



OCT 11 2000

WARNING LETTERVIA FEDERAL EXPRESS

Mr. Terry W. Schwalenberg
Director, Quality Assurance & Regulatory Affairs
Norland Medical Systems, Inc.
W6340 Hackbarth Road
Fort Atkinson, Wisconsin 53538

Dear Mr. Schwalenberg:

We reviewed the July 28 letter from Ms. M Elizabeth Bierman regarding labeling issues related to the Orbasone™ Therapeutic Vibrator (Orbasone™), a device marketed by Norland Medical Systems, Inc. (Norland). We also reviewed your website for the Orbasone™ at <http://www.norland.com>. In the July 28 letter, Ms. Bierman noted that Norland had removed all the objectionable claims from the labeling for the Orbasone™, and from their website. She also noted that Norland had taken steps to ensure that sales representatives and distributors were aware that the Orbasone™ can only be marketed for general pain relief without reference to specific sites on the body.

Our review of your revised labeling for the Orbasone™ enclosed with the July 28 letter and your website shows that they still reference the following: "Muscle, tendon and ligament pain can affect your overall health, comfort and attitude. Whether the pain affects soft tissue in your heel, knee, shoulder or elbow area, it is hard to concentrate and perform even the simplest everyday tasks when pain is present. The Orbasone (TM) can be used to offer your patients a treatment designed to provide soft tissue relief."

We understand that you market the Orbasone™ as a therapeutic vibrator. Therapeutic vibrators have been classified under Title 21 Code of Federal Regulations (21 CFR) 890.5975 as class I devices that are exempt from the premarket notification requirements in subpart E of 21 CFR part 807. When marketed as such, the devices in this generic category are "...intended for various uses, such as relaxing muscles and relieving minor aches and pains."

The Orbasone™ is being marketed for a different intended use than the devices classified in 21 CFR 890.5975, which may only be marketed for general relaxation and minor pain relief. Because the specific claims on your labeling and website indicate a different intended use and utilize a different fundamental scientific technology than the therapeutic vibrators, the Orbasone™ is not exempt from premarket notification requirements. Without this exemption, you do not have marketing clearance from the Food and Drug Administration (FDA) and marketing your product is a violation of the law. The legal requirements of the Federal Food Drug and Cosmetic Act (Act) state that the product is adulterated under section 501(f)(1)(B) because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is also misbranded under section 502(o) of 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 the 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 and how you plan to prevent this from happening again. We also ask that you explain what actions you plan to take with regard to Orbasone™ units that have already been distributed in the U.S.

If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Edgardo Santiago, Chief, Orthopedic, Physical Medicine and Anesthesiology Devices Branch, HFZ-343, Division of Enforcement III, Office of Compliance at the address in the letterhead.

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 the Orbasone™ 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>.

A copy of this letter is being sent to FDA's Minneapolis District Office. Please send a copy of your response to District Director, Food and Drug Administration, Minneapolis District Office, HFR-CE300, 240 Hennepin Ave., Minneapolis, MN 55401

If you have questions about the contents of this letter, please feel free to contact Mr. Santiago at (301) 594-4659, extension 109.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices
And Radiological Health