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APPLICATION NUMBER: 20812

MEDICAL REVIEW(S)

**MEDICAL OFFICER
REVIEW**

NDA Number: 20-812, Supplemental Application
Date Received (letter date): December 12, 1996
Date Received (CDER stamp): December 18, 1996
Date Assigned for Review: December 30, 1996
Date Reviewed: January 2, 1997

Sponsor: Whitehall-Robins
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Madison, NJ 07940-0871
Sharon H. Heddish
Director, Regulatory Affairs
TEL: 201-660-5753

Drug Name: Children's ADVIL Drops (4% ibuprofen)

Drug Class: NSAID
Intended Use of Drug: Fever reducer and pain reliever

Consumer Safety Officer: Sandra Cook
Medical Officer: Rudolph M. Widmark, M.D., Ph.D.

This supplemental application is for two formulations of Children's ADVIL Drops (ibuprofen 200 mg/5 mL), one fruit-flavored formulation and a second formulation which is grape-flavored. These two formulations are identical, but for their double concentration of ibuprofen, to the already approved Children's ADVIL Suspension (ibuprofen 100 mg/5 mL).

The application includes a full Chemistry, Manufacturing, Controls, and Methods Validation section, Labeling (cartons and bottles), and a clinical study which documents bioequivalence to Children's ADVIL Suspension of the Children's ADVIL Drops.

Pending the assessments by the Chemist and Biopharm reviewers as well as a consulting review of the label (cartons and bottles) by the Division of Nonprescription Drug Products, this Reviewer considers the application acceptable and recommends its approval. As a reminder, an identical product (except for the flavoring) has been approved and is marketed by McNeil Consumer Products Co. under the trade name of Children's MOTRIN Drops.

The consulting Division (DNDP) should be asked to give us their assessment within 30 days after receipt of this request.

Rm. Widmark 1-2-97

Rudolph M. Widmark, MO

Date

JEH 1-8-97

cc: Orig. NDA 20-812
HFD-550
HFD-340
HFD-550/CSO/SCook
HFD-550/MChang
HFD-550/CHEM/BHo
HFD-550/PHARM/CChen
HFD-550/MO/RWidmark
HFD-550/SMO/JHyde
HFD-550/DIR/WChambers wmc 1/9/97
HFD-560 DVB 6/5/97

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