CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74975

CORRESPONDENCE

ANDA 74-975

Lilly Ranbaxy Pharmaceuticals, L.L.C.
Attention: Jeffrey R. Ferguson
U.S. Agent for: Ranbaxy Laboratories Limited
One College Park
8910 Purdue Road, Suite 230
Indianapolis, IN 46268

DEC 4 1996

Dear Sir:

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

We also refer to your correspondence dated October 21, 1996 and November 25, 1996.

NAME OF DRUG: Acyclovir Capsules, 200 mg

DATE OF APPLICATION: October 9, 1996

DATE OF RECEIPT: October 10, 1996

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

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

Should you have questions concerning this application contact:

Tim Ames
Project Manager
(301) 594-0305

Sincerely yours,

/S/ 12/4/96

Jerry Phillips
Director,
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 74-975

MAR 18 1997

Lilly Ranbaxy Pharmaceuticals, L.L.C.
Attention: Jeffrey R. Ferguson
U.S. Agent for: Ranbaxy Laboratories Limited
One College Park
8910 Purdue Road, Suite 230
Indianapolis, IN 46268

Dear Sir:

Reference is made to the Abbreviated New Drug Application submitted on October 9, 1996 for Acyclovir 200 mg Capsules.

The Office of Generic Drugs has reviewed the bioequivalence data submitted and the following comments are provided for your consideration:

1. The dissolution should be conducted using the following FDA recommended dissolution methodology and specifications:

   Apparatus: USP 23 Apparatus I (basket)
   Speed: 100 rpm
   Medium: Deaerated water
   Volume: 900 mL
   Specifications: 'Q': NLT % in 30 minutes.

   Comparative dissolution should be conducted on 12 units of the test and reference bio-study lots. The results should be reported in terms of the mean, range and percent coefficient of variation.

2. The dissolution has been conducted on the test lot CT04826. The relationship between CT04826 and the number used in the study CT04799 should be clarified.

3. You have stated that "one of the extracted blanks had an interference at the retention time of the analyte approximately % of the LOQ"; since no other statement was made in relation to specificity, please provide the chromatogram of that sample.

As described under 21 CFR 314.96 an action which will amend this application is required. The amendment will be required to address all of the comments presented in this letter. Should you have any questions, please call Lizzie Sanchez, Pharm.D., Project Manager, at (301) 594-2290. In future correspondence regarding this issue, please include a copy of this letter.

Sincerely yours,

/S/

Nicholas Fleischer, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Lilly Ranbaxy Pharmaceuticals, L.L.C.
One College Park
8910 Purdue Road, Suite 230
Indianapolis, IN 46268

FEDERAL EXPRESS

AMENDMENT

October 21, 1996

Mr. Douglas Sporn, Director
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

Re: ANDA# 74-975
Acyclovir Capsules, 200 mg
Amendment - Drug Substance DMF Number

Dear Mr. Sporn:

We are submitting an amendment to Ranbaxy Laboratories Limited's pending Abbreviated New Drug Application for Acyclovir Capsules, 200 mg in accordance with Section 505(j) of the Federal Food, Drug, and Cosmetic Act and as described in 21 CFR 314.60.

Per our commitment in the initial ANDA application dated October 9, 1996 for the above referenced product, we are updating the application to provide the Drug Master File number for the Acyclovir drug substance. The FDA assigned DMF number is An updated DMF Authorization Letter from Ranbaxy Pharmaceuticals, Inc. (DMF U.S. Agent for Ranbaxy Laboratories Limited) is attached. Please incorporate this information into the application.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the coverletter and return it in the self-addressed, stamped envelope.

Sincerely,

Jeffrey R. Ferguson

Mr. Jeffrey R. Ferguson
Regulatory Affairs Director
Lilly Ranbaxy Pharmaceuticals, L.L.C.
(U.S. Agent for Ranbaxy Laboratories Limited)

Attachment

Phone: (317) 655-2000 / (800) 577-3221
Fax: (317) 655-2010

RANBAXY
PHARMACEUTICALS INC.
4600 MARRIOTT DRIVE-SUITE 100 RALEIGH, NORTH CAROLINA 27612
PHONE : (919) 510 0949 **FAX** : (919) 510 0958.

NDA ORIG AMENDMENT
AB

January 9, 1998

FEDERAL EXPRESS

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

BIOEQUIVALENCE AMENDMENT

Reference : **ANDA 74-975**
Acyclovir Capsules, 200 mg

Dear Sir/Madam:

Reference is made to the pending ANDA 74-975 for Acyclovir Capsules, 200 mg.

Reference is also made to the FDA Bioequivalence Deficiency Letter dated March 18, 1997. The questions and responses follow in the same order as in the letter. They are attached.

If you have any questions, regarding the submission, please call me at (919) 510-0949 ext 224 or Shirley Ternyik at ext 237.

Sincerely,

for Shirley Ternyik
Jim Sibert
US Agent for Ranbaxy Laboratories Limited

RECEIVED
JAN 12 1998
GENERIC DRUGS

RANBAXY
PHARMACEUTICALS INC.
4600 MARRIOTT DRIVE-SUITE 100 RALEIGH, NORTH CAROLINA 27612
PHONE: (919) 510 0949 **FAX**: (919) 510 0958.

May 26, 1997

Mr. Douglas Sporn
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

FEDERAL EXPRESS

RE: ✓ANDA 74-975
Acyclovir Capsules, 200 mg

ANDA 74-980
Acyclovir Tablets, 400 & 800 mg

Dear Mr. Sporn:

Effective May 23, 1997, Mr. Jim Sibert from Ranbaxy Pharmaceuticals Inc. assumed the U.S. Agent responsibilities for the above mentioned ANDAs. The U.S. agent letter is attached. My address and phone number are provided below.

James L. Sibert
Executive Director, Regulatory Affairs
Ranbaxy Pharmaceuticals Inc.
4600 Marriott Drive, Suite 100
Raleigh, NC 27612
Phone: (919)510-0949 ext. 224

If you have any questions regarding the submission, please call me.

Sincerely,

Jim Sibert

Jim Sibert
Executive Director Regulatory Affairs, Ranbaxy Pharmaceuticals Inc.
U.S. Agent for Ranbaxy Laboratories Ltd.

H:\RCOLE\LTRS\MAJORA.DOC

Lilly Ranbaxy Pharmaceuticals, L.L.C.
One College Park
8910 Purdue Road, Suite 230
Indianapolis, IN 46268

May 23, 1997

Mr. Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, Maryland 20855-2773

NEW DRUGS
NC

Re: ✓ANDA 74-975
Acyclovir Capsules, 200 mg

ANDA 74-980
Acylcovir Tablets, 400 & 800 mg

Dear Mr. Sporn:

This letter is to advise you and your staff that effective May 23, 1997 I will be leaving my position as Director of Regulatory Affairs for Lilly Ranbaxy Pharmaceuticals. I'm currently the listed US agent for the Ranbaxy Laboratories Limited (India) Acyclovir ANDAs referenced above.

Effective May 23, 1997, Mr. Jim Sibert from Ranbaxy's North American Office will assume my US agent responsibilities. The official designation of Jim Sibert as the US agent will be provided by Ranbaxy under separate cover. All further communications regarding the above referenced ANDAs should be directed to Mr. Sibert at the following address:

James L. Sibert
Executive Director, Regulatory Affairs
Ranbaxy Pharmaceuticals Inc.
4600 Marriott Drive, Suite 100
Raleigh, NC. 27612
Phone: (919) 510-0949 ext. 224

If you have any questions regarding this submission, please call either Mr. Sibert or myself.

Sincerely,

Jeffrey R. Ferguson

Jeffrey R. Ferguson
Director, Regulatory Affairs

MAY 27 1997

cc: Jim Sibert, Ranbaxy Pharmaceuticals Inc.

Phone: (317) 655-2000
Fax: (317) 655-2010

RANBAXY
PHARMACEUTICALS INC.

March 26, 1998

FEDERAL EXPRESS

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

MAJOR AMENDMENT

Reference: **ANDA 74-975**
Acyclovir Capsules, 200 mg

Dear Sir/Madam:

Reference is made to the pending ANDA 74-975 for Acyclovir Capsules, 200 mg.

Reference is also made to the FDA Major Deficiency Letter dated August 20, 1997. The questions and responses follow in the same order as in the letter. They are attached.

Also, please note that the name and address of the US Agent has changed. See attached US Agent letter from Ranbaxy Laboratories Ltd., India.

We certify that a true copy of the technical section described in 21 CFR 314.50 (d)(1) of this submission has been provided to the Food and Drug Administration Detroit District Office in Detroit, Michigan.

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

Sincerely,

Shirley Ternyik

Shirley Ternyik
US Agent for Ranbaxy Laboratories Limited

ST/mtr

RECEIVED
MAR 30 1998
GENERIC DRUGS

600 COLLEGE ROAD EAST • PRINCETON, NEW JERSEY 08540
PHONE: (609) 720-9200 FAX: (609) 720-1155

FPL

ORIG AMENDMENT

N/AF

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

August 24, 1998

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

FEDERAL EXPRESS

LABELING AMENDMENT

Reference: ANDA 74-975
Acyclovir Capsules, 200 mg

Dear Sir/Madam:

Reference is made to the pending ANDA 74-975 for Acyclovir Capsules, 200 mg.

Reference is also made to the FDA Labeling Deficiency Letter dated July 26, 1998 and the response submitted July 22, 1998.

Reference is also made to a telephone call on August 24, 1998 requesting twelve copies of real Final Printed package inserts. They are attached.

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

Sincerely,

Shirley Ternyik

Shirley Ternyik
US Agent for Ranbaxy Laboratories Limited

RECEIVED
AUG 25 1998
GENERIC DRUGS

FPL

RANBAXY
PHARMACEUTICALS INC

ORIG AMENDMENT
N/AF

July 22, 1998

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

FEDERAL EXPRESS

LABELING
AMENDMENT

Reference: **ANDA 74-975**
Acyclovir Capsules, 200 mg

Dear Sir/Madam:

Reference is made to the pending ANDA 74-975 for Acyclovir Capsules, 200 mg.

Reference is also made to the FDA Labeling Deficiency Letter dated July 26, 1998 (copy attached). Twelve copies of revised Final Printed Labeling are attached. They have been revised as requested.

To facilitate your review and in accordance with 21 CFR 314.914, we have provided a side-by-side comparison of our Final Printed Labeling, versus the last amendment, with all differences annotated.

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

Sincerely,

Shirley Ternyik

Shirley Ternyik
US Agent for Ranbaxy Laboratories Limited

Enclosures

RECEIVED
AUG 03 1998
GENERIC DF...

600 COLLEGE ROAD EAST • PRINCETON, NEW JERSEY 08540
PHONE: (609) 720-9200 **FAX**: (609) 720-1155

Lilly Ranbaxy Pharmaceuticals, L.L.C.
One College Park
8910 Purdue Road, Suite 230
Indianapolis, IN 46268

FEDERAL EXPRESS

October 9, 1996

Mr. Douglas Sporn, Director
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

Re: Initial ANDA Submission
Acyclovir Capsules, 200 mg

Dear Mr. Sporn:

Ranbaxy Laboratories Limited, New Delhi, India is hereby submitting an Abbreviated New Drug Application for Acyclovir Capsules, 200 mg as required by Section 505 of the Federal Food, Drug, and Cosmetic Act, and described in 21 CFR 314.94.

This application is submitted by Lilly Ranbaxy Pharmaceuticals, L.L.C., as the U.S. Agent/Representative to FDA for Ranbaxy Laboratories Limited. A letter appointing Mr. Jeffrey R. Ferguson as U.S. Agent can be found on the next page. Correspondence concerning this submission should be addressed as follows:

Mr. Jeffrey R. Ferguson
Regulatory Affairs Director
Lilly Ranbaxy Pharmaceuticals, L.L.C.
One College Park
8910 Purdue Road, Suite 230
Indianapolis, Indiana 46268

Please note that the drug substance manufacturer is also Ranbaxy Laboratories Limited. Their Drug Master File (DMF) was filed on October 8, 1996. The DMF number has not been assigned by the FDA. We commit to file an amendment to the ANDA application providing the DMF number as soon as it is assigned.

This drug product was developed by Ranbaxy Research Laboratories (a division of Ranbaxy Laboratories Limited) and technology transferred to Eli Lilly and Company, Indianapolis, Indiana. Eli Lilly and Company manufactured the exhibit batch and will manufacture the commercial batches for Ranbaxy Laboratories Limited. The drug product will be marketed in the United States by Lilly Ranbaxy Pharmaceuticals, L.L.C., a marketing joint venture between Ranbaxy Laboratories Limited and Eli Lilly and Company.

A comprehensive table of contents is provided which shows the volume and page number of our submission's contents, as required by the regulations part 314.94(a)(2).

This submission consists of the following designated volumes:

Contents	Jacket Color	Number of Volumes
Complete Application (total of 9 volumes):		
FDA Chemistry and Labeling Archival Copy	Blue	2
FDA Pharmacokinetic Archival Copy	Blue	7
Partial Applications:		
FDA Chemistry and Labeling Review Copy	Red	2
FDA Pharmacokinetic Review Copy	Orange	7
Methods Validation Package (in triplicate)	Purple	3

As instructed by the Indianapolis FDA office, a field copy in a burgundy jacket containing the technical section has been forwarded to the District Office at this address:

John P. Dempster
Director Enforcement Branch
U.S. Food and Drug Administration
1560 East Jefferson Avenue
Detroit, MI 48207

Section I of this submission contains a field copy certification of the authenticity of this copy.

Please acknowledge receipt of this submission by signing and dating the enclosed copy of the cover letter and return it in the self-addressed envelope provided.

Feel free to contact me by telephone at (317) 655-2006 if any questions arise with which I may help. We thank you for your time in the review of this application and look forward to receipt of your response.

Sincerely,

Jeffrey R. Ferguson

Mr. Jeffrey R. Ferguson
Regulatory Affairs Director
Lilly Ranbaxy Pharmaceuticals, L.L.C.
(U.S. Agent for Ranbaxy Laboratories Limited)