



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Detroit District Office
Central Region
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: (313) 226-6260
FAX: (313) 226-3076

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER

00-DT-13

March 8, 2000

Edward Burford, President
Oxygen Therapy Institute
4851 Keller Springs Road, Suite 211
Dallas, Texas 75248-5928

Dear Mr. Burford:

We are writing you because on December 1 - 22, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the "Berman Resusi CPR Mask". This product is made and marketed by your facility located at 11800 Belden Court, Livonia, Michigan 48150.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (Act), this product is considered to be a medical device because it is 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 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 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 product 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, 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.

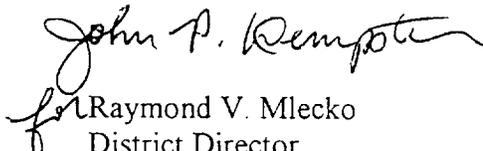
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue 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 Ms. Kathleen M. Lewis, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Avenue, Detroit, Michigan 48207.

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 Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific question about how FDA marketing requirements affect your particular device, or need any technical assistance, please feel free to contact our Medical Device Experts James E. Szalc at 313-226-6260 extension 151 or Eric Joneson at extension 113. Questions specifically related to this letter may be addressed to Ms. Lewis at extension 178.

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District

cc: Robert J. Donohue, Plant Manager
Oxygen Therapy Institute
11800 Belden Court
Livonia, Michigan 48150