CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65-059

CHEMISTRY REVIEW(S)

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Application Review

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1. **CHEMISTRY REVIEW NO.** 2

2. **ANDA #** 65-059

3. **NAME AND ADDRESS OF APPLICANT**
   Ranbaxy Laboratories Limited
   Sector 18, Udyog, Vihar Industrial Area
   Gurgaon-122 001, India

4. **LEGAL BASIS FOR SUBMISSION**
   Amoxil® Tablets 500 mg and 875 mg manufactured by SmithKline Beecham Pharmaceuticals (NDA 50-754)

5. **SUPPLEMENT(s)** N/A

6. **PROPRIETARY NAME** N/A

7. **NONPROPRIETARY NAME** Amoxicillin Tablets, USP

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

9. **AMENDMENTS AND OTHER DATES:**
   Minor Amendment 8/8/00
   Acceptance for filing 3/2/00
   Amendment to refusal to file 3/1/00
   Refusal to file 2/3/00
   Original Application 12/17/99

10. **PHARMACOLOGICAL CATEGORY** Antibiotic

11. **Rx or OTC** R_x

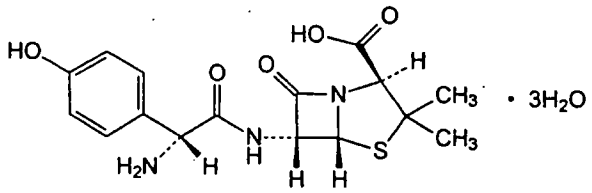
12. RELATED IND/NDA/DMF(s)

DMF #	LOA page #	Manufacturer	Component

13. **DOSAGE FORM** Tablets

14. **POTENCIES** 500 mg and 875 mg per tablet

15. **CHEMICAL NAME AND STRUCTURE**
Amoxicillin. 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo, trihydrate [2*S*-[2α,5α,6β(*S**)]]-.
$C_{16}H_{19}N_3O_5S \cdot 3H_2O$. 419.46. 61336-70-7. Antibacterial.



16. **RECORDS AND REPORTS** N/A

17. **COMMENTS**
All CMC deficiencies have been resolved.
Recommend Approval

18. **CONCLUSIONS AND RECOMMENDATIONS** Recommend Approval

19. **REVIEWER**: Susan Zuk **DATE COMPLETED**: 8/17/00

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

Chem Rev 2

8/17/00