



Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98041-3012

March 2, 1999

Telephone: 425-486-8788
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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-09

Thomas H. Charters
President
T.H. Charters, Inc.
9985 SW Heather Lane
Beaverton, Oregon 97008

WARNING LETTER

Dear Mr. Charters:

On January 11-13, 1999, Engineer Neil F. Sheller collected information that revealed a serious regulatory problem involving the product called the Precision Current Source (PCS) which is manufactured by your firm for [REDACTED]. This device is intended for use in the mouth to stimulate bone growth and as an antibacterial.

The Federal Food, Drug, and Cosmetic Act (Act), United States Federal law, considers this 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 manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration 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.

You have claimed that the PCS is exempt from premarket notification under 21 Code of Federal Regulations, sections 807.85(a) and (a)(2). Section 807.85(a) states, in part, "A device is exempt from premarket notification requirements . . . if the device . . . is not generally available in finished

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form. . ." Devices for promotion of bone growth are *generally available* in finished form and are considered Class III devices. Section 807(a)(2) states, in part, that a device is exempt if it, "is intended solely for use by a physician or dentist. . .and is not generally available to, or generally used by, other physicians or dentists. . ." Although the PCS is intended solely for one physician [REDACTED], there are devices on the market *generally available* and *generally used* for the intended use of bone growth stimulation. Hence, because other devices are generally available for the same intended uses as the PCS, the PCS cannot qualify for premarket exemption under this section of the regulations.

Marketing your product is a violation of the law until you have marketing clearance from FDA. 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.

This is a serious violation of the law and 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. 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.

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 and additionally, what actions you have taken to remove the PCS devices, which are violative products, from the market. 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 Thomas S. Piekarski, Compliance Officer, at the above mailing address.

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>.

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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 Ronald L. Swann, Center for Devices and Radiological Health, 301-594-4613, ext. 109.

Sincerely yours,

Roger L. Lowell
Roger L. Lowell
District Director

Enclosure:
Premarket Notification

cc: 