CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-253

CHEMISTRY REVIEW(S)

ADDENDUM

1. CHEMISTRY REVIEW # 3

2. ANDA 75-253

3. NAME AND ADDRESS OF APPLICANT
Purepac Pharmaceutical Co.
Attention: Joan Janulis
200 Elmora Avenue
Elizabeth, New Jersey 07207

4. LEGAL BASIS FOR SUBMISSION
Purepac as required under Section 505(j)(2)(A)(vii) of the Federal Food, and Cosmetic Act, includes the applicable patent numbers and expiration dates as taken from the Approved Drug Products with "Therapeutic Equivalence Evaluations" 17th Edition. The firm states that according to the information published, Ticlid® Tablets 250 mg are not entitled to a period of marketing exclusivity under section 505(j)(4)D).

Listed drug: Synthex's Ticlid® Tablets 250 mg.
Applicable patent number and expiration date:
4,591,592 May 27, 2003

Statement of notification to the patent holder has been provided, and Certified Mail return receipt has been submitted to the Agency (Firm's N. C. dated December 23, 1997)

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Ticlopidine Hydrochloride

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

9. AMENDMENTS AND OTHER DATES:
November 14, 1997: Original Submission
November 17, 1997: Acceptable for filling
December 11, 1997: FDA acknowledgment and request for

	compliance with patent certification notice requirements.
December 16, 1997:	Patent Amendment (response to FDA letter).
December 23, 1997:	New correspondence proving copy of the certified mail receipt from Synthex (patent holder).
March 11, 1998:	Fax amendment
April 8, 1998:	Bioequivalence acceptable
April 16, 1998:	Telephone amendment
April 21, 1998:	Chemistry Review #2
July 15, 1998:	Tentative approval Letter
March 30, 1999:	Minor amendment for new raw material supplier
April 28, 1999:	Withdrawal of Minor amendment
April 29, 1999:	Minor amendment for final ANDA approval
June 15, 1999:	Request for Educational Program
June 18, 1999:	Submission of Educational Program
July 12, 1999:	Educational Program acceptable
July 22, 1999:	Request for final Approval
July 28, 1999:	Telephone Amendment (Commitment to provide postmarketing program to OGD for review at the time of marketing.
August 9, 1999:	Amendment (Revised package insert labeling)
August 9, 1999:	Labeling Review acceptable

10. PHARMACOLOGICAL CATEGORY
Platelet Aggregation Inhibitor

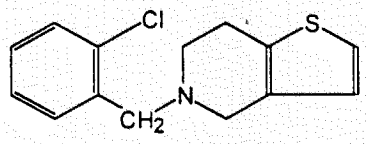
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Tablet

14. POTENCY
250 mg

15. CHEMICAL NAME AND STRUCTURE
$C_{14}H_{14}ClNS.HCl$
5-[(2-Chlorophenyl)methyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridine



16. RECORDS AND REPORTS
N/A

17. COMMENTS
After the issuance of a tentative approval letter in July 1998, the firm submitted a minor amendment (dated March 30, 1999) for an alternate source of active raw material. This minor amendment was withdrawn on April 28, 1999. Purepac later submitted a minor amendment updating changes made after the tentative approval.

Inactive raw material and drug product specification sheets were revised. Specifications for l [illegible] yl

were updated in accordance with pp 6 - 16 of amendment dated April 29, 1999). Finished product and stability specifications were revised to include water as the dissolution medium in accordance with guidance from Division of Bioequivalence (pp 17 - 22 of amendment dated April 29, 1999). Revised packaging component specification sheets are included (pp 23 - 33). Most of the changes are company name

changes of manufacturers of the bottle resin and the inner seal of the closure. The firm states that these changes have been documented in the original ANDA.

The firm submitted an educational program for Ticlopidine, and this program has been found acceptable by OGD (July 12, 1999). Torpharm's generic exclusivity has expired according to a ruling by the U.S. Court of Appeals on the 20th of July 1999. Therefore, Purepac is entitled to a final approval.

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable

19. REVIEWER: Ijeoma N. Nnamani, Ph.D.

DATE COMPLETED: August 20, 1999