



m 30801

Food and Drug Administration  
Rockville MD 20857

OCT 22 1999

**WARNING LETTER**

4nRx  
P.O. Box 863  
Otego, New Zealand

Ref. No. 99-HFD-310-10

Dear Chief Executive:

We have evidence that your firm is soliciting the citizens of the United States to purchase various unapproved prescription drugs. Those drugs which you offer are limited to prescription in the U.S. and differ from those approved for marketing. Our personal use importation policy does not provide for the entry of unapproved versions of drugs marketed in this country. 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.

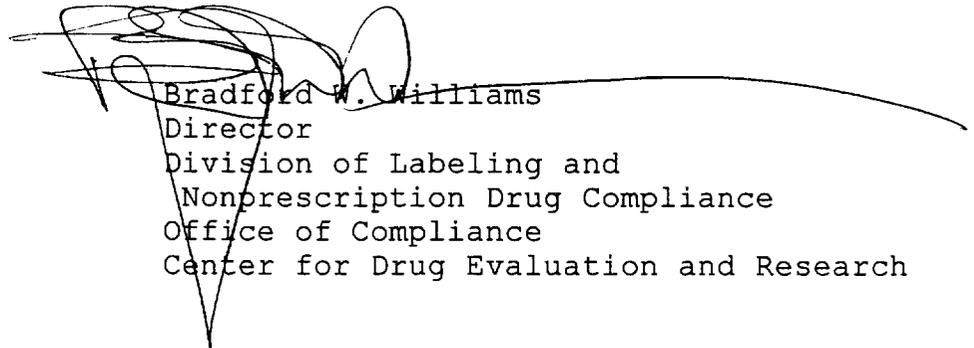
Please notify this office in writing within fifteen (15) working days from the receipt of this letter as to the specific steps you intend to take to correct these violations.

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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