HFD -205

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 25 1997

Warning Letter

Ref: No. 97-HFD-310-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chief Executive Officer
Baxamed
Haupstrasse 4
CH - 4102 Sinningen
Switzerland

Dear Chief Executive Officer:

The United States Food and Drug Administration (FDA) has been informed that your firm has solicited citizens in the United States to purchase unapproved prescription drugs, examples include Somatropin. These drugs may not be legally marketed in the United States, and therefore your activities are in serious violation of the Federal Food, Drug, and Cosmetic Act.

The Food and Drug Administration considers these drugs to be in violation of Title 21 United States Code (U.S.C.) 355(a) because they are new drugs without approved new drug applications. In addition, these prescription drugs are misbranded, as they lack English language labeling and adequate directions for use as described under Title 21 U.S.C. 352(f)(1).

The Food and Drug Administration does not permit the personal importation of drugs when: 1) When shipments are commercial; 2) when they are promoted to persons residing in the United States; 3) when approved versions of these drugs are presently available in this country; and 4) when they pose an unreasonable risk to public health.

We are taking steps to warn our citizens that these drugs are not approved for marketing in this country and may not be legally imported. By this letter we are advising the regulatory drug officials in the countries from which you operate of these violations. We have advised other federal officials through an Import Alert that all shipments found entering the United States as

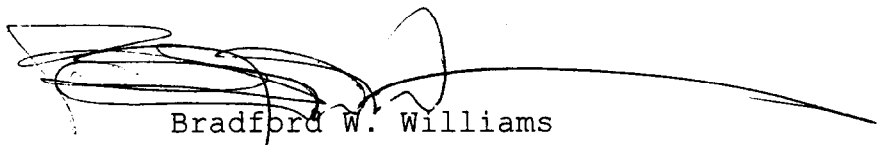
a result of such activities shall be automatically detained and refused entry.

The violations listed above are not intended to be all-inclusive.

Within 15 working days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these serious violations.

Your reply should be addressed to Mr. Donald L. Leggett at the above address. You may also contact us at (301) 594-0063.

Sincerely,



Bradford W. Williams
Director
Division of Labeling and NonPrescription
Drug Compliance, HFD-310
Office of Compliance
Center for Drug Evaluation and Research

Attachment
Import Alert/Press Release

cc:
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