

74879

1. CHEMIST'S REVIEW NO. 2

2. ANDA # 74-879

3. NAME AND ADDRESS OF APPLICANT

Elan Pharmaceutical Research Corporation
Attention: Sharon L. Hamm, Pharm. D.
1300 Gould Dr.
Gainesville, GA 30504-3947

4. LEGAL BASIS FOR ANDA SUBMISSION:

Listed drug: Oruvail® NDA #19,816
Exclusivity until September 24, 1996
Active ingredient, route of administration, dosage form, and
strength are the same for ANDA and NDA.

5. SUPPLEMENT(S): N/A

6. PROPRIETARY NAME: N/A

7. NONPROPRIETARY NAME

Ketoprofen

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

9. AMENDMENTS AND OTHER DATES:

April 1, 1996: Date of submission

November 8, 1996: Amendment in response to deficiency letter

December 20, 1996: Amendment, additional information

March 12, 1997: Amendment for change in method of synthesis
of DS

Amendments are the subject of this review.

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC

NSAID

Rx

12. RELATED IND/NDA/DMF(S)

See checklist

13. DOSAGE FORM

14. POTENCY

Extended-Release Capsules

200 mg

16. RECORDS AND REPORTS: None

18. CONCLUSIONS AND RECOMMENDATIONS : Not Approvable

DMF is deficient.

19. REVIEWER:

DATE COMPLETED:

Devinder S. Gill

May 12, 1997

Redacted 10

pages of trade

secret and/or

confidential

commercial

information

Chem # 2

38. Chemistry Comments to be Provided to the Applicant

ANDA: 74-879 APPLICANT: Elan Pharmaceutical Research Corporation

DRUG PRODUCT: Ketoprofen Extended-release Capsules, 200 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiency:

1. Please be advised that DMF is currently deficient and the DMF holder has been advised of the deficiencies. A satisfactory resolution of the DMF deficiencies is required prior to the approval of this ANDA.
2. Please revise your dissolution specification for release and stability to comply with the recommendation made by Division of Bio-Equivalence in the letter date October 31, 1996.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. The firms referenced in the application relative to the manufacture and testing of the product must be in compliance with cGMPs at the time of approval. We have requested the Division of Manufacturing and Product Quality for an evaluation report.
2. Since this drug product is not covered by an official monograph in the USP, the analytical methods must be validated by an FDA field laboratory. Samples for the methods validation will be requested up by the FDA at the appropriate time.

Sincerely yours,

/S/

Shr/57

Dr. Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research