



MST407

FEB 12 2001

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Certified Mail
Return Receipt

WARNING LETTER

Lin Kenny, President
Bioray, Inc.
9220 A1 Parkway East
Birmingham, Alabama 35206

Dear Mr. Kenny:

We are writing to you because the Food and Drug Administration (FDA) obtained information from your internet web site www.rifeworks.com that revealed a serious regulatory problem involving the "Bioray Sound and Light Generator" which is marketed by your firm.

Under a United States 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. See section 201(h) of the Act. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are 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 the Bioray Sound and Light Generator for sale in the United States. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from the FDA, marketing your product is in 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.

Page 2 - Mr. Kenny

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.

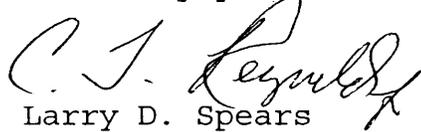
Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. 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 Louis Kaufman, HFZ-320, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 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 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 Mr. Kaufman at (301) 594-4598 x 179.

Sincerely yours,



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