CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65-059

CORRESPONDENCE

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-124) 342001-10, Fax: (91-124) 342017, 342030

August 8 , 2000

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

UPS

MINOR AMENDMENT

NDA ORIG AMENDMENT

Reference: **ANDA 65-059**
Amoxicillin Tablets USP
500 mg and 875 mg

Dear Sir/Madam:

Reference is made to the pending ANDA 65-059 for Amoxicillin Tablets USP, 500 mg and 875 mg.

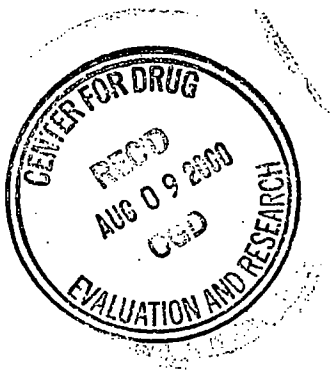
Reference is also made to the FDA Minor Deficiency Letter dated July 27, 2000. The questions and responses follow in the same order as in the letter. They are attached.

Field Copy:
We certify that a true copy of the technical section described in 21 CFR 314.50 (d)(5) of this amendment has been provided to the Office of Generic Drugs for FDA's International Operations Group.

If you have any questions, regarding the submission, please call me at (609) 720-5612 or Pat Strasser at (609)-720-5617.

Sincerely,

Shirley Ternyik
US Agent for Ranbaxy Laboratories Limited



8-10-00

RANBAXY
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SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-124) 342001-10, Fax: (91-124) 342017, 342030

March 1, 2000

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

FAX AND FEDERAL EXPRESS

REFUSAL TO FILE RESPONSE

RE: ANDA 65-059
Amoxicillin Tablets 500 mg and 875 mg

Dear Sir or Madam:

Reference is made to our pending Abbreviated New Drug Application for Amoxicillin Tablets 500 mg and 875 mg.

Reference is also made to the FDA correspondence, dated February 8, 2000, regarding the Refusal to File for the aforementioned submission.

The attached questions and responses follow in the same order as in the deficiency letter.

If you have any questions, regarding this supplement, please call me at 609-720-5612.

Field Copy: We certify that a true copy of the technical section described in 21 CFR 314.94(d)(5) of this supplement has been provided to the Office of Generic Drugs for International Operations Group.

Sincerely,

Shirley Ternyik

Shirley Ternyik
U.S. Agent for Ranbaxy Laboratories Limited