CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20812

PHARMACOLOGY REVIEW(S)

THE DIVISION OF ANTI-INFLAMMATORY, ANALGESIC, AND OPHTHALMIC DRUG PRODUCTS

PHARMACOLOGY/TOXICOLOGY REVIEW

NDA 20-812

ORIGINAL REVIEW

SPONSOR:	WHITEHALL ROBINS Five Giralda Farms Madison, NJ 07940-0871
DRUG:	Pediatric Advil® Drops Children's Advil® Ibuprofen Oral Suspension 100 mg/2.5 mL
SUBMISSION:	December 12, 1996
REVIEWER:	Almon W. Coulter, Ph.D.
REVIEW COMPLETED:	January 28, 1997

DRUG CATEGORY: NSAID - analgesic, anti-inflammatory, antipyretic

RELATED INDs/NDAs:

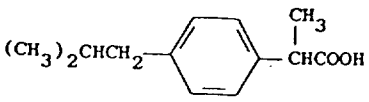
NDA 19-784 RUFEN® (ibuprofen) Pediatric Suspension, 100 mg/5 mL Knoll Pharmaceutical (approved 12/18/89).

NDA 19-842 Children's Motrin® (ibuprofen Oral Suspension), 100 mg/5 mL, (approved 9/19/1989)

NDA 20-589 Children's Advil (ibuprofen) Suspension, Whitehall-Robins Healthcare, 100 mg/5 mL (approved 9/19/89).

PROPOSED INDICATIONS: For temporary reduction of fever and the minor aches and pains due to cold, flu, sore throat, headaches, and toothaches.

DRUG SUBSTANCE:



(±) 2-(4-Isobutylphenyl)propionic acid
CAS Registry Nº 15687-27-1

Molecular Formula: $C_{13}H_{18}O_2$ Molecular Weight: 206.28

FORMULATIONS:

Comparative Formulations

Component	% W/V (theoretical)		
	Grape Flavored Drops WH-0694-0002	Fruit Flavored Drops WH-0694-0001	Fruit Flavored Suspension* WH-438-029
Ibuprofen, USP	4.000	4.000	2.000
Sucrose, NF			
Glycerin, USP (96%)			
Sorbitol Solution, USP			
Microcrystalline Cellulose and CMC Sodium, NF			
Polysorbate 80, NF			
Sodium Benzoate, NF			
Citric Acid, USP (Hydrous)			
Xanthan Gum, NF			
CMC Sodium, USP			
Artificial Flavor			
Artificial Flavor			
Artificial Flavor			
Edetate Disodium, USP			
FD&C Blue Nº 1			
FD&C Red Nº 40			
Purified Water, USP (Deionized)			

* Approved for Rx use per NDA 19-833 and for OTC use per NDA 20-589

NEW PRECLINICAL STUDIES:

None submitted in this application.

LABELING:

There are no labeling issues concerning preclinical pharm-tox of this OTC product.

SUMMARY:

There are no preclinical studies with this application. has authorized FDA to refer to their Vol. 2.1, page 211, for all nonclinical pharmacology and toxicology data in support of this NDA.

Pediatric Advil® Drops will be available in 1/4 Fl Oz (7.5 mL) and ½ Fl Oz (15 mL) drops. Manufacturing will be done in Richmond, VA by Wyeth-Ayerst Laboratories. Both Whitehall-Robins Healthcare and Wyeth-Ayerst Laboratories are under the umbrella of American Home Products Corporation.

RECOMMENDATIONS:

This application is approvable based on the preclinical pharmacology-toxicology.

Almon W Coulter
Almon W. Coulter, Ph.D.

Conrad H. Chen 2-5-97
Acting Team Leader: Conrad Chen, Ph.D.

cc:
NDA 20-812
HFD-550/Division File
/ACoulter
/MO RWidmark
/Chemist BHo
/CSO SCook

WAC 6/4/97
DRB 6/5/97