



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 18, 2000

Ref. No. 00-HFD-310I-019

Spank Products
Amsterdam, The Netherlands

Dear Sirs:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.xtc.nl> and has determined that the product (s) "Final E", "E-booster", "Stargate", "Ecstatic", and "Kryptonite" are being promoted for conditions which may cause them to be drugs as defined in the Federal Food, Drug, and Cosmetic Act. These products may also be considered new drugs, which may not be legally marketed in the U.S. without prior approval from FDA. Therefore, the sale and distribution of these products 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 these products are labeled as containing potent herbal mixes, bearing names that are intended to promote the products as alternative illicit street drugs. Examples include in part: "E-booster" containing 740 mg. Ma Huang extract, Stargate" containing 400 mg. Ma Huang extract and 166 mg. of euphoric herbal mixture, "Ecstatic" containing Yohimbine, Tribulus terrestris and Maca, among other herbs like Ginseng, and Muira puama, and "Kryptonite" containing 350 mg. Sida Acuta extract, 100 mg. Rivea Corymbosa seeds (powdered), 100 mg. Maytenus Ehrifolia extract, 25 mg. Phenylalanine, 25 mg. L-Tyrosine, and 12 mg. Pyroglutamine. "E-booster" is identified in your promotional material as "a natural variation to the chemically fabricated and illegal substance MDMA...." and "Kryptonite" is promoted as producing a mind-altering (psychedelic) effect, while "Final E" is the next generation "Herbal Ecstasy."

These street drug alternative claims do not fall within the scope of claims permitted for dietary supplements. These products, inter alia, are not used to supplement the diet, and therefore may not be considered to be dietary supplements. Furthermore, these products are offered for abuse as narcotic substitutes. As such, there does not appear to be any legitimate drug use for these products and the continued sale of them as narcotic substitutes to U.S. citizens may be illegal.

The agency is taking steps to warn our citizens that products that mimic the effects of illicit controlled substances, promoted and sold 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. 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.

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 Nychis@CDER.FDA.GOV. You may also provide a written response via fax at (301) 594-0165 or hard copy letter to the letterhead address. FDA may be reached by telephone at (301) 594-0063.

Sincerely yours,

/s/

Betty L. Jones
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration