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AUG 14 2001

WARNING LETTER
VIA EXPRESS MAIL

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

Dr. Steven K. Sue
President
Nose Breathe
P.O. Box 10515
Honolulu, Hawaii 96815

Dear Dr. Sue:

This letter is in response to your March 14, 2001, letter in which you replied that "the Nose Breathe Mouthpiece for Heavy Snorer (NBM/HS) is not a medical device." You also state in your letter that you "have a disclaimer to the product" which states your "products and information are not intended to diagnose, prescribe, or replace the need for medical consultation; or prevent or treat medical conditions or disease."

The Center for Devices and Radiological Health (CDRH) has determined that your response is not adequate. Under a United States Federal law, of the Federal Food, Drug, and Cosmetic Act (Act), the NBM/HS is a device as that term is defined by section 201(h) of the Act. The Act defines a "device", as an "instrument, apparatus, implement, machine, [or] contrivance..., which is intended to affect the structure or any function of the body of man..." NBM/HS is intended to relieve snoring and therefore it is intended to affect the function of the body.

The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering the NBM/HS for sale. The kind of information you need to submit in order to obtain this clearance can be sent to you by contacting our Division of Small Manufacturers Assistance (DSMA) at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>. The FDA will then evaluate your information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the NBM/HS is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

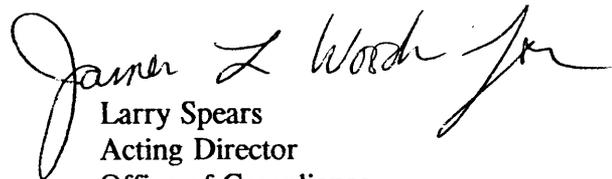
It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to:

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

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting DSMA.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Ernest N. Smith at (301) 594-4613.

Sincerely yours,



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

Enclosure