CENTER FOR DRUG EVALUATION AND RESEARCH

74-937

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4

2. ANDA # 74-937

3. NAME AND ADDRESS OF APPLICANT
L. Perrigo Company
Attention: David A. Jespersen
117 Water street
Allegan, MI 49010

4. LEGAL BASIS FOR SUBMISSION
Approved Application of McNeil Consumer Products for **Children's Motrin®.**

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Ibuprofen Oral suspension

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Original Application Date: July 26, 1996.
Amendment: Patent Non-infringement Certification,October 15, 1996
Amendment: Notice of Patent Non-infringement, October 30, 1996.
Minor Amendment: Bioequivalence Study, November 13, 1996.
Minor Amendment (Facsimile) Date February 14, 1997 (This Review).
Telephone Amendment Date March 7, 1997 (finished product specs.)
Telephone Amendment Date June 23, 1997 (This Review).
Facsimile Amendment Date June 23, 1997 (labeling issues).
Tentative Approval Letter Issue Date September 5, 1997.
Amendment: Date November 7, 1997 (This Review).
Amendment Date February 9, 1998 (Re: Labeling).
Tcon. Date February 27, 1998 (J. Wilson & V. Sayeed vs V. Lutke).
Amendment Date March 4, 1998 (This Review).
Amendment Date April 24, 1998 (This Review).
Facsimile Amendment Date May 4, 1998 (Re: 180-Day Exclusivity).

10. PHARMACOLOGICAL CATEGORY: Analgesic

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s)
See Section 37

13. DOSAGE FORM
Oral Suspension

14. POTENCY
100 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE

Chemical Name: ∝-methyl-4-(2-methylpropyl) benzene acetic acid
Structure: As in USP 23

16. RECORDS AND REPORTS N/A

17. COMMENTS: See individual review sections

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable Pending Acceptable EER

19. REVIEWER:
U.S. Atwal

DATE COMPLETED:
May 21, 1998

Page(s) 11

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

chem Rev 4

5/21/98

RECORD OF TELEPHONE CONVERSATION

After discussion with Pat Beers-Block and Vilayat Sayeed, I called Perrigo (Lee McGinnis). I was unable to speak directly to her so I left a message and asked her that, since it appears that they use ibuprofen in the manufacture of their ibuprofen products, we would like confirmation that their bulk drug supplier is capable of doing in-house . If they are not, I asked if she could identify where the material was

an associate of McGinnis, called me back and left message for me to call her. I called back and informed me that she had discussed my request with the firm's R&D department. They say that they do not use ibuprofen bulk. The specification is for material and which has a median particle size of microns . (This information is consistent with the COA for the drug substance in the application.) She said IF the firm used material it would have a particle size in the range of crons.

I thanked her for the information and this concluded our conversation.

DATE
9/25/98

APPLICATION NUMBER
75-217
74-937

TELECON

INITIATED BY FDA

PRODUCT NAME
Ibuprofen Oral Susp; Oral Drops and Ped. Tablets

FIRM NAME
Perrigo

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Ginger Lutky
Reg Affairs

TELEPHONE NUMBER
616-673-8451

SIGNATURE
Mark D Anderson

ANDA 74-937 APPROVAL SUMMARY

DRUG PRODUCT: **Ibuprofen Oral Suspension, USP**

FIRM: **L. Perrigo Company**

DOSAGE FORM: **Oral Suspension**

STRENGTH: **100 mg/5 mL**

cGMP STATEMENT/EIR UPDATE STATUS: EER Acceptable Date October 15, 1996; EER Withhold Date February 9, 1998

BIO STUDY: APPROVE, Letter Sent on February 4, 1997

VALIDATION: DS and DP are compendial

STABILITY: Three months of accelerated, 40°C/75% RH, and three months room temperature, 25°C/60% RH, data in the market package size, 4 fluid ounce, provided. The container/closure system used for the stability study is equivalent to the system proposed for commercial use. All reported data are within specifications as listed. Thus, a 24 month expiration date is justified.

Tests and specifications for the drug product on stability include:

cus,

LABELING: APPROVE, Review Date February 19, 1998

STERILIZATION VALIDATION (IF APPLICABLE): N/A

SIZE OF BIO BATCH: The bio batch (#5ZA02V), size is also the test batch. The DS supplier is Corp., DMF is adequate as of March 6, 1998.

SIZE OF STABILITY BATCHES: Stability batch is the same as the biobatch.

PROPOSED PRODUCTION BATCHES: Production batch size is the same as the test batch size, i.e.,). The manufacturing process for the proposed production runs also remains the same as that used for the test batch.

CHEMIST: DATE: 5/22/98

SUPERVISOR: DATE: