



Medtronic

MINIMED

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325-1219
Tel 800-933-3322
www.minimed.com

June 23, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061- HFA 305
5630 Fishers Lane
Rockville, Maryland 20852

Re: DOCKET No. 94P-0268, Petition for Essential Use Exemption from Sections 610(b) of the Clean Air Act

Dear Sir/Madame:

Medtronic MiniMed (aka MiniMed), is providing additional information regarding the above referenced petition submitted under section 601(8)(42 U.S.C.7671(8)) of the Clean Air Act to request the Commissioner of Food and Drugs to exempt its use from the ban set forth in section 604(b) of the Clean Air Act.

The MIP is unique in its design and performance features. The device is intended for use in those patients with insulin dependent diabetes mellitus who are resistant to subcutaneous insulin infusion or injection. Currently there is no other therapy available for patients who have difficulty in gaining glycemic control using standard methods of care.

The Medtronic[®] MiniMed[®] Implantable Pump (MIP) is currently under clinical investigation in the United States for the treatment of Type 1 (insulin-dependent) diabetes. Medtronic MiniMed has completed patient enrollment in the ongoing clinical trial and anticipates submitting a premarket approval application (PMA) by December 2004 - January 2005.

Use of CFC in the MIP

The drug reservoir in the MIP holds a two to three months supply of insulin and is filled and refilled by a physician. The reservoir is required to be maintained at a negative pressure. This negative pressure serves two important safety features:

- it allows the medication to be drawn into the reservoir of the implanted device without application of pressure to the syringe by the physician performing the

94P-0268

SUP 1

refill procedure. This ensures that the medication is delivered to the device and not by mistake to the patient directly; and

- it retains the medication drawn into the device drug reservoir in the unlikely event of a system valve failure.

CFC-113 was originally chosen for this device because it (i) has the necessary pressure characteristics, and (ii) has low toxicity

While the low toxicity of CFC-113 provides for additional patient safety, leakage of CFC from the MIP under ordinary usage is highly unlikely. The gas chamber of the device is hermetically sealed. Returned MIP devices are quarantined as hazardous material and stored for analysis without the need to compromise the hermetic chamber containing the CFC-113. Once analysed, the devices are sent to an approved disposal site and handled in accordance to EPA regulation and disposed of by a licensed hazardous materials processor.

Description of Change

In order to meet environmental and performance requirements, Medtronic MiniMed is in the process of replacing the use of Freon in the MIP with the non-CFC propellant Cyclopentane. Cyclopentane has been shown to have the same properties and performance as Freon and is widely used as a replacement for CFCs in both Europe and the United States. To date, Medtronic MiniMed has not been made aware of a Freon leak and the new version pump will be manufactured using the same validated manufacturing process as the previously approved devices. No design modifications to the device were required.

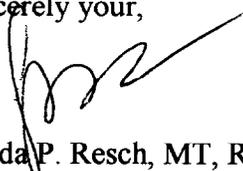
Conclusion

1. Medtronic MiniMed wished to inform the agency that we have completed enrollment of all subjects in our ongoing clinical trial (Protocol 310) and no more new implants are anticipated with *one possible exception*. In the event of a device failure, current subjects will be eligible for an immediate pump replacement.
2. Medtronic MiniMed is currently engaged in conducting the necessary verification and validation activities associated with switching the pump designs to use Cyclopentane.
3. Emergency pump replacements (mentioned in item 1, above) occurring prior to the completion of validation will involve CFC containing pumps. Pumps using Cyclopentane will be introduced once the verification and validation activities associated with the change are complete.

Food and Drug Administration
June 23, 2004
Page 3 of 3

If the agency requires additional information, please do not hesitate to contact Gerda Resch at 818-576-4198.

Sincerely your,



Gerda P. Resch, MT, RAC
Regulatory Affairs Manager
Medtronic MiniMed