DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-533/S-020

SUPPLEMENTAL APPROVAL

APP Pharmaceuticals
1501 East Woodfield Road
Suite 300 East
Schaumburg, IL 60173

Attention: Dale Carlson
Director, Regulatory Affairs

Dear Mr. Carlson:

Please refer to your supplemental new drug application (sNDA) dated and received December 11, 2009, submitted under Section 505(b) of the Federal Food, Drug, Cosmetic Act (FDCA) for Naropin (ropivacaine HCl).

We acknowledge receipt of your submissions dated December 14, 2009 and February 3 and 5, 2010.

Reference is also made to our letter dated November 12, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Naropin (ropivacaine HCl). This information pertains to the risk of chondrolysis in patients receiving intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures.

This supplemental new drug application provides for revisions to the labeling for Naropin (ropivacaine HCl) consistent with our November 12, 2009 letter and our teleconference with you on February 2, 2010.

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

CONTENT OF LABELING

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20533/S-020**."

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.
Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTER TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letters to this NDA and a copy to the following address:

MEDWATCH
Food and Drug AdministrationSuite 12B-05
5600 Fishers Lane
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 contact Allison Meyer, Regulatory Project Manager, at (301) 796-1258

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20533	SUPPL-21	APP PHARMACEUTICALS LLC	NAROPIN (ROPIVACAINE HCL MONOHYDRATE) IN
NDA-20533	SUPPL-20	APP PHARMACEUTICALS LLC	NAROPIN (ROPIVACAINE HCL MONOHYDRATE) IN

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

/s/

LARISSA LAPTEVA
02/19/2010