HFD-310 Assgnmt file

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 4 1998

WARNING LETTER

Cheminova International, S.A.
Macarena, 14
28016 Madrid, Spain

Ref: 98-HFD-310-01

Dear Chief Executive Officer:

The United States Food and Drug Administration (FDA) has been informed that your firm is soliciting the citizens of the United States to purchase SKIN-CAP drugs. These drugs may not be legally marketed in this country, and, therefore, your activities are in serious violation of the Federal Food, Drug, and Cosmetic Act.

The FDA 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 drugs are misbranded in that they lack adequate directions for use [Title 21 U.S.C. 352(f)(1)].

The FDA does not permit the personal importation of drugs when: 1) they are promoted to persons residing in the United States; and 2) 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 also advising the regulatory drug officials in the countries from which you operate of these violations.

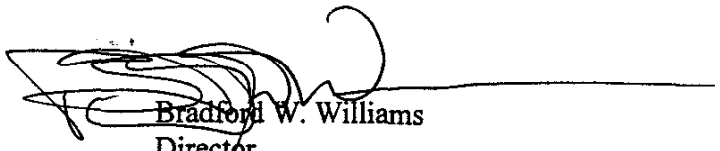
We have advised other federal officials through an Import Alert that all shipments found entering the United States as a result of such activities shall be automatically detained and refused entry.

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

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

Your reply should be addressed to this division.

Sincerely,



Bradford W. Williams
Director
Division of Labeling and Nonprescription
Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research

Enclosure:
Import Alert/Press Release