



Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

May 26, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marc S. Jensen, President
Nortrade Medical, Inc.
9382 South 670 West
Sandy, Utah 84070

DEN-99-08

**REVIEWED
NOTHING PURGED**

Dear Mr. Jensen:

We are writing to you because on January 15, 25, and February 23, 1999, Investigator Juan A. Morales, from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving your BURNFREE products, including BURNFREE Pain Relieving Gel, BURNFREE Sterile Burn Dressing, and Hydrogel Survival Fire/Trauma Blankets, which are marketed by your firm.

Under United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are 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 ensure that the products they market are labeled correctly and adequately.

Your products are misbranded within the meaning of the Act, Section 502(a), in that your labeling is false and misleading because your product labels, literature, and website at <http://www.burnfree.com> make the following claims:

- "...protects the wound from infection." This claim is found on your flyer "ALL TOO OFTEN, RECIPES CALL FOR *BURNFREE* !" The claim has not been cleared for your devices.
- "...Lessen the pain and emotional trauma of a burn injury." This claim is found on your flyer "Burnfree Makes the Choice Simple," and has not been cleared for your devices. To claim pain reduction for a hydrogel product, you must modify the claim with statements such as "by cooling the wound site," as you have done elsewhere on your labeling and literature. Pain reduction is a very subjective endpoint that is hard to state clearly without some type of study.

- "Non-irritating." This claim is found on all your product labels and your flyer "Burnfree Makes the Choice Simple." The claim has not been cleared for your devices, and requires the successful completion of an irritation study.
- "Bacteriostatic." This claim is found on your flyer "Burnfree Makes the Choice Simple." It has not been cleared for your devices, and your test data shows your products are not bacteriostatic.
- "...use on all types of burn injuries." This claim is found on your flyer "Burnfree Makes the Choice Simple." Your devices are cleared for first and second degree burns only. Your labeling must be modified by stating that your products are for use on "first or second degree burns" or "minor burns."

For your information, the same claims are found on your website noted above.

Our records do not show that you obtained marketing clearance through the 510(k) process prior to making the above claims for your products. The information you need to submit in order to obtain use these claims is the same as you have used previously to obtain your 510(k)s.

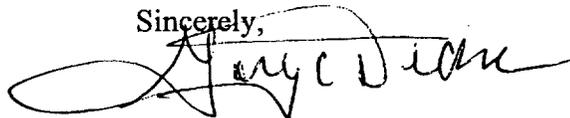
This is a serious violation of the law, which may result in FDA taking regulatory action without further notice to you. Regulatory sanctions we have available include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your products, or assessing 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 receive this letter as to the steps you are taking to correct the problem. We request 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 Shelly L. Maifarth, Compliance Officer, at the address above.

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 labeling 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 Ms. Maifarth at (303) 236-3046.

Sincerely,



Gary C. Dean
District Director

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