



September 29, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER

CHI-31-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert W. Sessions, President
Ferris Manufacturing Corporation
16W300 83rd Street
Burr Ridge, IL 60521-5848

Dear Mr. Sessions:

We have received information that reveals a serious regulatory problem involving your products known as Ferris Pain Pad[™] and Ferris Pain Wrap[™].

Under the Federal Food, Drug, and Cosmetic Act (the Act), Section 201(h), these products are defined as medical devices because they are used to diagnose or treat a medical condition, or to affect the structure or function of the body.

The Act requires that manufacturers of medical devices obtain marketing clearance from the 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 or effective, or substantially equivalent to other devices already legally marketed in this country.

Our records show that FDA's Center for Devices and Radiological Health (CDRH) sent your firm a letter (attached), dated January 13, 2000, addressed to Mr. Theodore R. Thorsen, Director, Quality Assurance. This letter indicated that CDRH reviewed your Section 510(k) notification of intent to market the Ferris Pain Pad[™] and determined that the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device that has been classified into Class I (General Controls) or Class II (Special Controls). The CDRH letter indicated that the Ferris Pain Pad[™] is classified by statute into class III (Premarket Approval), under Section 513(f) of the Act. The CDRH letter indicated Section 515(a)(2) of the Act requires a Class III device to have an approved premarket approval application (PMA) before it can be legally marketed, unless the device is reclassified. The CDRH letter also indicated that any commercial distribution of the Ferris Pain Pad[™] before FDA approval of a PMA, Product Development Protocol (PDP), or the effective date of any order by FDA reclassifying this device into Class I or II would be a violation of the Act.

Because the Ferris Pain Wrap™ is a version of the Ferris Pain Pad™ that is intended to be placed on different parts of the body, the Ferris Pain Wrap™ is also classified by statute into Class III (Premarket Approval), under Section 513(f) of the Act. Section 515(a)(2) of the Act requires a Class III device to have an approved premarket approval application (PMA) before it can be legally marketed, unless the device is reclassified.

Our records do not show that you have submitted a PMA for the Ferris Pain Pad™ and the Ferris Pain Wrap™. The information that we received indicates that you have started commercial distribution of these devices. Because you do not have marketing approval from FDA, commercial distribution of these devices is a violation of the law. In legal terms, these devices are adulterated under Section 501(f)(1)(B) of the Act. Your devices are 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.

You should know that this serious violation of the law may result in FDA taking regulatory actions without further notice. These actions may include, but are not limited to, seizing your product inventory, obtaining 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 15 working days from the date you receive 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 Michael Lang, Compliance Officer.

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 approval for your Ferris Pain Pad™ and Ferris Pain Wrap™ and does not necessarily address other obligations you have under the law. It is your responsibility to ensure adherence to each requirement of the Act and regulations. If you determine that your systems caused the problems, you must promptly initiate permanent corrective actions. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturer's

Page 3

Assistance at 800-638-2041 or through the Internet at <http://www.fda.gov>. If you have any questions regarding this letter, please contact Mr. Lang at 312-353-5863 x171.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Attachment

cc: Theodore R. Thorsen
Director, Quality Assurance
Ferris Manufacturing Corporation
16W300 83rd Street
Burr Ridge, IL 60521-5848