



**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 4, 2002

Ref. No. 01-HFD-310I-140

Mr. Xoch Linnebank
Info@sjamaan.com
Sjamaan Internet Department
Hommelseweg 170
6821 LP Arnhem
The Netherlands
(via e-mail and Federal Express)

Dear Mr. Linnebank:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.de-sjamaan.nl> and has determined that the product "Yellow Jacket" is being promoted for conditions which may cause it to be a drug as defined in the Federal Food, Drug and Cosmetic Act. This product may also be considered a new drug which may not be legally marketed in the U.S. without prior approval from FDA. Therefore, the sale and distribution of this product on your Internet web site may be illegal and in violation of Title 21 of the United States Code, Sections 331(a), 331(d), and 355(a).

The information on your web site indicates that this product is intended to be used as an alternative to illicit street drugs. Examples include:

- 1) "Yellow Jacket (3 caps herbal XTC)"
- 2) "This new and powerful euphoric herbal XTC will power your day!"
- 3) "This herbal XTC is definitely one of the strongest party means of the moment."
- 4) "The Yellow Jacket has an extremely stimulating rush, with sensations one would attribute to E or amphetamines."
- 5) "Energy, rush and euphoria packed all in a few caps."

According to your web site, Yellow Jacket contains ingredients including ephedra extract, sida cordifolia, citrus aurantium (standardized to 4% synephrine), kola nut extract (contains caffeine), and capsicum.

These street drug alternative claims do not fall within the scope of claims permitted for dietary supplements. This product, *inter alia*, is not used to supplement the diet, and therefore, may not be considered to be a dietary supplement. Furthermore, this product is offered for abuse, as a substitute for controlled substances. As such, there does not appear to be any legitimate drug use for this product and its continued sale as a substitute for controlled substances to U.S. citizens may be illegal.

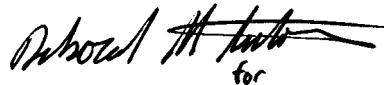
For your information, the Food and Drug Administration's "Guidance for Industry, Street Drug Alternatives" can be found at the Internet web site:
<http://www.fda.gov/cder/guidance/3602fnl.pdf>.

With a copy of this letter, we are advising the drug regulatory officials in the country from which you operate of these potential violations. In addition, we intend to advise 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.

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. We are also aware that your firm is marketing numerous other products as herbal XTC, as well as numerous other street drug alternatives. This letter may also be applicable to those products. It is your responsibility to ensure that all products marketed by your firm are in compliance with United States 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 nychis@cderr.fda.gov. You may also provide a written response via fax to (301) 594-0165 or hard copy letter to the letterhead address. FDA may be reached by telephone at (301) 594-0063.

Sincerely Yours,



for

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

cc:

Lex van Nes
Health Care Inspectorate
Regional Office South Holland
Steenvoordelaan 370
P.O. Box 5837
2280 HV Rijswijk
The Netherlands
(via fax and Federal Express)

D.P. Schrauwen
Postmaster@de-sjamaan.nl

A. Steevels
Postmaster@is.nl

Niceware
Oosterstraat 33
3581 ML UTRECHT
The Netherlands
(via Federal Express)

InterNed Services
Weberstraat 50
1446 VV Purmerend
The Netherlands
(via Federal Express)