

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

75-217

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 75-217
3. NAME AND ADDRESS OF APPLICANT
L. Perrigo Company
Attention: Brian R. Schuster
117 Water street
Allegan, MI 49010
4. LEGAL BASIS FOR SUBMISSION
Approved Application for Children's Motrin Drops,
Holder - McNeil Consumer Products Company
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Ibuprofen Oral Suspension, USP
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
Original Application Date September 30, 1997
Tcon. (Gregg Davis vs. Brian Schuster) Date November 10, 1997
Additional Information Date November 12, 1997 (Re:Packaging
Reconciliation).
Patent Amendment Date January 9, 1998
Patent Amendment Date January 28, 1998
Facsimile Amendment April 15, 1998
Amendment Date June 9, 1998 (This Review)
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
OTC
12. RELATED IND/NDA/DMF(s)
ANDA 74937
For DMF's see section 37
13. DOSAGE FORM
Oral Suspension
14. POTENCY
40 mg/mL (per dosage unit = 2x1.5 mL
dropperful = 2.5 mL)
15. CHEMICAL NAME AND STRUCTURE

Chemical Name: α -methyl-4-(2-methylpropyl) benzene acetic acid
Structure: As in USP
16. RECORDS AND REPORTS N/A
17. COMMENTS:
See Review
18. CONCLUSIONS AND RECOMMENDATIONS
Approvable
19. REVIEWER: U.S. Atwal
DATE COMPLETED: August 17, 1998

Page(s)

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 3

8/17/98