

HFI - 35



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

NOV 21 2002

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Tracy Campbell
President
Elanra.com, Inc.
778 Poppy Rd.
San Marcos, CA 92078

7447 East Quien Sabe Way
Scottsdale, AZ 85262

7832 Soaring Eagle Way
Scottsdale, AZ 85262

RE: Elanra Therapeutic Ionizers

Dear Mr. Campbell:

We are writing to you because we are in receipt of information from your firm's website, <http://www.elanra.com>, that indicates your firm is marketing the above referenced product in the United States for providing "major benefits for asthma, sinus, hay fever, allergies, depression, emphysema, CFS, CS, fibromyalgia, and migraines." Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is intended for use in the diagnosis or treatment of a medical condition or to affect the structure or function of the body (Section 201(h) of the Act.)

The law requires that the manufacturer or the distributor 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 both safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of our records has determined that there is no premarket clearance or approval in effect for the device you are offering for sale in this country. The kind of information you need to submit in order to obtain this clearance is described on the agency's Internet website at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate this information and decide whether your product may be legally marketed in this country.

Because your therapeutic ionizer devices do not have marketing clearance or approval from FDA, marketing them in this country 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 is a serious violation of the law and 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.

Given the serious nature of these violations of the Act, these therapeutic ionizer devices may be detained without physical examination upon entry into the United States until these violations are corrected.

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:

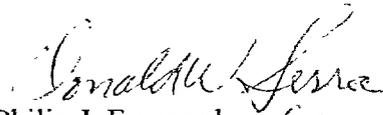
James W. Eisele
U.S. Food and Drug Administration
CDRH, Office of Compliance
OPMADB, HFZ-343
Center for Devices and Radiological Health
2098 Gaither Rd.
Rockville, MD 20850

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

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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 James Eisele at (301) 594-4659.

Sincerely yours,



Philip J. Frappaolo *for*
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Copy to:

President
Bionic Products Pty., Ltd.
63 Manly Dr.
P.O. Box 555
Robina, Queensland, Australia 4226