CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-811

CORRESPONDENCE

AMERICAN PHARMACEUTICAL PARTNERS, INC.

ARCHIVAL

January 23, 2001

Gary Buehler, Acting Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
FA

Re: ANDA 75-811
Mesna Injection
100 mg/mL
1 g in a 10 mL multidose vial
Product Code 730310
Manufacturing Site: Melrose Park, IL

FAX AMENDMENT

Dear Mr. Buehler:

Reference is made to our February 25, 2000 submission of an Abbreviated New Drug Application (ANDA) for Mesna Injection ANDA # 75-811. Reference is also made to the attached December 15, 2000 Fax Amendment for this application, which is provided immediately after this letter.

American Pharmaceutical Partners, Inc. (APP) is submitting this Amendment in response to each of the comments made in the facsimile deficiency letter dated December 15, 2000. For ease of review, each of the reviewer's observation is provided in bold, followed by APP's response.

Furthermore, in compliance with 21 CFR 314.94(d)(5), a true and complete copy (the Field Copy) of this Fax Amendment is being provided to Mr. Raymond Mlecko, District Director, Chicago District Office, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, HFR-MW100, Chicago, IL 60606.

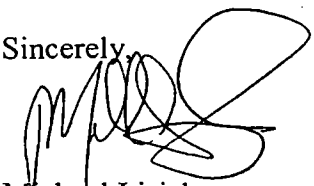
CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JAN 24 2001
OGD

2045 NORTH CORNELL AVENUE
MELROSE PARK, IL 60160-1002

MAIN TELEPHONE (708) 343-6100
TELEFAX (708) 547-4429
www.appdrugs.com

Should you have any questions or require additional information concerning this application, please do not hesitate to contact the undersigned at **(708) 547-2365** or Mitchall Clark, Vice President, Regulatory Affairs at **(708) 547-3618**.

Sincerely,



Michael Lisjak
Senior Regulatory Scientist

APP AMERICAN PHARMACEUTICAL PARTNERS, INC.
2045 N. Cornell Avenue
Melrose Park, IL 60160
Main (708) 343-6100
Direct (708) 547-2365
Fax (708) 343-4269

Facsimile Transmittal

January 3, 2001

FAX: 301-594-0180
Page: 2, Including cover

Michelle Dillahunt
FDA – Project Manager

Re: Mesna ANDA 75-811
Meeting with Frank O. Holcombe, Jr., Ph.D.,
Associate Director for Chemistry, FDA

Dear Ms. Dillahunt,

As per our conversation this morning, APP would like to formally request a telephone conference call with Frank O. Holcombe, Jr., Ph.D. This meeting is to discuss the Fax Amendment received December 15, 2000 regarding process impurities in the Mesna drug product. APP feels we have made an adequate argument for not developing a method to test for these process impurities in our response dated November 13, 2000. For your convenience, attached is a copy of our response to the FDA deficiency (dated September 1, 2000).

If you need anything else, please do not hesitate to contact me at the above numbers or via e-mail at mikelisjak@appdrugs.com.

Kind Regards,

Michael Lisjak
Sr. Regulatory Scientist

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AMERICAN PHARMACEUTICAL PARTNERS, INC.

2045 N. Cornell Avenue
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Facsimile Transmittal

December 15, 2000

Ms. Shirley Brown
FDA - Chemistry

FAX: 301-594-0180
Page: 4, including cover

Re: Mesna ANDA 75-811
SOP 10-08-01-6087, Sodium content

Dear Ms. Brown,

As requested, attached is the SOP for Content.

If you need anything else, please do not hesitate to contact me at the above numbers or via e-mail at mikelisjak@appdrugs.com.

Kind Regards,

Michael Lisjak
Sr. Regulatory Scientist

Page(s) 3

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

12/15/00

AMERICAN PHARMACEUTICAL PARTNERS, INC.

1.1

ARCHIVAL

November 13, 2000

Gary Buehler, Acting Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
N/A C

Re: ANDA 75-811
Mesna Injection
100 mg/mL
1 g in a 10 mL multidose vial
Product Code 730310
Manufacturing Site: Melrose Park, IL

MAJOR AMENDMENT

Dear Mr. Buehler:

Reference is made to our February 25, 2000 submission of an Abbreviated New Drug Application (ANDA) for Mesna Injection ANDA # 75-811. Reference is also made to the attached September 1, 2000 Deficiency Letter for this application, which is provided immediately after this letter.

Reference is also made to a conversation on October 2, 2000 between Mr. Michael Lisjak, Senior Regulatory Scientist, APP and Michelle Dillahunt, Project Manager, Office of Generic Drugs to reclassify this "Major Amendment" to a "Minor Amendment." In this conversation, Ms. Dillahunt advised that APP request the reclassification directly in this cover letter. Since the majority of the deficiencies concerned clarification of items in the ANDA or acknowledgement of reviewer comments, there is only a minimal amount of new information provided in this response. APP believes the Chemistry Manufacturing Controls portion of this response may take less than one (1) hour to review, and therefore respectfully request reclassification of this response as a "Minor Amendment."

American Pharmaceutical Partners, Inc. (APP) is submitting this Amendment in response to each of the comments made in the deficiency letter dated September 1, 2000. For ease of review, each of the reviewer's observation is provided in bold, followed by APP's response. Final Printed Labeling (FPL) is included in this response along with a separate binder containing twelve (12) copies of the FPL.

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Furthermore, in compliance with 21 CFR 314.94(d)(5), a true and complete copy (the Field Copy) of this Major Amendment is being provided to Mr. Raymond Mlecko, District Director, Chicago District Office, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, HFR-MW100, Chicago, IL 60606.

Should you have any questions or require additional information concerning this application, please do not hesitate to contact the undersigned at **(708) 547-2365** or Mitchall Clark, Vice President, Regulatory Affairs at **(708) 547-3618**.

Sincerely,

Michael Lisjak
Senior Regulatory Scientist

AMERICAN PHARMACEUTICAL PARTNERS, INC.

ack for filing
Solicitation
3/1/00
505(j) EM

February 25, 2000

Douglas Sporn, Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

Re: Mesna Injection
100 mg/mL
1 g in a 10 mL multidose vial (Code 730310)
Manufacturing Site: Melrose Park, IL
Number of Volumes: 5 Volumes

ORIGINAL ANDA

Dear Mr. Sporn:

This Abbreviated New Drug Application is submitted in accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) to seek marketing clearance for Mesna Injection. The reference listed drug is Mesnex® Injection manufactured by Asta.

American Pharmaceutical Partners, Inc. will manufacture this product in manufacturing facilities located at 2020 Ruby Street, Melrose Park IL 60160. This application contains all the information required describing the chemistry, manufacturing and control of Mesna Injection 100 mg/mL (1 g multi dose 10 mL vial). This application contains a request for the waiver of *in vivo* bioequivalence studies. This application also contains microbiology and sterility assurance information, which is provided in Section XXII. For the reviewer's convenience, a copy of the product labeling (package insert) is also provided in Section XXII.

The application has been formatted according to the information in the Guidance for Industry: Organization of an ANDA, dated February 1999. An executive summary explaining the organization of this application is included after the cover letter. The application consists of 5 volumes.

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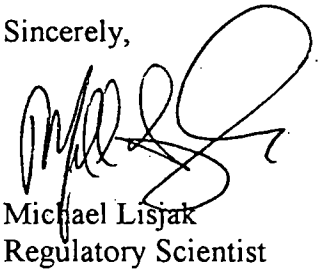
American Pharmaceutical Partners Inc. is filing an archival copy (in a blue folder) of the ANDA that contains all the information required in the ANDA and a technical review copy (in a red folder) which contains all of the information in the archival copy with the exception of the bioequivalence section (Section VI). Three copies of the analytical methods validation section are included in red folders. Four copies of the draft labeling are included in both the archival and the review copies. A separate copy of the bioequivalence section is provided in an orange folder. The bioequivalence section consists of a request for a waiver from the need to conduct a bioequivalence study.

Furthermore, in compliance with 21 CFR 314.94(d)(5), a true and complete copy (the Field Copy) of this abbreviated application is being provided to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606. We certify that the field copy is a true and complete copy of the Abbreviated New Drug Application.

Should you have any questions or require additional information concerning this application, please do not hesitate to contact the undersigned at **(708) 547-2365** or Nancy Bauer, Associate Director, Regulatory Affairs at **(708) 547-3618**.

Sincerely,



Michael Lisjak
Regulatory Scientist