DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20075/S-028

**SUPPLEMENT APPROVAL**

Medtronic, Inc.
Attention: Anneli Icenogle
Regulatory Affairs Specialist
7000 Central Ave., N.E.
Minneapolis, MN 55432

Dear Ms. Icenogle:

Please refer to your Supplemental New Drug Application (sNDA) 020075/S-028 dated April 24, 2013, received April 25, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lioresal Intrathecal (baclofen injection) co-packaged with a refill kit (# 856X) for intrathecal administration.

We acknowledge receipt of your 2013 amendments dated July 3, October 18, and October 30.

We also refer to your Premarket Approval Application (PMA) #860004 for a companion intrathecal refill kit that contains no drug (#8551). This application is regulated by the Center for Devices and Radiologic Health (CDRH).

We further refer to your supplemental PMA #860004/S-179 approved on December 20, 2012, that provides for the addition of information to the *Instructions for Use* (IFU) manual contained in refill kit #8551 regarding the risk of inadvertent subcutaneous injection (pocket fill) as a cause of overdose and withdrawal.

"Prior Approval" sNDA 020075/S-028 provides for harmonization of the IFU Manual for Refill Kit #856X with the IFU Manual for Refill Kit #8551. In a teleconference dated October 10, 2013, between Medtronic, Inc., CDRH's Division of General Hospital Devices Branch (GHDB), and CDER's Division of Neurology Products (DNP), it was agreed that the IFUs for refill kits #856X and #8551 be maintained as two separate documents. The IFUs will remain harmonized; however, the IFU Manual for Refill Kit #856X will contain only information for the refill procedure with Lioresal. (b) (4)

## APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text with the minor editorial revision listed below in the enclosed labeling.

- All occurrences of the revision date "2013-04" were changed to a revision date of "2013-10".

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## REPORTING REQUIREMENTS

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, contact Taura Holmes, PharmD, Regulatory Project Manager, via email or telephone at taura.holmes@fda.hhs.gov or (301) 796-1932.

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, M.D.
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Instructions for Use Manual for Refill Kit #856X

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

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/s/

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ERIC P BASTINGS
11/19/2013