Dear Ms. Antons:

Please refer to your supplemental new drug application dated June 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Neoprofen (ibuprofen lysine) Injection, 10 mg/ml.

This “Prior Approval” supplemental new drug application provides for labeling revised in the Physician’s Labeling Rule format.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text, which is identical to the content of labeling submitted on June 29, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 021903/S-004.” Approval of this submission by FDA is not required before the labeling is used.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**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, please call Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

Sincerely,

[See appended electronic signature page]

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Content of Labeling
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<td>LUNDBECK INC</td>
<td>NEOPROFEN (IBUPROFEN LYSINE) 10MG/ML</td>
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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.

/s/

NORMAN L STOCKBRIDGE
12/22/2009