



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

0597 '00 JUN -8 P1 39
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2000

William T. Woncheck, Jr.
Sikov & Woncheck PC
1625 Union Avenue
Plaza 5, Suite 5
Natrona Heights, Pennsylvania 15065

Re: Docket No. 00P-1240

Dear Mr. Woncheck:

This responds to your citizen petition, on behalf of CPR Medical Products, dated April 7, 2000, and your follow-up addendum, dated May 15, 2000. We understand that CPR Medical Products (CPR) is a distributor of 63 different types of muscle stimulators and nerve stimulators from 28 different manufacturers. CPR is requesting a temporary variance from the Performance Standard for Electrode Lead Wires and Patient Cables to allow time to obtain and install lead wire adapters and new compliant lead wires on all units they have rented or sold to device users. The amended petition requests three years to convert all existing devices, and notes that at the time of submission, no adapters were available. However, in a follow-up telephone conversation with Mr. Fran Constantino of CPR on May 23rd, Mr. Stewart Crumpler, in our Office of Compliance, identified several sources of adapters for the type lead wires connectors identified in your petition. Mr. Constantino acknowledged that adapter suppliers have been identified; however, he has had difficulty in arranging for the timely delivery of adapters, which are needed for required conversion of all devices.

I am granting your client a temporary variance until November 9, 2000. A three-year period to effect compliance, beyond what the agency has already provided when it publicly announced the standard on May 9, 1997, (62 Federal Register 25497) is an unacceptably long period of time. You cited economic hardship and financial burden as the basis for your request. However, you did not provide any specific prohibitive cost information, and you offered no details regarding the joint or severable responsibilities of CPR and their customers for bearing the costs of conversion. In the meantime, CPR should continue to work with OEM device manufacturers and third-party suppliers to identify viable sources of adapters and lead wires. Mr. Crumpler is also available for additional consultation, if needed.

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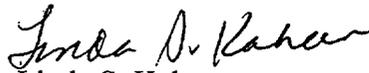
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During the next six months, CPR customers may continue to use their devices with unprotected lead wires while CPR is working to obtain and install the necessary adapters and new compliant electrode lead wires. However, healthcare facilities may not continue to use non-compliant lead wires indefinitely. Healthcare facilities must discontinue use of non-compliant electrode lead wires as soon as adapters and new compliant lead wires are received.

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

cc: Fran Constantine
CPR Medical Products
2840 Leechburg Road
Lower Burrell, Pennsylvania 15068