

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**ANDA 76-243**

**CORRESPONDENCE**



**West-ward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724  
732-542-1678 FAX 732-542-6150

505(j)(2)(a) ack  
11/15/01 Beth Fisher

September 24, 2001

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Doug Sporn, M.D.  
Director, Office of Generic Drugs

**Copy 1 – Archival**  
**Copy 2 – Review**  
**Copy 3 – Field**

**UPS NEXT DAY AIR**

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**ORIGINAL ANDA**

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Dear Dr. Sporn:

In accordance with the statutory provisions governing ANDA requirements outlined in Section 505(j) of the Federal Food, Drug and Cosmetic Act we submit herewith an Abbreviated New Drug Application for **Lithium Carbonate Capsules USP, 300 mg**. This drug product is the generic equivalent of **ESKALITH®** Capsules manufactured by Smithkline Beecham Pharmaceuticals.

The drug product for which the applicant seeks approval will be manufactured, packaged and labeled at West-ward Pharmaceutical Corp. located at 435/465 Industrial Way West, Eatontown, NJ 07724.

In support of this ANDA submission enclosed please find the following:

- **VOLUME 1.1 (1 Red Binder)**

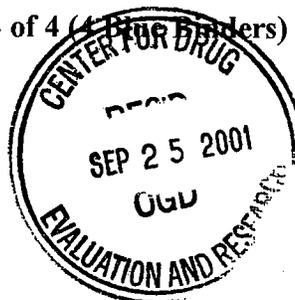
LABELING, CHEMISTRY AND MANUFACTURING CONTROLS

- **VOLUME 1.1, 1.2, and 1.3 (3 Orange Binders)**

2 *IN VIVO* BIOEQUIVALENCE STUDIES (2-way fed and fasting) & *IN VITRO* DISSOLUTION DATA

- **VOLUMES 1 of 4, 2 of 4, 3 of 4, and 4 of 4 (4 Blue Binders)**

ARCHIVAL COPY



In addition, a Third Copy (**FIELD COPY**) of Volumes 1.1 through 1.4 (4 Volumes) is being submitted as required under Title 21 CFR Part 314. This third copy is to be used for a Pre-approval Inspection by FDA investigators to audit application commitments and statements against actual manufacturing practices. The applicant certifies that this **FIELD COPY** is a true copy of the original submission and it has been forwarded to the District Office. (**See SECTION XXI – FIELD COPY Certification**).

All correspondence regarding this application should be directed to the undersigned. All telephone communications should be directed to 732-542-1678; ext. 68 or 732-460-0763. The fax number is 732-542-6150.

We look forward to your review of this ANDA and await notification of receipt of this submission.

Sincerely,



Elizabeth A. Marro  
Senior Director, Regulatory Affairs and Quality Assurance

**APPEARS THIS WAY  
ON ORIGINAL**



**West-ward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724

732-542-1678 FAX 732-542-6150

September 24, 2001

U.S. Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3<sup>rd</sup> Floor  
Parsippany, NJ 07054

**UPS NEXT DAY AIR**

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**ORIGINAL ANDA- FIELD COPY**

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Dear Sirs:

As required by the regulations governing ANDA requirements amending 21 CFR §314.50 of the Federal Food, Drug and Cosmetic Act, we submit herewith the third copy (**FIELD COPY**) of the original ANDA submission for the above-referenced product (4 Volumes).

This **FIELD COPY** is to be used for a Pre-Approval Inspection by FDA investigators to audit application commitments and statements against actual manufacturing practices.

If you have any questions regarding this submission, please contact the undersigned directly at 732-542-1678; ext. 68 or 732-460-0763. The fax number is 732-542-6150.

Sincerely,

Elizabeth A. Marro  
Senior Director, Regulatory Affairs and Quality Assurance



**West-ward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724  
732-542-1678 FAX 732-542-6150

# MINOR AMENDMENT TO ORIGINAL ANDA

October 26, 2001

*76-243*

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Doug Sporn, M.D.  
Director, Office of Generic Drugs

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**NEW CORRESP**  
*NC*

**UPS NEXT DAY AIR**

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**MINOR AMENDMENT TO ORIGINAL ANDA – Container Permeating Testing Results**

Dear Dr. Sporn:

Reference is made to our original ANDA submission for Lithium Carbonate Capsules USP, 300 mg dated September 24, 2001. While reviewing the ANDA it was noticed that the Container Permeation Testing results \_\_\_\_\_ in Section XIII "Container/Closure Testing" – pages 1989 – 1992 were incorrect. Please replace pages 1989 – 1992 with the correct pages.

We look forward to your review of this ANDA and await notification of receipt of this submission.

Sincerely,

*Colleen M. Kriessler*

Colleen M. Kriessler  
Regulatory Affairs Specialist





**West-ward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724  
732-542-1678 FAX 732-542-6150

## AMENDMENT TO PENDING ANDA CHANGE IN REFERENCE LISTED DRUG

November 9, 2001

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Paras Patel  
Regulatory Support Branch

NEW CORRESP

NC

Copy 1 – Archival  
Copy 2 – Review  
Copy 3 – Field

UPS 2nd DAY AIR

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**ANDA 76-243 : AMENDMENT TO PENDING ANDA – Change In Reference Listed Drug**

Dear Mr. Patel:

Reference is made to our original ANDA submission for Lithium Carbonate Capsules USP, 300 mg dated September 24, 2001. On November 6, 2001, a telephone request for information was made by you stating that there was a change in the Reference Listed Drug (RLD) from Eskalith® 300mg Capsules manufactured by SmithKline Beecham (application number 16-860) to Lithium Carbonate Capsules USP, 600mg manufactured by Roxane (application number 17-812).

We request that the FDA remove all references to Eskalith® 300mg Capsules as the RLD and replace them with Lithium Carbonate Capsules USP, 600mg. Enclosed please find the following 505j ANDA sections updated to reflect this change:

- **Section I- 356h FORM**
- **Section II- BASIS FOR ANDA SUBMISSION**
- **Section III- PATENT CERTIFICATION AND EXCLUSIVITY STATEMENT**
- **Section IV- COMPARISON BETWEEN GENERIC DRUG AND REFERENCE LISTED DRUG**

We are aware that the **Section V LABELING** requires revision; however, we are awaiting receipt of copies of the Roxane Lithium Carbonate Capsules USP, 600mg labeling and commit to amend the application as soon as received.



For informational purposes, you commented that the **Section VI BIOEQUIVALENCE** information was acceptable since the study was performed prior to the change and notification of the RLD.

We are confident that the above information is satisfactory to merit a critical review of the ANDA and await receipt of your ANDA assignment notification.

If you have any additional questions, please contact the undersigned at 732-542-1678, XT 68.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth A. Marro", with a long horizontal flourish extending to the right.

Elizabeth A. Marro  
Senior Director, Regulatory Affairs and Quality Assurance

**APPEARS THIS WAY  
ON ORIGINAL**

ANDA 76-243

West-ward Pharmaceutical Corp.  
Attention: Elizabeth A. Marro  
435/465 Industrial Way West  
Eatontown, NJ 07724

NOV 15 2001

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 November 6, 2001 and to your correspondence dated November 9, 2001.

NAME OF DRUG: Lithium Carbonate Capsules USP, 300 mg

DATE OF APPLICATION: September 24, 2001

DATE (RECEIVED) ACCEPTABLE FOR FILING: September 25, 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:

Kassandra Sherrod  
Project Manager  
(301) 827-5849

Sincerely yours,



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



# CHEMISTRY TELEPHONE AMENDMENT

ORIG AMENDMENT  
N/A

February 28, 2002

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Karen Bernard- Review Chemist

Copy 1 – Archival  
Copy 2 – Review

UPS NEXT DAY AIR

**Re: Lithium Carbonate Capsules USP, 300mg**  
**ANDA 76-243: TELEPHONE AMENDMENT TO ORIGINAL ANDA-Chemistry**

Dear Ms. Bernard:

Reference is made to a telephone request for information on February 27, 2002. Our response follows your comments below.

**COMMENT 1**

We note that you did not submit \_\_\_\_\_  
Please provide a copy.

**RESPONSE**

**Attachment 1** includes \_\_\_\_\_ for the commercial marketed package sizes of 100, 500 and 1000 which are included in the product literature.

**COMMENT 2**

For full clarification purposes, provide a list of all \_\_\_\_\_ and the \_\_\_\_\_. This should be provided in tabular form and include the \_\_\_\_\_.

**RESPONSE**

**Attachment 2** contains a side by side comparison (in tabular form) of the \_\_\_\_\_ after approval of this ANDA and \_\_\_\_\_.



for routine \_\_\_\_\_ . For informational purposes, a general side by side comparison was provided in the Original ANDA submission Section XII, pages 1907, 1937 and 1938.

**COMMENT 3**

We note that on the \_\_\_\_\_ Record you report a \_\_\_\_\_  
\_\_\_\_\_ Normally an acceptable \_\_\_\_\_

**RESPONSE**

**Attachment 3** contains the updated \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

We hope the information contained in this amendment is satisfactory for your review and prompt approval of this ANDA. If you have any additional questions, please contact me directly at 732-542-1678, XT 68.

**APPEARS THIS WAY  
ON ORIGINAL**

Sincerely,



Elizabeth A. Marro  
Senior Director, Regulatory Affairs and Quality Assurance



**Westward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724

732-542-1678 FAX 732-542-6150

## MINOR FACSIMILE AMENDMENT – LABELING

April 4, 2002

ORIG AMENDMENT  
N/A/M

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Koung Lee

Copy 1 – Archival  
Copy 2 – Review

UPS NEXT DAY AIR

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**ANDA 76-243/MINOR FACSIMILE AMENDMENT – LABELING**

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Dear Mr. Lee:

Reference is made to your facsimile letter dated March 4, 2002 regarding Labeling deficiencies to ANDA 76-243.

In accordance with the recommendations in your facsimile, the container labels and package outsert (Iss. 03/02: 3189-0302-00) have been revised. Enclosed please find 12 final printed container labels and package outserts and one side-by-side comparison for your review and approval.

Should you have any questions regarding this MINOR AMENDMENT, please feel free to contact me at 732-542-1191; ext. 7059.

Sincerely,

Colleen M. Kriessler  
Regulatory Affairs Specialist

RECEIVED

APR 05 2002

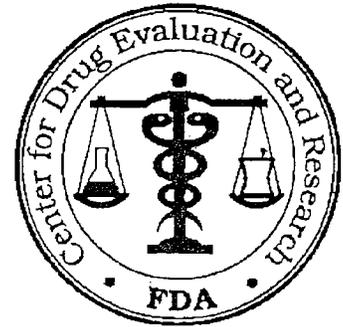
OGD / CDER

## MINOR AMENDMENT

ANDA 76-243

APR - 8 2002

OFFICE OF GENERIC DRUGS, CDER, FDA  
Document Control Room, Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773 (301-594-0320)



TO: APPLICANT: West-ward Pharmaceutical Corp. TEL: 732-542-1678, ext. 68

ATTN: Elizabeth A. Marro

FAX: 732-542-6150

FROM: Nicole Park

PROJECT MANAGER: 301-827-5849

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated September 24, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Lithium Carbonate Capsule USP, 300 mg.

Reference is also made to your amendment(s) dated: February 28, 2002.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (1 pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. The designation as a MINOR AMENDMENT should appear prominently in your cover letter. You will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

### SPECIAL INSTRUCTIONS:

**THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.**

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

*N Park 4/8/02*

APR - 8 2002

38. Chemistry Comments to be Provided to the Applicant

ANDA: 76-243

APPLICANT: Westward Pharmaceutical  
Corporation

DRUG PRODUCT: Lithium Carbonate Capsule USP, 300 mg

The deficiencies presented below represent MINOR deficiencies.

Deficiencies:

1. The Division of Chemistry has no further questions at this time. However, Labeling deficiencies were sent to you on March 4, 2002 and have not been responded. Please provide a response to the labeling deficiencies. Your bioequivalence information is pending review. Deficiencies, if any, will be communicated separately.

Sincerely yours,

*R.C. Adams for*

Florence Fang  
Acting Director  
Division of Chemistry II  
Office of Generic Drugs  
Center for Drug Evaluation and Research

**APPEARS THIS WAY  
ON ORIGINAL**



**West-ward**  
PHARMACEUTICAL CORP.

465 Industrial Way West, Eatontown, NJ 07724  
732-542-1678 FAX 732-542-6150

## CORRESPONDENCE LETTER – LABELING

April 9, 2002

NEW CORRESP.

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Nicole Park  
Project Manager

Copy 1 – Archival  
Copy 2 – Review

UPS NEXT DAY AIR

**Re: Lithium Carbonate Capsules USP, 300 mg**  
**ANDA 76-243/CORRESPONDENCE LETTER – LABELING**

Dear Ms. Park:

Reference is made to your facsimile dated April 8, 2002 requesting a response to the March 4, 2002 Labeling Deficiency. West-ward has responded to the March 4, 2002 Labeling Deficiency on April 4, 2002 and was received by the Agency on April 8, 2002.

Should you have any questions regarding this MINOR AMENDMENT, please feel free to contact me at 732-542-1191; ext. 7059.

Sincerely,

Colleen M. Kriessler  
Regulatory Affairs Specialist

RECEIVED

APR 10 2002

OGD / CDER

## CHEMISTRY TELEPHONE AMENDMENT

NC to Bio  
NEW CORRESP

April 23, 2002

Office of Generic Drugs, CDER, FDA  
Document Control Room  
Metho Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773  
Attn: Steven Mazzella

Copy 1 – Archival  
Copy 2 – Review

UPS NEXT DAY AIR

Re: **Lithium Carbonate Capsules USP, 300mg**  
**ANDA 76-243: TELEPHONE AMENDMENT TO ORIGINAL ANDA-Chemistry**

Dear Mr. Mazzella:

Reference is made to your telephone request for information on April 23, 2002. This is to inform you that West-ward Pharmaceutical Corp. located at 465 Industrial Way West, Eatontown, NJ 07724 conducted the dissolution profiles contained in Sections VI and XIV.

We hope the information contained in this amendment is satisfactory for your review and prompt approval of this ANDA. If you have any additional questions, please contact me directly at 732-542-1678, XT 7068.

Sincerely,



Elizabeth A. Marro  
Senior Director, Regulatory Affairs and Quality Assurance

RECEIVED

APR 24 2002

OGD / CDER