



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018878/S-027

SUPPLEMENT APPROVAL

Lundbeck Inc.
Attention: Kathryn B. Patterson
Associate Director, U.S. Post-Approval
Regulatory Affairs
Four Parkway North
Suite 200
Deerfield, IL 60015

Dear Ms. Patterson:

Please refer to your supplemental new drug application dated October 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Indocin I.V. (indomethacin) 1 mg Injection.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. Under ADVERSE EVENTS/*Renal*, "renal failure" has been added.
2. Under ADVERSE EVENTS/*Hematologic*, "thrombocytopenia" has been added.
3. The revision number and date have been updated.

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 draft labeling submitted on October 8, 2009.

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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
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
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NDA-18878	SUPPL-27	LUNDBECK INC	INDOCIN I.V.

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

/s/

MARY R SOUTHWORTH
01/19/2010