DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019771/S-036 **SUPPLEMENT APPROVAL**

Wyeth Consumer Healthcare
Attention: Erica Sinclair, MBA
Senior Manager, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Sinclair:

Please refer to your Supplemental New Drug Application (sNDA) dated March 2, 2010, received March 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil® Cold & Sinus (ibuprofen 200mg and pseudoephedrine HCl 30 mg) capsule-shaped tablets (caplets).

This "Changes Being Effected" supplemental new drug application provides for the addition of the organ-specific warnings specified in the Organ-Specific Warnings final rule (74 FR 19385) and the removal of the statement "do not take longer than 10 days, unless directed by a doctor (see new warnings)" per the FDA's General Advice letter dated September 4, 2009.

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

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling for the Advil® Cold & Sinus capsule-shaped tablets (2-count immediate container (pouch), 10-count immediate container (blister card), 50 x 2-count carton (pouch dispenser), 20- and 40-count cartons with peel-back Drug Facts labels (piggyback) submitted on March 2, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19771/S-036**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, call Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Immediate Container and Carton Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19771	SUPPL-36	WYETH CONSUMER HEALTHCARE	COADVIL (IBUPROFEN/PSEUDOEPHEDRINE)

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

/s/

ANDREA LEONARD SEGAL
09/02/2010