DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-393
NDA 21-394

Wyeth Consumer Healthcare
Attention: Sharon C. Heddish
Vice President, Global Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Ms. Heddish:

Please refer to your new drug applications (NDA) dated October 16, 2001, received October 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil PM Liqui-Gels (200 mg ibuprofen/25 mg diphenhydramine HCl capsules) and Advil PM Caplets (200 mg ibuprofen/38 mg diphenhydramine citrate tablets).

We acknowledge receipt of your submissions dated December 6, 2001; January 7, 11 and 24, February 15, March 11 and 19, May 8, 17, and 23, July 9, August 15, 19 and 29 (2 submissions), September 9 and 13, and December 10, 2002; February 5, April 23, May 29, June 30, November 20, and December 23, 2003; January 5 and 20, February 25 (2 submissions), March 5, May 6 and 14, and September 23, 2004; June 27, July 19, August 10, and 31, September 16, November 17, December 13 and 14, 2005.

The June 27, 2005 submission constituted a complete response to our December 18, 2003 action letter.

These new drug applications provide for the use of Advil PM Liqui-Gels and Caplets for relief of occasional sleeplessness when associated with minor aches and pains.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted representative labeling (blister pack and carton labels for NDA 21-393 and immediate container and carton labels for NDA 21-394 submitted December 13, 2005; 4-count gravity feed dispenser and shelf tray labels for NDA 21-393 and 2-count professional pouch dispenser label for NDA 21-394 submitted December 14, 2005), and must be in the "Drug Facts" format (21 CFR 201.66). **FPL must be submitted for all marketing SKUs, identical to the representative labeling, except for declaration of net quantity of contents statement to reflect the package size, submitted December 13, 2005.** Marketing the products with FPL that is not identical to the approved labeling text and in the required format may render the products misbranded and unapproved new drugs.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15

of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions **"FPL for approved NDA 21-393"** or **"FPL for approved NDA 21-394**", respectively. Approval of these submissions by FDA is not required before the labeling is used.

We remind you to remove the "NEW" flag from the Principal Display Panel after 12 months of OTC marketing.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We reference the waiver granted on October 11, 2001 for the pediatric study requirement for the age range of birth to less than 12 years of age for these applications.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

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}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Office of New Drugs
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/

Charles Ganley

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