



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Ombudsman
5600 Fishers Lane (HF-7)
Room 14B-03
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

April 9, 2001

Medtronic Drug Delivery
Medtronic, Inc.
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604

Re: Request for Designation (21 CFR Part 3)
Medtronic SynchroMed®
Our file: RFD 2001.004

Dear Ms. [redacted]

The Food and Drug Administration (FDA) has completed its evaluation of the above-referenced request for designation, received and filed on February 9, 2001. The request was supplemented by information dated March 13, 2001.

The request concerns the SynchroMed [redacted] a product that is intended for use as an accessory to the SynchroMed Infusion System (the "System"). The System itself is a Class III, fully implantable, microinfusion delivery device, approved under Premarket Applications to deliver various drug products by a variety of routes of administration. The [redacted] an external, hand-held device that is designed to communicate via telemetry with the System, is intended to "enable patients to direct the SynchroMed pump to deliver physician-prescribed supplemental doses of medication ..."

[redacted] the request for designation focused on the use of the Activator with morphine sulfate. Specifically, the request for designation was prompted by Medtronic's plan to develop the [redacted] to enable patients that have the System implanted [redacted] to activate physician-prescribed doses of morphine sulfate, for delivery of "supplemental doses of intrathecal morphine in patients who are experiencing [redacted] pain." A fuller description of the [redacted] and its use with the System in the patient-activated administration of [redacted] is contained in the request for designation; that description is incorporated here by reference.

The request for designation was submitted at the urging of staff in the Center for Drug Evaluation and Research (CDER), who advised Medtronic that "patient-activated dosing information needed to be added to the labeling of preservative-free morphine sulfate solution.. ." Based on the assumption that market approval of the [redacted] would be conditioned on the relabeling of morphine sulfate, Medtronic recommended a parallel regulatory path for the review and regulation of the [redacted] and morphine sulfate. Specifically, the company proposed: (1) an investigational new drug application and supplemental NDA submissions to CDER for the patient-activated dosing of the morphine sulfate, and (2) an investigational device exemption application and supplemental PMA submission to FDA's Center for Devices and Radiological Health (CDRH) for the Activator.

We have considered the information in your request, reviewed the pertinent provisions of the Intercenter Agreement ("ICA") between CDER and CDRH, and discussed the issues raised with staff in the two centers. Based on that review – and after extensive discussions with senior management in the two centers – we conclude that market approval of the [redacted] for patient-activated administration of morphine sulfate will not require the relabeling of morphine sulfate drug products that are already approved for intrathecal administration. In other words, market entry of the [redacted] will not be conditioned on the relabeling via a supplemental new drug application of existing drug products.

As recommended by the company, CDRH will be primarily responsible for the premarket review and regulation of the [redacted]. The [redacted] as a medical device will be subject to review and regulation under the PMA requirements of 21 U.S.C. § 360e. Clinical investigations of the [redacted] with the System should be conducted in accordance with the investigational device provisions of 21 CFR Part 812. A separate investigational new drug application will not be required.

Assignment of principal review responsibility to CDRH is consistent with the guidance set out in section VII.A.1(a)(ii) of the ICA, which assigns CDRH primary responsibility for premarket review of devices "intended for use with a category of drugs that are on the market." (Although, as noted in section VII.A.1(a)(ii), "device and drug labeling must be mutually conforming with respect to indications, general mode of delivery (e.g. topical, I.V.) and drug dosage/schedule equivalents," in this case, we have concluded that the labeling of the device is likely to conform to the labeling of the marketed drug products.)

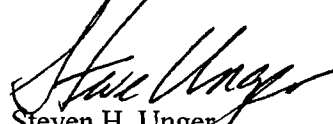
The Division of Dental, Infection Control, and General Hospital Devices (DDIGD) in CDRH will be the primary review group. Because review of the [redacted] will entail review of clinical data on patient-activated administration of intrathecal morphine sulfate, CDRH will conduct its review in collaboration with CDER review staff. For further information about device submission requirements and the agency's plans for collaborative review, contact Patricia Cricenti, Chief, General Hospital Products

Medtronic, Inc.
April 9, 2001
Page 3

Branch, DDIGD, CDRH, 9200 Corporate Blvd., (HFZ-480), Rockville, MD 20850, or by telephone at 301-443-8879. Please include a copy of this letter in your submission to CDRH.

If you have any questions concerning this matter, please contact Tracey Forfa, of this office, at 301-827-3390.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steve Unger", written over the typed name.

Steven H. Unger
Acting Ombudsman

cc: Patricia Cricenti (HFZ-480)