



M30710

Food and Drug Administration
Rockville MD 20857

OCT 20 1999

WARNING LETTER

Servicios Medicos Internacionales de Mexico
A.k.a. SMI A.k.a. MexRx
4735 Clairemont Square
PMB #321
San Diego, California 92117-2704

Ref. No. 99-HFD-310-07

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 drugs which you offer on your Internet site, <http://www.mexrx.com>, are limited to sale by prescription in the U.S. and differ from those approved for U.S. marketing. These drugs may not be legally marketed in this country without an approved New Drug Application (NDA), 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 Mexico of these violations.

We may advise 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.

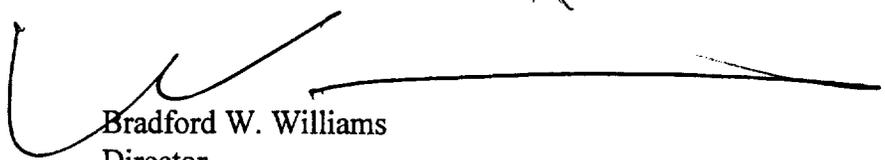
Please notify this office in writing within fifteen (15) working days from the receipt of this letter as to the specific steps you intend to take to correct these violations.

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Your reply should be addressed to the following:

United States Food and Drug Administration
7520 Standish Place
Rockville, Maryland 20855

Sincerely,

A handwritten signature in black ink, appearing to read 'Bradford W. Williams', with a long horizontal flourish extending to the right.

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