug alternative drug product, to citizens residing in the United States. This may be in violation of federal law, as indicated in the attached communication between the FDA and the contact for the web site.

The FDA is aware that some Internet distributors may not know that the product that they offer may not be in compliance with the laws of other countries. Therefore, the intent of our communication to the web site holder is two fold: (1) to advise him of our federal law and regulations, and (2) to inform him that drug products he offers for importation into the United States, as a result of the web activities, may be subject to detention and denied entry.

The rapid growth in marketing regulated products via the Internet presents a unique challenge to regulatory officials worldwide. I look forward to hearing from you. You may reach FDA electronically at szymanskim@cder.fda.gov or I may be contacted by telephone at (301) 827-7311 or by fax at (301) 594-0165.

Sincerely,

Melvin F. Szymanski Internet Coordinator

Office of Compliance

Attachment