CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40262

CORRESPONDENCE

ANDA 40-262

Pharmachemie USA, Inc.
Attention: Hellen de Kloet
U.S. Agent for Pharmachemie B.V
323 Davis Street
Northborough, Massachusetts 01532

AUG 27 1997

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.

NAME OF DRUG: Leucovorin Calcium for Injection, 350 mg

DATE OF APPLICATION: July 28, 1997

DATE OF RECEIPT: July 29, 1997

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:

Sheila O'Keefe
Project Manager
(301) 827-5848

Sincerely yours,

/S/

Jerry Phillips 8/24/97
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

1510 Delp Drive
Kulpsville, PA19443
USA
Phone: (215) 256 8400 ext: 5228
Fax : (215) 256 7856
email : hdekloet@tevausa.com

PHARMACHEMIE U.S.A., INC.

October 11, 1999

Office of Generic Drugs
Center for Drug Evaluation and Research
FOOD AND DRUG ADMINISTRATION
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Subject: Minor Amendment #4 and Response to Microbiological Deficiencies (your letters from 05/04/99 and 07/21/99).

ANDA 40-262, Leucovorin Calcium for Injection, 350 mg

Dear Sir/Madam,

Enclosed is Pharmachemie B.V.'s Minor Amendment #4 in response to your May 04, 1999 and July 21, 1999 deficiency letters.

A copy - Field Copy - is also enclosed and is certified to be a "true' copy of the submission.

Please contact me if I can be of service to you.

Sincerely,

Ms. Hellen de Kloet
Vice President
Medical & Regulatory Affairs

Cc: K van Halderen - PCH BV

323 Davis Street
Northborough
Massachusetts 01532
Telephone: (508) 393-0973
Fax: (508) 393-0974
email: pchusa@gis.net

PHARMACHEMIE U.S.A., INC.

Office of Generic Drugs
Center for Drug Evaluation and Research
FOOD AND DRUG ADMINISTRATION
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Labeling review completed
C. Holquist
9-18-97

July 28, 1997

Subject: Submission Abbreviated New Drug Application
Leucovorin Calcium for Injection, 350 mg

Dear Sir/Madam,

Pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act, Pharmachemie BV is submitting an Abbreviated New Drug Application for Leucovorin Calcium for Injection, 350 mg. According to the 17th edition of Approved Drug products with Therapeutic Equivalence Evaluations (the "Orange Book"), the drug product in this application is the same as the approved in a new Drug Application held by Immunex (Lederle Laboratories) under the trade name Leucovorin Calcium for Injection.

The application is in the format described in Guidance for Industry: Organization of an ANDA and AADA of April 1997. It consists of two volumes plus two extra copies of section 16 for the Methods Validation Package. Also note that this application contains Sterility Assurance Data. A third copy - Field Copy - is also enclosed and is certified to be a "true' copy of the submission (see section II).

The attached Table of Contents outlines the information contained in the application. Pharmachemie B.V.'s Letter of Authorization for me to act as their Responsible Agent is found on page 4.
If you have any questions regarding this application, you may contact me at: 508 393 0973.

Sincerely,

Ms. Hellen de Kloet
Vice President Medical & Regulatory Affairs

RECEIVED
JUL 29 1997
GENERIC DRUGS

NB: could you please confirm receipt