

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20812

CHEMISTRY REVIEW(S)

Anti-inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-812 **REVIEW # 1** **DATE REVIEWED:** April 23, 1997
SUBMISSION TYPE **DOCUMENT DATE:** **ASSIGNED DATE** **USER FEE DATE**
Original submission* 12-12-96 12-20-96 6-12-97
Being reviewed: Above.

* The application was submitted as a supplement to NDA 20-589, Children's Advil[®], 100 mg/5 mL. Current submission, Pediatric Advil, 100 mg/2.5 mL, contains twice the amount of active of NDA 20-589 for children's Advil. Therefore, the submission should be treated as a new NDA. An NDA number 20-812 was assigned to the application. The decision to treat the submission as a new drug application has been forwarded to the applicant. However, the user fee date remains six months.

NAME & ADDRESS OF APPLICANT: Whitehall-Robins Healthcare, 5 Giralda Farms,
Madison, NJ 07940-0871

DRUG PRODUCT NAME

Proprietary: Pediatric Advil[®] Drops

Established: Ibuprofen

Code Name/#:

Chem.Type/Ther.Class: For the reductions of fever and the temporary relief of minor aches and pains.

PHARMACOL. CATEGORY: NSAID

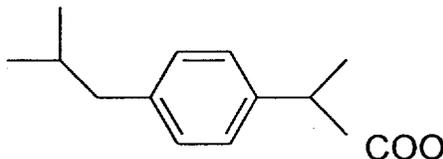
DOSAGE FORM: Suspension

STRENGTHS: 100 mg/2.5 mL

ROUTE OF ADMINISTRATION: Oral

DISPENSED: Rx OTC

CHEMICAL STRUCTURE:



COMMENTS: The submission is deficient.

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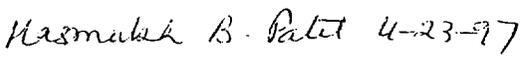
information

5. Expiration dating period: Requests 24 month expiration date.
6. Container/closure (C/C) system:

7. **Environmental Assessment:** Reviewed separately.

CONCLUSION OF THE REVIEW: Approvable with comments.


Bart Ho, Review Chemist


Team Leader, Husmukh Patel

cc:
Orig. NDA 20-812
HFD-550/Division File
HFD-550/BHo.
HFD-550/Cook

Filename: N20812R1.FHo

IMC 6/4/97
DLB 6/3/97

Anti-inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-812 **REVIEW # 2** **DATE REVIEWED:** April 23, 1997
SUBMISSION TYPE **DOCUMENT DATE:** **ASSIGNED DATE** **USER FEE DATE**
Original submission* 12-12-96 12-20-96 6-12-97
Amendment 1 2-3-97 2-19-97

Being reviewed: Amendment 1.

NAME & ADDRESS OF APPLICANT: Whitehall-Robins Healthcare, 5 Giralda Farms,
Madison, NJ 07940-0871

DRUG PRODUCT NAME

Proprietary: Pediatric Advil[®] Drops

Established: Ibuprofen

Code Name/#:

Chem.Type/Ther.Class: For the reductions of fever and the temporary relief of minor aches and pains.

PHARMACOL. CATEGORY: NSAID

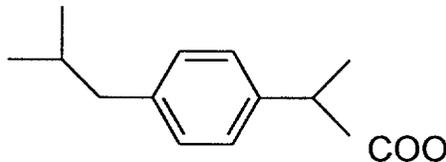
DOSAGE FORM: Suspension

STRENGTHS: 100 mg/2.5 mL

ROUTE OF ADMINISTRATION: Oral

DISPENSED: Rx OTC

CHEMICAL STRUCTURE:

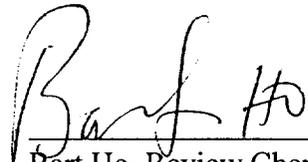


COMMENTS: Information provided in this amendment is adequate. See Review #1 for details.

REMARKS: This review deals with the information provided in this amendment only.

CONCLUSION OF THE REVIEW: See Review #1 for details.

**APPEARS THIS WAY
ON ORIGINAL**


Bart Ho, Review Chemist

**APPEARS THIS WAY
ON ORIGINAL**

Husmukh B. Patel 4-23-97
Team Leader, Husmukh Patel

WAC 4/5/97

cc:
Orig. NDA 20-812
HFD-550/Division File
HFD-550/BHo
HFD-550/Cook

Filename: N20812R2.fHo

Dub 6/6/97

**APPEARS THIS WAY
ON ORIGINAL**

**APPEARS THIS WAY
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