



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CST Purged 11/27/97
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[Signature]

JUL 15 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Warning Letter

Certified Mail
Return Receipt

Mr. Bruce Livingston
President
Boyd Industries, Inc.
Podiatric Products Division
12275 75th Street North
Largo, Florida 33773-3031

Dear Mr. Livingston:

We are writing you because on March 24, 1997, Cory Tylka of my staff spoke with you regarding your firm's advertised Aqua Spray podiatric device. During the conversation you stated that the Aqua Spray does not have marketing clearance from the Food and Drug Administration (FDA), due to a misunderstanding of the medical device regulations.

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.

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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, 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 inform this office within 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 submit your response to: Director, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland, 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 phone: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website 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 call Ms. Cory Tylka of the General Surgery Devices Branch at (301) 594-4595, or FAX: (301) 594-5636.

Sincerely yours,

for 
Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

enclosure