DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

91263d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

MAY 15 2001

Mr. Joe Hepworth, President
SnorBan (UK)
PO 294, Chichester
West Sussex PO18 9QU
ENGLAND

Re: SnorBan ®Mouthpiece

Dear Mr. Hepworth:

The United States Food and Drug Administration (FDA) has documented your firm's distribution of the SnorBan® mouthpiece in the United States. Your firm is offering that product for sale on the Internet site http: www.snorban.co.uk. As detailed below, SnorBan® is a medical device that requires marketing clearance and, without such clearance, it may not be legally marketed in the United States.

SnorBan® is a device as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act). The Act defines a "device," among other things, as an "instrument, apparatus, implement, machine, [or] contrivance . . ., which is intended to affect the structure or any function of the body of man . . . ." SnorBan® is intended to relieve snoring and sleep apnea, and therefore it is intended to affect the function of the body.

SnorBan® is adulterated under section 501(f)(1)(B) of the Act. The device has been classified under section 513(f) of the Act into class III, and under section 515(a) it requires an approved premarket application or an exemption from section 515 under section 520(g). No such approval or exemption is in effect. SnorBan's status as an adulterated device has been litigated between the United States government and Snoring Relief Labs, Inc. and its president, David Snyder. In 1997, the United States Department of Justice, on behalf of FDA, filed a seizure action against the SnorBan® device. That lawsuit resulted in a decision by the United States District Court for the Eastern District of California that SnorBan® is adulterated under section 501(f)(1)(B) of the Act. The District Court's decision has been affirmed by an appellate court. Distribution of SnorBan® in interstate commerce is a violation of the Act.

The SnorBan® device is also misbranded. FDA considers SnorBan® to be a prescription device and therefore adequate directions for use cannot be written for safe use of this device by a layman. As a prescription device, SnorBan® is not exempt from the regulatory requirements, as described in Title 21 of the Code of Federal Regulations, section 801.109. Therefore SnorBan® is also misbranded within the meaning of section 502(f)(1) of the Act because its labeling does not bear adequate directions for use.

We are taking steps to warn our citizens that this device has not been cleared for marketing in this country and may not be legally imported. With copies of this letter, we are advising the regulatory device officials in the United Kingdom of these violations.

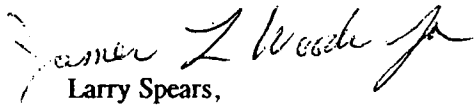
Given the serious nature of the violations, the product may be detained upon entry into the U.S. until the violations are corrected. Further, SnorBan devices can be seized and those participating in the devices' U.S. distribution may be subject to injunction or criminal prosecution without further notice.

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

Your response should be addressed to Mr. Ronald L. Swann, Dental, ENT, and Ophthalmic Devices Branch, at the address listed below:

Food and Drug Administration
Dental, ENT & Ophthalmic Devices Branch
2094 Gaither Road, HFZ-331
Rockville, MD 20850

Sincerely yours,



Larry Spears,
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

Snoring Relief Labs.
4007 Pretense CT.
Fair Oaks, California 95628

Snoring Relief Labs., Inc.
1140 Sunrise Gold Circle #7
Rancho Cordova, CA 95742