



WARNING LETTER

JUL 26 1999

Ref. No. 99-HFD-310-05

Glebe Apothecary
778 Bank Street
Ottawa, Ontario
K1S3V6
Canada

Dear Chief Executive:

We have evidence that your firm is soliciting the citizens of the United States to purchase various unapproved prescription drugs. For example, those versions of Claritin (loratadine) and Allegra (fexofenadine) which you offer are limited to prescription in the U.S. and differ from those approved for marketing. These drugs may not be legally marketed in this country, and, therefore, your activities are in 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 appear to be misbranded because 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; 2) the drugs are available from approved US sources, and/or 3) 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. With copies of 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 your activities shall be automatically detained and refused entry.

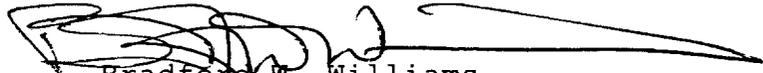
Please notify this office in writing within fifteen (15) working days from the receipt of this letter as to the specific steps you intend to take to correct these violations.

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Your reply should be addressed to the following:

Donald L. Leggett
United States Food and Drug Administration
7520 Standish Place
Room 168/HFD-316
Rockville, Maryland 20855

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