

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
65115

CORRESPONDENCE

ANDA 65-115

Ranbaxy Pharmaceuticals Inc.
U.S. Agent for Ranbaxy Laboratories Limited
Attention: Abha Pant
600 College Road East
Princeton, NJ 08540
|||||

FEB -6 2002

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is made to the telephone conversation dated February 5, 2002 and your correspondence dated February 5, 2002.

NAME OF DRUG: Cefadroxil for Oral Suspension USP, 125 mg/5 mL, 250 mg/5 mL and 500 mg/5 mL

DATE OF APPLICATION: December 17, 2001

DATE (RECEIVED) ACCEPTABLE FOR FILING: December 18, 2001

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Mark Anderson
Project Manager
(301) 827-5848

Sincerely yours,

ISR *or*
Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

RANBAXY

LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

February 5, 2002

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 20855-2773

FAX and UPS

**Amendment to
Pending Application**

**Reference: Cefadroxil for Oral Suspension USP,
125 mg/5ml, 250 mg/5ml and 500 mg/5ml
ANDA - 65-115**

NEW CORRESP

NC

Dear Sir/Madam:

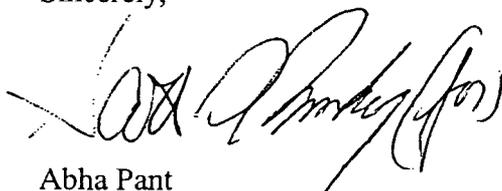
Reference is made to our pending ANDA 65-115 for Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml submitted to the Agency on December 17, 2001.

Reference is also made to the telephone contact of February 5, 2002, in which the Agency requested us to amend our application in order to clarify the packaging configurations for the 125 mg/5 mL and the 250 mg/5 mL bottle sizes.

In the original submission our package insert incorrectly referenced the 125 mg/5 mL strength as supplied in a 50 mL bottle, and the 250 mg/5 mL strength supplied in a 75 mL bottle, while we had provided draft bottle labels for both strengths in the 100 mL bottle size. Please amend our application to include the two revised pages for the package insert, (revised page 0035 for Section IV, and revised page 0056 for Section V) to be replaced in the original ANDA submission.

Please contact the undersigned at 609-720-5666 if you have any questions regarding this submission.

Sincerely,



Abha Pant
US Agent for Ranbaxy Laboratories Limited.



RANBAXY

LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

December 17, 2001

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 20855-2773

UPS

505(j)(2)(A) OK
06-FEB-2002
Jugay D. Dan

**Reference: Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml
Abbreviated New Drug Application**

Dear Sir/Madam:

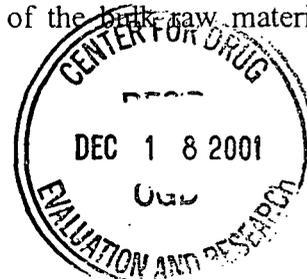
Ranbaxy Laboratories Limited (RLL) herewith submits an abbreviated new drug application (ANDA) for Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

This ANDA refers to the listed drugs, Duricef® for Oral Suspension manufactured by Bristol Myers Squibb, the holder of approved NDA 50-527 and which are listed in the 2001 "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as Orange Book), 21st Edition, page 3-67

Ranbaxy Laboratories Limited herewith certifies that in the opinion and to the best of its knowledge, no patent claims have been submitted to the FDA regarding Cefadroxil for Oral Suspension USP, for which this abbreviated new drug application is submitted. In addition, the applicant is not aware of any marketing exclusivity.

The drug product manufacturer is Ranbaxy Laboratories Limited. Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml will be manufactured at Ranbaxy Laboratories Limited's FDA registered and inspected Dewas, India facility in accordance with 21 CFR 210 and 211.

The manufacturer of the Cefadroxil drug substance used to produce the ANDA batches of drug product is _____ The Drug Master File (DMF) No. _____ has been filed by _____ with US FDA. A sample of the bulk raw material is available and will be provided to the Agency upon request.



The required bioavailability/bioequivalence study conducted on Ranbaxy's Cefadroxil for Oral Suspension USP, 500 mg/5ml and Bristol Myers Squibb's Duricef[®] for Oral Suspension 500 mg/5 mL (Cefadroxil for Oral Suspension) by

is included in this section. The study results indicate that Cefadroxil for Oral Suspension USP 500 mg/5mL is bioequivalent to Duricef[®] for Oral Suspension 500 mg/5ml. The *in-vitro* dissolution profiles for Ranbaxy's Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml are comparable to those of Bristol Myers Squibb's Duricef[®] for Oral Suspension 125 mg/5ml, 250 mg/5ml and 500 mg/5ml. Therefore, a waiver of *in-vivo* bioavailability/bioequivalence study requirements for Ranbaxy's Cefadroxil for Oral Suspension USP, 125 mg/5ml and 250 mg/5ml is requested.

Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml are stable and a two year expiration dating is requested. The two year expiration dating for these products is supported by one, two and three months accelerated stability data (40°C/75% relative humidity).

The dosage form, route of administration, indications and usage, dosage, route of administration, active ingredient, potency and labeling (except DESCRIPTION and HOW SUPPLIED sections) for Ranbaxy's Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml are same as those for Bristol Myers Squibb's Duricef[®] for Oral Suspension 125 mg/5ml, 250 mg/5ml and 500 mg/5 ml (Cefadroxil for Oral Suspension)

This ANDA is submitted in seven volumes :

Volume I:	Section I through Section V
Volume II: through Volume IV	Section VI
Volume V:	Section VII through Section XI
Volume VI:	Section XII through Section XIV
Volume VII:	Section XV through Section XXII

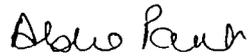
Food and Drug Administration
Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml
and 500 mg/5ml
Abbreviated New Drug Application
Page 3

Ranbaxy Laboratories Limited commits to resolve any issues identified in the method validation process after approval

Please contact the undersigned at 609-720-5666 if you have any questions regarding this submission.

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

Sincerely,



Abha Pant
US Agent for Ranbaxy Laboratories Limited.

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

March 13, 2002

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 20855-2773

FAX and UPS

**Bioequivalence
Amendment**

**Reference: Cefadroxil for Oral Suspension USP,
125 mg/5ml, 250 mg/5ml and 500 mg/5ml
ANDA - 65-115**

ORIG AMENDMENT

N/AB

Dear Sir/Madam:

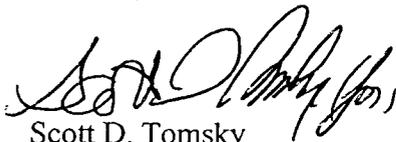
Reference is made to our pending ANDA 65-115 for Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml submitted to the Agency on December 17, 2001.

Reference is also made to the telephone contact of March 5, 2002, in which the Agency requested us to provide additional dissolution testing data.

The deficiency question and response is addressed on the following pages.

Please contact Scott D. Tomsy at 609-720-5609, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment.

Sincerely,



Scott D. Tomsy
Regulatory Affairs Associate (for)
Abha Pant
US Agent for Ranbaxy Laboratories Limited

RECEIVED

MAR 15 2002

OGD / CDER

RANBAXY

LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

June 14, 2002

Office of Generic Drugs
Division of Bioequivalence
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

UPS

**BIOEQUIVALENCE
COMMENTS
RESPONSE**

**Reference: Cefadroxil for Oral Suspension USP,
125 mg/5ml, 250 mg/5ml and 500 mg/5ml
ANDA - 65-115**

ORIG AMENDMENT

N/AB

Dear Sir/Madam:

Reference is made to our pending ANDA 65-115 for Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml submitted to the Agency on December 17, 2001.

Reference is also made to the Bioequivalence comments fax received May 31, 2002.

Responses and acknowledgments for each comment are addressed on the following pages.

Please contact Scott D. Tomsy at 609-720-5609, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment.

Sincerely,



Anthony M. Maffia, III
Regulatory Affairs Associate (for)
Abha Pant
US Agent for Ranbaxy Laboratories Limited

RECEIVED

JUN 18 2002

OGD / CDER

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

June 14, 2002

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 20855-2773

UPS

MINOR
AMENDMENT
RESPONSE
ORIG AMENDMENT
N/AM

Reference: Cefadroxil for Oral Suspension USP,
125 mg/5ml, 250 mg/5ml and 500 mg/5ml
ANDA - 65-115

Dear Sir/Madam:

Reference is made to our pending ANDA 65-115 for Cefadroxil for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml and 500 mg/5ml submitted to the Agency on December 17, 2001.

Reference is also made to the Minor Amendment letter of April 11, 2002.

The deficiency questions and our response to each question are addressed on the following pages.

FIELD COPY: This is to certify that the field copy, provided to the International Operation Group, is a true copy of the technical sections described in the 21 CFR 314.94 (d)(5), chemistry, manufacturing and controls section contained in the archival and review copies of the application.

Please contact Scott D. Tomsy at 609-720-5609, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment.

Sincerely,



Scott D. Tomsy
Regulatory Affairs Associate (for)
Abha Pant
US Agent for Ranbaxy Laboratories Limited

RECEIVED
JUN 18 2002
OGD / CDER

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

N/AF

July 23, 2002

ORIG AMENDMENT

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 20855-2773

UPS

LABELING AMENDMENT

Reference: ANDA 65-115
Cefadroxil for Oral Suspension, USP 125 mg/5 mL, 250 mg/5 mL
and 500 mg/5 mL

Dear Sir/Madam:

Reference is made to the pending ANDA 65-115 Cefadroxil for Oral Suspension, USP 125 mg/5 mL, 25 mg/5 mL and 500 mg/5 mL

Reference is also made to the facsimile labeling deficiency, dated July 22, 2002, in which Ranbaxy was asked to further revise the labels and package insert for the above referenced product.

The labels and package insert have been revised as requested. The faxed labeling deficiency responses, 4 draft copies of the revised labels and 4 draft copies of the package insert are included as attachment 1. To facilitate review we have provided a side-by-side labeling comparison with Ranbaxy's revised labeling and previously submitted, with all differences explained and shown with the use of color, as attachment 2.

Please contact the undersigned at 609-720-5633, or Abha Pant at 609-720-5666, if you have any questions regarding this labeling amendment.

Sincerely



Iris Feliciano
Regulatory Labeling Specialist

RECEIVED

JUL 26 2002

OGD / CDER

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

August 6, 2002

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 20855-2773

UPS

LABELING AMENDMENT

DRUG AMENDMENT
NIAF

Reference: ANDA 65-115
Cefadroxil for Oral Suspension, USP 125 mg/5 mL, 250 mg/5 mL
and 500 mg/5 mL

Dear Sir/Madam:

Reference is made to the pending ANDA 65-115 Cefadroxil for Oral Suspension, USP 125 mg/5 mL, 250 mg/5 mL and 500 mg/5 mL

Reference is also made to the facsimile labeling deficiency, dated July 22, 2002, in which Ranbaxy was asked to further revise the labels and package insert for the above referenced product.

The labels and package insert have been revised as requested. To facilitate review we have provided a side-by-side labeling comparison with Ranbaxy's revised labeling and previously submitted, with all differences explained and highlighted, as **Attachment 1**. Final printed copies of the revised labeling and package insert are included as **Attachment 2**. A side-by-side comparison of the previously submitted package insert and the newly submitted revised package insert is in **Attachment 3**.

Please contact the undersigned at 609-720-5336, or Abha Pant at 609-720-5666, if you have any questions regarding this labeling amendment.

Sincerely,



Anthony M. Maffia, III (for)
Abha Pant, U.S. Agent for Ranbaxy Laboratories Limited

RECEIVED

AUG 07 2002

OGD / CDER

RANBAXY
LABORATORIES LIMITED

SECTOR-18, UDYOG VIHAR INDUSTRIAL AREA, GURGAON-122001
PHONE: (91-1246) 342001-10, Fax: (91-1246) 342017, 342036

*Noted -
To Ruth*

October 11, 2002

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 20855-2773

UPS

ORIG AMENDMENT
N/AM

Minor Amendment

**Reference: Cefadroxil for Oral Suspension USP, 125 mg/5 mL, 250 mg/5 mL and 500 mg/5 mL
ANDA 65-115**

Dear Sir/Madam:

Reference is made to the pending ANDA 65-115 for Cefadroxil for Oral Suspension USP, 125 mg/5 mL, 250 mg/5 mL and 500 mg/5 mL. Reference is also made the Agency's Minor Amendment letter dated August 13, 2002.

The deficiency questions and responses are addressed on the following pages.

FIELD COPY: We certify that a true copy of the technical sections described in 21 CFR 314.94 (d)(5) of this submission has been provided to the FDA International Operations Group since manufacturing is done at Ranbaxy's facility, in Dewas, India.

Please contact Alexander Mironov at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment.

Sincerely,

Alex Mironov

Alexander Mironov
Regulatory Affairs Associate (for)
Abha Pant
US Agent for Ranbaxy Laboratories Limited

RECEIVED

OCT 15 2002

OGD / CDER

[Handwritten signature]
11/10/02

RANBAXY

PHARMACEUTICALS INC.

600 COLLEGE ROAD EAST PRINCETON, NEW JERSEY 08540

PHONE: 1-888-RANBAXY

ORIG AMENDMENT

January 22, 2003

UPS

N/AM

Office of Generic Drugs
Center for Drug Evaluation and Research
Division of Bioequivalence
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

**TELEPHONE AMENDMENT
BIOEQUIVALENCE COMMENTS**

**RE: CEFADROXIL FOR ORAL SUSPENSION, USP,
125 mg/5 mL, 250 mg/5 mL, 500 mg/5 mL
ANDA 65-115**

Dear Sir/Madam:

Reference is made to the above pending ANDA 65-115 for Cefadroxil for Oral Suspension, USP, 125 mg/5 mL, 250 mg/5 mL, 500 mg/5mL and the telephone contact between Ranbaxy and Mark Anderson at OGD on January 21, 2003.

Further to our December 6, 2002 acknowledgment letter, and as per the Agency's recent request, we are including the revised STP with the revised dissolution method as per the Agency's request of Nov 21, 2002. This revised STP may be found in **Attachment 1**. In addition, for reference, we are including copies of QC Release Specifications in **Attachment 2**, Stability Specifications in **Attachment 3** and the Stability Protocol in **Attachment 4**.

If you have any questions or comments, please call me at 609-720-5336 or Ms. Abha Pant at 609-720-5666.

Sincerely,



Anthony M. Maffia, III
Regulatory Affairs Associate (for)
Abha Pant
US Agent For Ranbaxy Laboratories Limited

RECEIVED

JAN 23 2003

OGD / CDER

RANBAXY

PHARMACEUTICALS INC.

600 COLLEGE ROAD EAST PRINCETON, NEW JERSEY 08540
PHONE: 1-888-RANBAXY

L NEW CORRESP

January 30, 2003

Office of Generic Drugs
Center for Drug Evaluation and Research
Division of Bioequivalence
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

UPS & FAX

NC

TELEPHONE RESPONSE

**RE: CEFADROXIL FOR ORAL SUSPENSION, USP,
125 mg/5 mL, 250 mg/5 mL, 500 mg/5 mL
ANDA 65-115**

Dear Sir/Madam:

Reference is made to the above pending ANDA 65-115 for Cefadroxil for Oral Suspension, USP, 125 mg/5 mL, 250 mg/5 mL, 500 mg/5mL and the telephone contact between Ranbaxy and OGD on January 30, 2003.

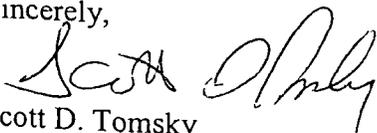
As per the Agency's request, we are including a description of the peel off container label.

These labels have been designed to enable the pharmacist to peel off a portion of the label to allow for the Pharmacy label to be placed in the peeled off area. Please note, there is no information contained under the peel off area. After peeling off this portion of the label, the following information is still attached to the container:

- lot number
- product name, strength
- brief directions
- UPC code which contains the product NDC code

If you have any further questions or comments, please call me at 609-720-5609 or Ms. Abha Pant at 609-720-5666.

Sincerely,



Scott D. Tomsky
Manager Regulatory Affairs (for)
Abha Pant
US Agent for Ranbaxy Laboratories Limited

RECEIVED

JAN 31 2003

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