

CITIZEN PETITION

DATE: April 27, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23,
12420 Parklawn Drive
Rockville, MD 20857

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to extend the lead wire compliance deadline of May 9th, 2000 to July 9th, 2000, for Chattanooga Group, Inc., 4717 Adams Road, Hixson, Tennessee 37343-0489 along with Chattanooga Group Dealers and Chattanooga Group Customers.

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A. Action requested

- 1) This petition requests an extension to 21 CFR, 898.13, Compliance Dates for "electrode lead wires and patient cables used with or intended for use with, or any other device, the date for which compliance is required is May 9, 2000".
- 2) Extension of compliance deadline to July 9, 2000

B. Statement of grounds

This variance request is due to the fact that we rely on vendors to supply components necessary for our retrofit kit and/or adapter kit, which are necessary to meet the 21 CFR Regulations on Patient Lead Wire Compliance. We have experienced a difficult time sourcing some of the components at reasonable pricing. Some of these components are specially designed items that are not common off the shelf components. Most of the components are supplied by international suppliers and the delivery lead times are longer than expected. We expect that we would be better prepared for customer and dealer demands if we were allowed more time for our suppliers to manufacture and ship the components we need. Our customers and dealers rely on us to incorporate a fix to this requirement. Therefore, this request is also for a deadline variance for those who sell or use equipment manufactured by Chattanooga Group, Inc.

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C. Environmental impact

In our opinion, there would not be a measurable environmental impact as a result of a variance extending the time deadline for compliance to 21 CFR Regulations on Patient Lead Wire Compliance.

D. Economic impact

Not required unless requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature on behalf of Chattanooga Group, Inc.



Name of Petitioner: Chattanooga Group, Inc.

Mailing Address: P.O. Box 489
4717 Adams Road
Hixson, Tennessee 37343

Contact Person Michael Treas

Telephone (423) 870-7218

Facsimile (423) 870-7402



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 Company CHATTANOOGA GROUP INC
 Address 4717 ADAMS RD
 City HIXSON State TN ZIP 37343

2 Your Internal Billing Reference

3 To Recipient's Name Dockets Management Branch Phone 301 5944646
 Company Food and Drug Administration
Dept. of Health and Human Services
 Address Room 123
12420 Parklawn Dr.
 City Rockville State MD ZIP 20857



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