DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021903/S-004 **SUPPLEMENT APPROVAL**

Lundbeck Inc.
Attention: Ilze K. Antons, M.S., R.A.C.
Senior Director, Global Regulatory Affairs
Four Parkway North
Deerfield, IL 60015

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21903	SUPPL-4	LUNDBECK INC	NEOPROFEN (IBUPROFEN LYSINE) 10MG/ML

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