



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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NOV 18 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

**WARNING LETTER via
Overnight Delivery**

Mr. John Fisher
Owner
Nature's Way
1300 Augusta Road
West Columbia, South Carolina 29169

Re: Ear Candles

Dear Mr. Brown:

We are writing to you because on March 5, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as "Ear Candle," which is marketed and distributed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or 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.

Please be aware that the FDA has determined that similar products known as "Ear Candles" are dangerous to health when used in the manner suggested in the catalog, and thus are misbranded under, section 502(j) of the Act.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described in the enclosed [Premarket Notification 510(k)] materials. The FDA will evaluate this 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 product 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 send a copy of your response to the District Director, Atlanta District, Food and Drug Administration, 60 Eighth Street NE, Atlanta, GA 30309. We request that any action being taken to remove this product from the market be reported to the above mentioned District Office.

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 our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

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. Ronald L. Swann, Dental, ENT and Ophthalmic Devices Branch, HFZ-331, at the letterhead address.

Sincerely yours,


Lillian J. Gill

Director
Office of Compliance
Center for Devices and
Radiological Health