

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**65-056**

**CORRESPONDENCE**



**Corporate Headquarters:**  
TEVA PHARMACEUTICALS USA  
650 Cathill Road  
PO BOX 904  
Sellersville, PA 18960

**Corresponding Address:**  
TEVA PHARMACEUTICALS USA  
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Kulpsville, PA 19443

Phone: (215) 256-8400  
FAX: (215) 721-9669

Phone: (215) 256-8400  
FAX: (215) 256-7855

August 30, 2000

Gary Buehler, Acting Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

**TELEPHONE AMENDMENT**

**ORIG AMENDMENT**

N/A F

ANDA #65-056  
AMOXICILLIN TABLETS USP, 500 mg and 875 mg  
TELEPHONE AMENDMENT - RESPONSE TO AUGUST 28, 2000 AND AUGUST 29, 2000  
TELEPHONE CONVERSATIONS

Dear Mr. Buehler:

We submit herewith a telephone amendment to the above-referenced pending ANDA in response to comments set forth in an August 28, 2000 telephone conversation with Mark Anderson and the Review Chemist and on August 29, 2000 with Richard Adams and the Review Chemist.

Based on these discussions, Teva has reduced the stability water specification to be the same as the release specification. Please find the revised Finished Product Procedures Manual (Version 2.2) and Finished Product Stability Protocol for your review (Attachments 1 & 2, respectively). While the impurity specifications listed on page 1841 of our original application contained the drug substance manufacturer's stability limits of *Total* we do not intend to accept material which does not comply with Teva USA's limits of *Total* as listed in our laboratory procedure manual for the bulk drug.

It is Teva Pharmaceutical USA's opinion that the information provided herein represents a complete response to all of the Agency's comments presented in the August 28, 2000 and August 29, 2000 telephone conversations. This information is submitted for your continued review and approval. If there are any further questions, please do not hesitate to contact me at (215) 591-3142 or facsimile at (215) 591-8812.

Sincerely,

Deborah A. Jaskot  
Executive Director, Regulatory Affairs  
DAJ/brb  
Enclosures





Noted:  
① To Jackie Council  
② To Ruth Gonopsis  
M Anderson  
7/7/00

Deborah A. Jaskot  
Sr. Director, Regulatory Affairs

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June 30, 2000

Gary Buehler, Acting Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
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FACSIMILE AMENDMENT

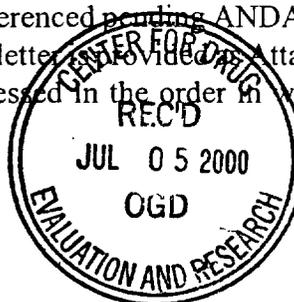
NDA ORIG AMENDMENT

N/FA

ANDA #65-056  
AMOXICILLIN TABLETS USP, 500 mg and 875 mg  
FACSIMILE AMENDMENT - RESPONSE TO REVIEW LETTER DATED JUNE 5, 2000

Dear Mr. Buehler:

We submit herewith a Facsimile Amendment to the above referenced pending ANDA in response to your letter of June 5, 2000. A copy of the June 5, 2000 review letter is provided as Attachment 1. The deficiencies presented in the aforementioned letter are addressed in the order in which they were presented.



- I. Chemistry
  - A. Deficiencies

1.

2.

1  
1  
1

B.

A  
C

2. [unclear] an alternative method for identification of

## II. Labeling

Final printed labels, insert, and a side-by-side comparison which incorporate revisions from deficiency comments are enclosed as Attachment 4. With regard to comment 1.a., please note that different colors are used on the container labels for the different strengths in order to easily differentiate them. Regarding comment 1.b., we have made your requested change, however, we have modified the wording slightly based on TEVA Pharmaceuticals USA format. Regarding comment 2.a., based on TEVA Pharmaceuticals USA format and recently approved labeling for other products, "Rx only" has not been included in our insert.

## III. Bioequivalency

We have previously incorporated the comments presented by the Division of Bioequivalence into our testing. We note that a food-effect study is not required for drug products containing

ANDA #65-056

AMOXICILLIN TABLETS USP, 500 mg and 875 mg

FACSIMILE AMENDMENT - RESPONSE TO REVIEW LETTER DATED JUNE 5, 2000

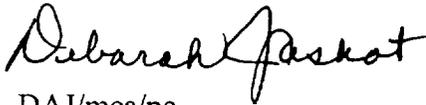
PAGE 3 of 3

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only amoxicillin. Additionally we note that the bioequivalency comments provided are preliminary and are subject to revision after review of the entire application.

The information provided herein represents, in our opinion, a complete response to your letter of June 5, 2000 and is submitted towards the continued review and approval of this pending ANDA. If any additional information or clarification is needed, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or by facsimile at (215) 256-8105.

Sincerely,



DAJ/mea/pe

Enclosures

29-03  
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21  
**TEVA**  
Deborah A. Jaskot  
Sr. Director, Regulatory Affairs

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**NDA ORIG AMENDMENT**

N/AB

February 29, 2000

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Hetro Park North II  
500 Standish Place, Room 150  
Rockville, MD 20855-2773

**BIOEQUIVALENCE  
TELEPHONE AMENDMENT**

ANDA #65-056  
MOXICILLIN TABLETS USP, 500 mg and 875 mg  
BIOEQUIVALENCE TELEPHONE AMENDMENT - RESPONSE TO TELEPHONE  
CONVERSATION ON FEBRUARY 22, 2000

Dear Mr. Sporn:

We submit herewith a Bioequivalence Telephone Amendment to the above-referenced pending ANDA in accordance with a telephone conversation with Ms. Jennifer Fan from the Division of Bioequivalence on February 22, 2000. Specifically, per that conversation, we are providing individual patient plasma concentration plots for the Fed Study.

This information is submitted for your review and approval of ANDA 65-056. If you have any questions, do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8405.

Sincerely,

*Deborah Jaskot*

J/mea  
Enclosures



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-100  
2/



Deborah A. Jaskot  
Sr. Director, Regulatory Affairs

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NDA ORIG AMENDMENT

N/AB

February 29, 2000

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Hetro Park North II  
500 Standish Place, Room 150  
Rockville, MD 20855-2773

BIOEQUIVALENCE  
TELEPHONE AMENDMENT

NDA #65-056  
MOXICILLIN TABLETS USP, 500 mg and 875 mg  
BIOEQUIVALENCE TELEPHONE AMENDMENT - RESPONSE TO TELEPHONE  
CONVERSATION ON FEBRUARY 22, 2000

Dear Mr. Sporn:

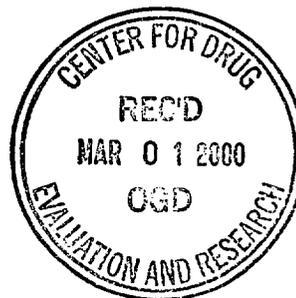
We submit herewith a Bioequivalence Telephone Amendment to the above-referenced pending ANDA in accordance with a telephone conversation with Ms. Jennifer Fan from the Division of Bioequivalence on February 22, 2000. Specifically, per that conversation, we are providing individual patient linear plasma concentration plots for the Fed Study.

This information is submitted for your review and approval of ANDA 65-056. If you have any questions, do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8405.

Sincerely,

*Deborah Jaskot*

J/mea  
Enclosures





Deborah A. Jaskot  
Sr. Director, Regulatory Affairs

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BIOEQUIVALENCE

February 14, 2000

**NDA ORIG AMENDMENT**

*N/A B*

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
7500 Standish Place, Room 150  
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**BIOEQUIVALENCE  
TELEPHONE AMENDMENT**

ANDA #65-056  
AMOXICILLIN TABLETS USP, 500 mg and 875 mg  
BIOEQUIVALENCE TELEPHONE AMENDMENT - RESPONSE TO TELEPHONE  
CONVERSATION ON FEBRUARY 7, 2000

Dear Mr. Sporn:

We submit herewith a Bioequivalence Telephone Amendment to the above-referenced pending ANDA in accord with a telephone conversation with Ms. Jennifer Fan from the Division of Bioequivalence on February 7, 2000. Specifically, per that conversation, we are providing individual patient linear plasma concentration plots for the Fasted Study.

This information is submitted for your review and approval of ANDA 65-056. If you have further questions, do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8105.

Sincerely,

DAJ/mea  
Enclosures



ANDA 65-056

Teva Pharmaceutical USA  
Attention: Deborah Jaskot  
1510 Delp Drive  
Kulpsville, PA 19443  
|||||

JAN 27 2000

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 December 21, 1999 and your correspondence dated December 21, 1999.

NAME OF DRUG: Amoxicillin Tablets USP, 500 mg and 875 mg

DATE OF APPLICATION: December 3, 1999

DATE (RECEIVED) ACCEPTABLE FOR FILING: December 6, 1999

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) 827-5849

Sincerely yours,



Robert L. West, M.S., R.Ph.  
Director  
Division of Labeling and Program  
Support  
Office of Generic Drugs  
Center for Drug Evaluation and  
Research

ANDA  
CC:

FILED IN 100-100000-1

..... of RSR  \_date 1/25/00  
\_date 1/24/00  
\_date



65-056

**Corporate Headquarters:**

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December 3, 1999

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

ORIGINAL ABBREVIATED NEW DRUG APPLICATION  
AMOXICILLIN TABLETS USP, 500 mg and 875 mg

Dear Mr. Sporn:

We submit herewith an abbreviated new drug application for the drug product Amoxicillin Tablets USP, 500 mg and 875 mg.

Enclosed are archival and review copies assembled in accord with Office of Generic Drugs February 1999 Guidance for Industry: Organization of an ANDA (OGD #1, Rev. 1). These copies are presented in a total of 15 volumes; 7 for the archival copy and 8 for the review copy.

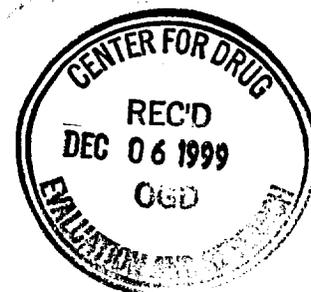
The application contains a full report of 2 *in vivo* bioequivalence studies. These studies compared Amoxicillin Tablets USP, 875 mg manufactured by TEVA Pharmaceuticals USA to the reference listed drug, Amoxil<sup>®</sup> Tablets, 875 mg, under both fasting and post-prandial conditions.

We look forward to your review and comment. Should there be any questions regarding the information contained herein, please do not hesitate to contact me by phone at (215) 256-8400, ext. 5249, or by facsimile at (215) 256-8105.

Sincerely,



DAJ/mea  
Enclosures





Deborah A. Jaskot  
Sr. Director, Regulatory Affairs

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December 21, 1999

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

NEW CORRESP

NC

ANDA # 65-056  
AMOXICILLIN TABLETS USP, 500 mg and 875 mg  
NEW CORRESPONDENCE

Dear Mr. Sporn:

We submit herewith an amendment to the above-referenced pending ANDA in accord with a telephone communication from Emily Thomas of your office and Philip Erickson on December 21, 1999. Specifically, at her request, we are providing the quantitative formulation of the  
: from

We look forward to your review and comment. Should there be any questions regarding the information contained herein, please do not hesitate to contact me by phone at (215) 256-8400, ext. 5249, or by facsimile at (215) 256-8105

Sincerely,

*Deborah Jaskot*

DAJ/mea  
Enclosures

