



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

2077 '00 JUN 30 A9:47

JUN 23 2000

Mr. Michael Treas
Director of Regulatory Affairs
Chattanooga Group, Inc.
P.O. Box 489
4717 Adams Road
Hixson, Tennessee 37343

Re: Docket No. 00P-1279
Electrical Muscle Stimulators

Dear Mr. Treas:

This responds to your citizen petition, dated April 27, 2000, requesting a variance from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for your firm's electrode lead wires and patient cables. While not specifically stated in your petition, we understand that your lead wires and cables are used with electrical muscle stimulators. The rationale for your request is that your firm has experienced delays in obtaining from vendors the components needed for your retrofit kit and adapter kit. You requested an extension until July 9, 2000 for compliance with the performance standard.

I am granting your petition, in part, as it applies to the continued use of non-compliant lead wires. User facilities may continue to use their existing non-compliant lead wires with their Chattanooga muscle stimulators until July 9, 2000.

I am denying your petition as it regards further manufacturing and distribution. Your firm and your dealers may not distribute non-compliant lead wires and cables. The performance standard was first published in the Federal Register over three years ago, and FDA sent a copy to all device manufacturers (including your firm) in March of 1998. We believe there has been sufficient time for your firm to have developed and implemented a solution.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

00P-1279

PAVJ