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HFI - 35 7/7/98

JUN 11 1998
WARNING LETTER

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Certified Letter
Return Receipt Requested

•Mr. James J. Souder
Norso Biomagnetics, Inc.
4105 Starboard Court
Raleigh, North Carolina 27613

Dear Mr. Souder:

Information has come to our attention that your firm designs, manufactures, and markets biomagnetic products. These products are labeled and/or promoted for conditions, such as: lumbar and low back discomfort, swollen or painful joints, tendonitis, asthma, bronchitis, motion sickness and nausea, stress and anxiety, sinus congestion, TMJ syndrome, chronic joint or muscle conditions, repetitive motion injuries of the wrist and hand, damaged cartilage, post polio pain, arthritis, hot flashes, deep discomfort in the hip, back and legs, exogenous poisoning, soft tissue inflammation, osteoporosis, Parkinson's disease, epilepsy, multiple sclerosis, cancer, diabetic ulcers, joint disease, cervical spondylosis, painful feet, bone spurs, gout, plantar fasciitis, painful teeth and gums, fever blisters, menstrual cramps, GI irritation, ganglion cysts, muscle strains, bruises, muscle spasms, fibromyalgia, and migraine, cluster, tension, and chronic headaches. The products are also labeled and/or promoted for purposes which included: reducing swelling and inflammation, speeding healing, relieving pain and strengthening strained tendons and ligaments, preventing heart disease, reversing osteoporosis, slowing tumor growth, boosting mental function in Alzheimer's patients, slowing deterioration of cartilage inside arthritic joints, helping to prevent violent allergic reactions, speeding healing of stubborn fractures, and treating wrinkles, scars, and blemishes.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), your firm's biomagnetic products are considered to be medical devices because they are intended to be used in the cure, mitigation, treatment, or prevention of disease, and because they are intended to affect the structure or function of the body. The law requires that manufacturers of devices such as these obtain marketing clearance for their products from the United States Food and Drug Administration (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 your products for sale. The kind of information you need to submit in order to obtain this clearance is described in the enclosed 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, your devices are misbranded under section 502(o) because premarket notifications were not submitted as required by section 510(k) of the Act. Until your firm receives notice from the Center for Devices and Radiological Health clearing your devices for commercial distribution or they are reclassified, they are also adulterated within the meaning of section

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501(f)(1)(B) of the Act, because they are classified into Class III under section 513(f) and do not have approved applications for premarket approval as required by section 515(a) or an approved application for an investigational device exemption under section 520(g) of the Act.

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:

Donald W. Serra
Food and Drug Administration
Cardiovascular and Neurological Devices Branch, HFZ-341
2098 Gaither Road
Rockville, Maryland 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 and about petitioning FDA for the reclassification of 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 Donald W. Serra at (301) 594-4648.

Sincerely yours,



William J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: As stated.