



NDA 20-075/S-020

Medtronic Neurological
Attention: Jenny Anderson, RAC
710 Medtronic Parkway
MS LN145
Minneapolis, MN 55432

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated January 16, 2003, received January 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lioresal Intrathecal (baclofen injection) 0.05mg/ml.

This supplemental new drug application provides for the addition of the 20 ml ampule for the 2 mg/ml concentration of Lioresal Intrathecal.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted January 16, 2003 and immediate container and carton labels submitted January 16, 2003), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), 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

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lana Chen, Regulatory Project Manager, 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

**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

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