021587_Original_Approval_Pkg

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number 21-587

Trade Name Children's Advil Allergy Sinus

Generic Name ibuprofen/pseudoephedrine/chlorpheniramine

Sponsor Wyeth Consumer Healthcare

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APPLICATION 21-587

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	Included
Approval Letter	✓
Tentative Approval Letter	
Approvable Letter	
Final Printed Labeling	✓
Medical Review(s)	✓
Chemistry Review(s)	✓
EA/FONSI	
Pharmacology Review(s)	✓
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology Biopharmaceutics Review(s)	✓
Bioequivalence Review(s)	
Administrative Document(s) Correspondence	✓

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Application Number 21-587

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-587

Wyeth Consumer Healthcare
Attention: David S. Smith, PhD
Director, Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Dr. Smith:

Please refer to your new drug application (NDA) dated April 23, 2003, received April 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil® Allergy Sinus (ibuprofen 100 mg/pseudoephedrine HCl 15 mg/chlorpheniramine maleate 1 mg/5 mL suspension).

We acknowledge receipt of your submissions as follows:

Letter Date	Stamp Date
August 22, 2003	August 25, 2003
September 5, 2003	September 8, 2003
October 22, 2003	October 23, 2003
December 19, 2003	December 24, 2003
January 14, 2004	January 20, 2004
February 3, 2004	February 4, 2004
February 6, 2004	February 9, 2004
February 12, 2004	February 13, 2004
February 13, 2004	February 18, 2004
February 17, 2004	February 20, 2004
February 19, 2004 (#1)	February 20, 2004 (#1)
February 19, 2004 (#2)	February 20, 2004 (#2)
February 23, 2004	February 23, 2004

This new drug application provides for the use of Children's Advil® Allergy Sinus (ibuprofen 100 mg/pseudoephedrine HCl 15 mg/chlorpheniramine maleate 1 mg/5 mL suspension) for the relief of symptoms associated with allergic rhinitis and the common cold.

We completed our review of this application as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted February 6, 13, and 19, 2004).

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 note that you have fulfilled the pediatric study requirement for this application.
We remind you of your postmarketing study commitment in your submission dated February 23, 2004. These commitments are listed below.

1. **Description of Commitment** – Phase 4 study to answer the question of the consumer's ability to identify different ingredients in different Children's Advil products (including triple combination products, double combination products and single active ingredient products) and ability to select the correct product for their symptoms.

Protocol Submission:	by April 2004
Study Start:	by July 2004 (pending receipt of FDA comments)
Final Report Submission:	by April 2005

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence.**"

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one copy, along with labeling, to each of the Divisions signing below.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, please call Ms. Elaine Abraham, Regulatory Health Project Manager, at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Brian E. Harvey, MD, PhD
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
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
2/24/04 03:16:31 PM

Brian Harvey
2/24/04 03:27:06 PM

APPEARS THIS WAY
ON ORIGINAL