CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-944

PHARMACOLOGY/TOXICOLOGY REVIEW

Pharmacology Review

NDA : 20-944

Sponsor: Whitehall Robins, N.J.

Date submitted: Dec. 19, 1997

Date Received by CDR: Dec 22, 1997

Date Assigned: Dec 30, 1997

Date of Review: Feb 25, 1998

Drug: Advil Chewable tablets 100 mg

Category: Analgesic and antipyretic

Indications: Fever and pain for children

The NDA is submitted for the approval of chewable ibuprofen tablet for children. Each tablet will have 50 or 100 mg of ibuprofen. The indications are minor pain, flu, sore throat, headache and toothache. The proposed label has warnings for allergy and hypersensitivity reactions. The maximum dose is three tablets every 6-8 hour and the doses will not exceed 4 times a day. The formulation will contain following inactive ingredients.

Mannitol, microcrystalline cellulose, sodium starch glycolate, magnasweet, aspartame, artificial flavors, magnesium stearate and [redacted] silicone dioxide.

The sponsor referred to the approved NDA 18-197 and NDA 19-784 for the preclinical safety. Bioequivalency of the formulation to the ibuprofen suspensions and swallowed tablets has been investigated in human subjects. The NDA provided several summary reports of published studies that indicate the contraindication of ibuprofen for post operative pain. Efficacy of ibuprofen in several pain models, e.g., tonsillectomy and fever have been cited.

Conclusion:

Ibuprofen is an approved product for pediatric uses. Therefore, the NDA does not have any preclinical safety issue. The inactive ingredients do not have any preclinical safety issues. Most of the inactive ingredients used in the formulation have been used in other approved preparations.

Recommendations:

The product is approvable based on preclinical safety.

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Pharmacologist