DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 20-075/S-014
/S-016

Medtronic Drug Delivery
Attention: Victoria Pearson, RAC
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604

Dear Ms. Pearson:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lioresal (Baclofen) Injection.

	Dated	Received
S-014	05/17/00	05/18/00
S-016	07/26/01	07/27/01
Amended	10/17/01	10/19/01
Amended	10/20/01	10/21/01

Supplemental application S-014 provides for latex free Refill Kits 8561, 8562, and 8564.

Supplemental application S-016 provides for a new warning regarding baclofen withdrawal and for updated physostigmine dosing recommendations for baclofen overdose.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revision listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

Please change "2.0 mg" to 2 mg in **Physostigmine Doses for Adult Patients** to minimize the potential for medication error as follows:

Physostigmine Doses for Adult Patients: Administer 2 mg of physostigmine intramuscularly or intravenously at a slow controlled rate of no more than 1 mg per minute. Dosage may be repeated if life-threatening signs, such as arrhythmia, convulsions or coma occur.

A letter communicating information about baclofen withdrawal, prevention and treatment (i.e., a "Dear Health Care Practitioner" letter) should issue to physicians and others responsible for patient care. We request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed agreed upon draft labeling (dated February 13, 2002). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-075/S-016." Approval of this submission by FDA is not required before the labeling is used.

Additionally, we have reviewed the content of the following supplemental applications submitted both under "Changes Being Effected" and "Changes for which Prior FDA Approval is Needed" and have included information from these supplemental applications, as appropriate, in the attached draft labeling. Therefore, the following supplemental applications have been superceded by the labeling approved in supplemental applications S-014 and S-016 and will be retained in our files.

Date Submitted	**Supplement No.**
June 30, 1992	001
August 17, 1998	010
December 2, 1998	011
December 21, 1998	011 (amendment)
May 3, 2000	013

Finally, we note that Refill Kit 8551 is a generic refill kit used to fill the Medtronic pump with several different approved drugs. We note that this kit may still contain a latex-tipped syringe plunger. If so, we remind you to place a latex warning label on this refill kit.

Please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
3/6/02 07:49:53 AM