



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-441/S-009

Wyeth Consumer Healthcare  
Attention: Erica Sinclair  
Manager, Global Regulatory Affairs  
5 Giralda Farms  
Madison, NJ 08940

Dear Ms. Sinclair:

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<sup>®</sup> Allergy Sinus (2mg clorpheniramine maleate, 200 mg ibuprofen, and 30 mg pseudoephedrine HCl) tablets.

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<sup>®</sup> Allergy Sinus 20-count caplet carton submitted on November 19, 2008.

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 Michelle Poindexter, Regulatory Project Manager, at (301) 796-4795.

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  
5/19/2009 03:04:40 PM