



NDA 21-394/S-012

Wyeth Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your supplemental new drug application dated November 19, 2008, received November 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil PM (200 mg ibuprofen/ 38 mg diphenhydramine citrate tablets).

We also acknowledge receipt of your correspondences dated March 30, April 22, May 1, and 15, 2009.

This supplemental new drug application (NDA) provides for the revised cardiovascular warning statement "When using this product the risk of heart attack or stroke may increase if you use more than directed or for longer than directed" to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letter.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the Advil PM tablets 2-count front and back pouch labels, 2-count pouch dispenser (50 x 2-count pouches), 4-count blister carton card, 20-count (representative of the 20-, 40-, 80-, and 180-count) immediate container label, and 20-count (representative of the 20- and 40-count) and 80-count (representative of the 80- and 180-count) carton labels submitted on November 19, 2008.

We remind you of the following agreements listed below:

1. In your submission dated April 22, 2009, you agree to separate the net quantity of contents from the established name on the immediate container label of all stock keeping units within 6 months.
2. In your submission dated May 15, 2009, you agree to revise the statement of identity on the Principal Display Panel of the 2-count pouch dispenser (50 x 2-count pouches) to appear in bold type and in a size reasonably related to the most prominent printed matter (see 21 CFR 201.61(c)) within 6 months.

We note that any labeling submitted in a subsequent supplemental new drug application should incorporate the revisions listed above.

In addition, we have the following recommendation:

3. Consumers may not be aware that the Drug Facts information is provided on the 2-count pouch dispenser. We recommend that you add the statement “See full Drug Facts information on the back of this dispenser” or a similar statement.

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
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