DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-402/S-026

Wyeth Consumer Healthcare
Attention: Suzanne Yu
Associate Director, Global Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Ms. Yu:

Please refer to your supplemental new drug application dated March 9, 2009, received March 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Liquigels (200 mg ibuprofen capsules).

We acknowledge receipt of your correspondence dated May 13, 2009 providing further explanation of the representative labeling.

This supplemental new drug application provides for the addition of Catalent Argentina S.A.I.C. as an alternate manufacturing and testing site for Advil Liquigels. This supplemental NDA also provides for minor manufacturing changes related to the site and associated labeling revisions.

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

Submit final printed labeling (FPL) for all referenced stock keeping units, as soon as they are available, but no more than 30 days after they are printed. Representative labeling will not be acceptable in the FPL submission. The FPL must be identical to the enclosed labels (Advil Liqui-Gels 20-count carton label, 20-count (representative of the 20-, 40-, 120-, and 160-count) immediate container label, 80-count (representative of the 40-, 80-, 120-, and 160-count) carton label, and 80-and 240-count immediate container labels submitted on March 9, 2009), 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 (October 2005).* 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 20-402/S-026**." Approval of this submission by FDA is not required before the labeling is used.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joel Schiffenbauer

7/9/2009 10:46:27 AM