CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-811

ADMINISTRATIVE DOCUMENTS

ANDA NUMBER 75-811

FIRM: American Pharmaceutical Partners, Inc.

DOSAGE FORM: Injection

STRENGTH: 100 mg/mL (1 gram in 10 mL multiple dose vial)

DRUG: Mesna

CGMP STATEMENT/EIR UPDATE STATUS: Pending Acceptable as of 2/16/01 MJS

BIO STUDY: The waiver of an *in vivo* bioequivalence study for the drug product was granted per the Division of Bioequivalence's review dated 5/1/00.

METHODS VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

MV is pending in Philadelphia. Cover letter to the lab is dated 12/12/00.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION? Yes

Vial:

Closure:

Seal:

Data are provided for exhibit lot R199-008.

3-month data for samples stored upright and inverted at 40° C/75% RH and tested at 0, 1, 2 and 3-months. Accelerated data tentatively support the proposed 24-month expiry date.

12-month data for samples stored upright and inverted at 25° C± 2° C/60% RH ± 5% RH and tested at 0, 3, 6, 9 and 12-months.

LABELING: Satisfactory per the December 14, 2000 review.

STERILIZATION VALIDATION (IF APPLICABLE):

Microbiology Review #1 (November 20 ,2000) recommended the submission for approval on the basis of sterility assurance.

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.?): (Yes.

Exhibit lot R199-008:

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA SAME PROCESS):

Same Process

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?

Same Process

Review Chemist: Shirley S. Brown 1/29/01 Shirley S. Brown 2/21/01
Team Leader: Michael Smela
Date: January 29, 2001 M Smela 2/21/01

ANDA 75-811

American Pharmaceutical Partners, Inc.
Attention: Michael Lisjak
2045 North Cornell Avenue
Melrose Park, IL 60160

MAR 29 2000

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.

NAME OF DRUG: Mesna Injection, 100 mg/mL,
1 g in 10 mL Multidose Vial

DATE OF APPLICATION: February 25, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: February 28, 2000

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:

Michelle Dillahunt
Project Manager
(301) 827-5848

Sincerely yours,

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