DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

5199 MAR 2 AUG 2003 09:52

Mr. Mark J. Faillace
Senior Director, Clinical Regulatory Affairs
Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325-1219

Re: Docket No. 94P-0268

Dear Mr. Faillace:

This letter is an interim response to your petition dated July 11, 1994. In your petition, you request that the Food and Drug Administration (FDA), in accordance with § 601(8) (42 U.S.C. 7671(8)) of the Clean Air Act (CAA), amend § 2.125(e) (21 CFR 2.125(e)) to include the use of the MiniMed Implantable Pump (MIP) as essential and exempt from the CAA ban of products that contain Class I and Class II ozone-depleting substances. You state that the MIP utilizes Chlorofluorocarbon-113 (CFC-113), a Class I ozone-depleting substance (ODS). You also state that the MIP is being evaluated in human clinical trials under Investigational Device Exemption (IDE) G860065. Specifically, you request an interim exemption pending a decision on the petition.

Please excuse the delay in responding. A representative of your company contacted the Center for Devices and Radiological Health (CDRH) last year after finding a copy of the petition in your files but no response. It is not clear what happened after FDA received the petition in 1994 but we did a thorough search and did not find that we had issued a response. We, then, began a review of the petition. Since then, FDA has been in contact with representatives of your company concerning this petition and the review of your IDE. In the interim, your IDE continues to be in effect.

FDA issued a final rule amending § 2.125 on July 24, 2003 (enclosed). This rule went into effect on January 20, 2003. This has complicated the review of your petition. Therefore, we are unable to issue a final response to you at this time. We hope to be able to issue a final response to you in the next few months.

If you have any questions about your petition, please call Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely yours,

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

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