DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-771/S-028

Wyeth Consumer Healthcare
Attention: Mary Davis
Director, Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Ms. Davis:

Please refer to your supplemental new drug application dated August 25, 2005, received August 26, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Cold & Sinus (200 mg ibuprofen/ 30 mg pseudoephedrine HCl) tablets.

We also acknowledge receipt of your submissions dated October 4, November 8, and 18, 2005 and February 13, 2006.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the 20-count package size for Advil Cold & Sinus tablets, the 2-count package size for Advil Cold & Sinus caplets, and the 20-count package size for Advil Flu & Body Ache in response to the June 14, and July 15, 2005 supplemental labeling request letters. According to your February 13, 2006 submission, the Advil Cold & Sinus tablets 20-count package size is representative of the 20-, and 40-count Advil Cold & Sinus caplets package sizes except for the word “caplets”.

We have completed our review of this application, as amended. This application is approved for the Advil Cold & Sinus tablets 20-count package size (representative of the Advil Cold & Sinus caplets 20- and 40- count package sizes), Advil Cold & Sinus caplets 2-count pouch, and Advil Flu & Body Ache 20-count package size, 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 labeling (Advil Cold & Sinus blister card label submitted August 25, 2006, Advil Cold & Sinus tablets 20-count carton label, Advil Flu & Body Ache 20-count carton label, and Advil Cold & Sinus caplets 2-count pouch submitted November 8, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all represented stock keeping units** 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 this submission "**FPL for approved supplement NDA 19-771/S-028**". Approval of this submission by FDA is not required before the labeling is used.

According to your November 8, 2005 submission, Dristan Cold & Sinus has been discontinued. Should you decide to re-introduce Dristan Cold & Sinus in the future, you are reminded to submit revised labeling in response to the June 14, and July 15, 2005 supplemental labeling request letters at that time.

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

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 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, MD
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

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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