

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74285

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4 2. ANDA # 74-285
3. NAME AND ADDRESS OF APPLICANT
 Purepac Pharmaceutical Co.
 Attention: Joan Janulis
 200 Elmora Avenue
 Elizabeth, NJ 07207
4. BASIS OF SUBMISSION Dolobid® ; Merck Sarpe & Dohme
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME none
7. NONPROPRIETARY NAME Diflunisal Tablets USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
- | | |
|-------------------|-------------------------------------|
| December 11, 1992 | Date of application. |
| June 25, 1993 | Bio acceptable; R.Williams, V. 1.1. |
| May 12, 1993 | CMC/Label NA letter. |
| June 1, 1993 | Amendment. |
| June 20, 1993 | EER acceptable, V. 1.1. |
| September 9, 1993 | Labeling acceptable, V. 2.1. |
| December 2, 1993 | CMC NA letter. |
| December 6, 1994 | Amendment. |
| May 23, 1995 | NA letter. |
| March 29, 1996 | Amendment; this review. |
| April 18, 1996 | Telephone amendment |
10. PHARMACOLOGICAL CATEGORY NSAID
11. Rx or OTC Rx 12. RELATED IND/NDA/DMF(s) See sec. 37
13. DOSAGE FORM oral tablet 14. POTENCY 250mg and 500mg
15. CHEMICAL NAME AND STRUCTURE As per USAN and USP
16. RECORDS AND REPORTS N/A
17. COMMENTS
 All the CMC deficiencies have been satisfactorily addressed.
18. CONCLUSIONS AND RECOMMENDATIONS Approve pending EER
19. REVIEWER: Jon E. Clark DATE COMPLETED: April 11, 1996

cc: ANDA 74-285
 DUP File
 Division File
 Field Copy

Endorsements:

HFD-623/J.Clark/4-11-96
 HFD-623/V.Sayeed, Ph.D./4-15-96
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 F/T by: bc/4-29-96

IS/ *4-30-96*
V. Sayeed *4/30/96*