

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 22 2000

Mr. W. Tim Miller  
 Executive VP, Clinical Systems  
 IOMED, Inc.  
 3385 West 1820 South  
 Salt Lake City, Utah 84104

Re: Docket No. 00P-1319  
 Iontopheresis Devices

0659 00  
 JUN 26 19:46  
 HFI-001

Dear Mr. Miller:

This responds to your citizen petition, dated May 4, 2000, requesting a variance from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for electrode lead wires used with your firm's Phoresor Iontophoretic Dose Controller, Models PM600, PM700 and PM800. These devices use an electrical current for trans-dermal drug delivery to patients. The lead wire from the patient connects via a uniquely designed snap connector to an intermediate cable that is hard-wired into the dose controller. The snap connector does not comply with the performance standard, and there is currently no adapter available. You noted that in March 1999 your firm discontinued production of dose controllers with this non-compliant snap connector design. I also understand that as of May 9, 2000, you have discontinued further distribution of replacement lead wires with the snap connector, pending our decision on your variance request. Your petition asks for a variance from the performance standard for up to five years, to permit continued use of the non-compliant lead wires, and to permit your firm to replace customer lead wires during that time frame. If lead wires cannot be used or replaced, the customer would need to purchase a new device at a cost of approximately \$995 each. You estimated that as many as 7000 devices may be affected.

I am granting your petition in part as it applies to continued use of existing lead wires distributed to user facilities prior to May 9, 2000. Since there is no readily available adapter for these devices, user facilities may continue to use their existing non-compliant lead wires until May 9, 2003, or until a suitable adapter can be developed (whichever occurs first).

I am denying your petition as it regards further manufacturing and distribution of non-compliant lead wires. Your firm and your dealers may not distribute non-compliant lead wires and cables on or after May 9, 2000. In addition, I encourage you to further examine the design and production of an adapter for older devices. While there is no adapter available currently, there does not appear to be any technical reason why a short adapter cable cannot be developed to convert older devices to accept your new compliant lead wire connector. Since both the old snap connector and your new connector design are both readily available, a short adapter cable using these existing parts should be feasible. If your firm is not interested in creating such an adapter cable, there are several third-party lead wire vendors who might be interested in such a project.

00P-1319

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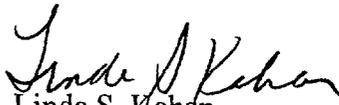
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As a condition of this variance approval, I ask that you prepare a notification letter to your current user facility customers. You should also provide them with a copy of this approved variance. Please make it clear that your customers cannot continue to use non-compliant lead wires indefinitely, and that they should consider whatever plans (if any) you may have regarding the development of an adapter. Your notification letter should issue to your customers within 15 days of your receipt of this letter, with a copy submitted to the Office of Compliance, HFZ-340, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, Maryland 20850.

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

cc:

HFA-224

HFA-305 (Docket No. 00P-1319)

HFR-SW200

HFZ-1

HFZ-215 (JSheehan, MHanna, Files)

HFZ-141 (RWalchle)

HFZ-300

HFZ-305 (Precedent Correspondence)

HFZ-340 (SCrumpler))

HFZ-343

HFZ-450 (BZimmerman)

Draft:ESCrumpler:5/31/2000

Review:CEUldriks 6/1/2000

Init:JSheehan:6/7/00

f/t:CFrye:6/20/00

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