CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-855

Chemistry Review(s)

NDA 20-855
REVIEW # 2

MESNEX (mesna) TABLETS

JOSEPHINE M. JEE
REVIEW CHEMIST

DIVISION OF ONCOLOGY
DRUG PRODUCTS
HFD-150/810

CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

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NDA 20-855
REVIEW # 3

MESNEX (mesna) TABLETS

JOSEPHINE M. JEE
REVIEW CHEMIST

DIVISION OF ONCOLOGY
DRUG PRODUCTS
HFD-150/810

CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

Chemistry NDA Review Data Sheet

1. NDA 20-855

2. REVIEW #: 3

3. REVIEW DATE: 20-MAR-2002

4. REVIEWER: JOSEPHINE M. JEE

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	20-Mar-1997 16-May-1997 17-Sep-1997 16-Dec-1997 23-Feb-1998
Review # 1 **Deficiency communication**	**25-Mar-1998**
Amendment [BZ]	24-AUG-2001
Amendment [BM]	24-SEP-2001
Amendment [NC}	25-SEP-2001
Amendment [BS]	02-OCT-2001
Amendment [BL]	05-OCT-2001
Amendment [BB]	08-OCT-2001
Facsimile (Carton Labels)	11-FEB-2002
e-mail (Carton and Blister Labels)	21-FEB-2002
Amendment [BC]	22-FEB-2002
Telecon Meeting Minutes	28-FEB-2002
Amendment [NC]	04-MAR-2002
Review # 2 (deficiency communication)	11-MAR-2002

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date

Facsimile (Response to comments)	19-MAR-2002 (7:00 PM)
BMS E-mail	20-MAR-2002 (7:31 AM)
BMS E-mail	20-MAR-2002 (8:24 AM)
BMS E-Mail	20-MAR-2002 (1:43 PM)

7. NAME & ADDRESS OF APPLICANT:

Name: (Former Owner) ASTA Medica AG	Weismuellerstrasse 45 D-60314 Frankfurt, Germany
Representative: Bristol-Myers Squibb	5 Research Parkway Wallingford, CT 06492
Name: (New Owner) Baxter Oncology GmbH	Daimlerstrasse 40 D-60314, Frankfurt

NOTE: As per Facsimile date 19-MAR-2002, 7:00 PM, Baxter Oncology GmbH is changed to Baxter Healthcare Corporation, Deerfield, Illinois 60015 USA

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: MESNEX TABLETS
b) Non-Proprietary Name (USAN): mesna
c) Code Name/# (ONDC only): MP-123456B
d) Chem. Type/Submission Priority (ONDC only):
   - Chem. Type: 3
   - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION:
MESNEX, TABLETS, 400 mg, ASTA Medica AG (Former Owner)
Baxter Oncology GmbH – New Owner

NOTE: As per Facsimile date 19-MAR-2002, 7:00 PM, Baxter Oncology GmbH is changed to Baxter Healthcare Corporation, Deerfield, Illinois 60015 USA

10. PHARMACOL. CATEGORY:

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
400 mg/ tablet

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note21]:
N/A

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Sodium-2-mercaptoethane sulfonate
$HS\text{-}CH_2\text{-}\ CH_2SO_3^-Na^+$
Mol. Formula: $C_2H_5O_3S_2Na$
M.W. 164.18

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
—	II	—	Mesna Drug Substance	3	Adequate	29-NOV-2001	
—	III	—	—	3	Adequate	18-SEP-1997	This DMF was adequate in Review # 1
—	I	—	—	2	Type 1 DMF	10-Sep-2001 (Inspection)	Type I DMF Satisfactory Inspection

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
	IND [redacted]	Mesna Tablets
	NDA 19-884	Mesnex Injection
	NDA 20-855	Mesna Tablets (CMC Review # 1)
	NDA 20-855	Mesna Tablets (CMC Review # 2)

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Acceptable	28-Feb-2002	Jasmine Choy
EES	Acceptable	10-Sep-2001	Melissa Garcia, CDER/OC
Pharm/Tox	Acceptable	25-Sep-2001	Wendelyn Schmidt, Ph.D.
Biopharm	Acceptable	08-Feb-2002	Zongyi John Duan, Ph.D.
LNC	Acceptable by	23-Jun-1997	D. Boring, Ph.D.
Methods Validation	Pending*	12-Mar-2002	Josephine M. Jee
OPDRA	Pending		
EA	Acceptable	23-Feb-1998	Josephine M. Jee
Microbiology	Not Applicable		

*** Pending after approval specifications and tests are finalized**

The Chemistry Review for NDA 20-855

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

NDA 20-855 is recommended for approval from the chemistry perspective based on the information submitted in the original NDA 20-855, 24-AUG-2001 amendment, amendments listed above (items 5 and 6), and the approved NDA 19-884, MESNEX Injection.
The amendment dated 24-AUG-2001 contained the applicant's response to those deficiencies cited in the 25-March-1998 Not Approvable letter (review #1) and proposed labeling. There are minor CMC comments related to labeling in the How Supplied section of the packaging insert, carton label, and blister label, CMC (review # 2). In addition, the in batches submitted for stability studies, tests for requalification for mesna drug substance, and reprocessing for mesna tablets deficiencies were communicated to the applicant on 13-MAR-2002 via facsimile by Debra Vause, Project Manger.

BMS, the US agent for Baxter Healthcare Corporation, has sent amendment via facsimile on March 19, 2002 and via e-mails on March 20, 2002 providing response to comments listed in CMC Review # 2. These responses were **adequately** addressed to issues listed in CMC Review # 2.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None.

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Mesnex (mesna) 400 mg immediate release Tablets are supplied as a white, oblong, scored biconvex film-coated tablets with the imprint M4.
Mesnex Tablets are made by [redacted] method.
Mesnex is a detoxifyng agent to inhibit the hemorrhagic cystitis induced by ifosfamide.
The active ingredient mesna is a synthetic sulfhydryl compound identified chemically as sodium-2-mercaptoethanesulfonate.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used orally. The maximum recommended daily dose is 400 mg.

C. Basis for Approvability or Not-Approval Recommendation

NDA 20-855 is recommended for approval from a CMC perspective. Chemistry review #1 on 25-Mar-1998 recommended Not Approvable. However, the information provided in the 24-AUG-2001 amendment has responded to the major CMC concerns listed in review #1. The comments cited in review # 2 were for minor changes. The responses received from the applicant in March 19, 2002 (facsimile) and in March 20, 2002 (e-mails) have adequately addressed all comments listed in review # 2. In addition, adequate labels and labeling have been provided from a CMC perspective.

III. Administrative

A. Reviewer's Signature

Josephine Jee

B. Endorsement Block

ChemistName/Date: Josephine Jee/ 20-MAR-2002
ChemistryTeamLeaderName/Date: Richard Lostritto
ProjectManagerName/Date: Debra Vause

C. CC Block

cc:
Org. NDA 20-855 Amendment
HFD-150/Division File
HFD-150/J.Jee/20-MAR-2002
HFD-150/D.Vause
HFD-150/R.Lostritto
HFD-810/J.Simmons
R/D Init by:
filename: **NDA20-855REV#3.r000.doc**

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/s/

Josephine Jee
3/21/02 09:47:06 AM
CHEMIST

Richard Lostritto
3/21/02 10:03:55 AM
CHEMIST

Chemistry NDA Review Data Sheet

1. NDA 20-855

2. REVIEW #: 2

3. REVIEW DATE: 11-MAR-2002

4. REVIEWER: JOSEPHINE M. JEE

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	20-Mar-1997 16-May-1997 17-Sep-1997 16-Dec-1997 23-Feb-1998
Review # 1 **Deficiency communication**	**25-Mar-1998**

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Amendment [BZ]	24-AUG-2001
Amendment [BM]	24-SEP-2001
Amendment [NC}	25-SEP-2001
Amendment [BS]	02-OCT-2001
Amendment [BL]	05-OCT-2001
Amendment [BB]	08-OCT-2001
Facsimile (Carton Labels)	11-FEB-2002
e-mail (Carton and Blister Labels)	21-FEB-2002
Amendment [BC]	22-FEB-2002
Telecon Meeting Minutes	28-FEB-2002
Amendment [NC]	04-MAR-2002

7. NAME & ADDRESS OF APPLICANT:

Name: (Former Owner) ASTA Medica AG	Weismuellerstrasse 45 D-60314 Frankfurt, Germany
Representative: Bristol-Myers Squibb	5 Research Parkway Wallingford, CT 06492
Name: (New Owner) Baxter Oncology GmbH	Daimlerstrasse 40 D-60314, Frankfurt

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: MESNEX TABLETS
b) Non-Proprietary Name (USAN): mesna
c) Code Name/# (ONDC only): MP-123456B
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 3
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION:
MESNEX, TABLETS, 400 mg, ASTA Medica AG (Former Owner)
Baxter Oncology GmbH – New Owner

10. PHARMACOL. CATEGORY:

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
400 mg/ tablet

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note22]:
N/A

Chemistry Review Data Sheet

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Sodium-2-mercaptoethane sulfonate
$HS\text{-}CH_2\text{-}\ CH_2SO_3^-Na^+$
Mol. Formula: $C_2H_5O_3S_2Na$
M.W. 164.18

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
—	II	—	Mesna Drug Substance	3	Adequate	29-NOV-2001	
—	III	—	—	3	Adequate	18-SEP-1997	This DMF was adequate in Review # 1
—	I	—	—	2	Type 1 DMF	10-Sep-2001 (Inspection)	Type I DMF Satisfactory Inspection

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
	IND —	Mesna Tablets
	NDA 19-884	Mesnex Injection
	NDA 20-855	Mesna Tablets (CMC Review # 1)

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Acceptable	28-Feb-2002	Jasmine Choy
EES	Acceptable	10-Sep-2001	Melissa Garcia, CDER/OC
Pharm/Tox	Acceptable	25-Sep-2001	Wendelyn Schmidt, Ph.D.
Biopharm	Acceptable	08-Feb-2002	Zongyi John Duan, Ph.D.
LNC	Acceptable by	23-Jun-1997	D. Boring, Ph.D.
Methods Validation	Pending*	12-Mar-2002	Josephine M. Jee
OPDRA	Pending		
EA	Acceptable	23-Feb-1998	Josephine M. Jee
Microbiology	Not Applicable		

*** Pending after approval specifications and tests are finalized**

APPEARS THIS WAY
ON ORIGINAL

The Chemistry Review for NDA 20-855

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

NDA 20-855 is recommended for approval from the chemistry perspective based on the information submitted in the original NDA 20-855, 24-AUG-2001 amendment, and amendments listed above (item 6), and the approved NDA 19-884, MESNEX Injection.

The amendment dated 24-AUG-2001 contained the applicant's response to those deficiencies cited in the 25-March-1998 Not Approvable letter (review #1) and proposed labeling. There are minor CMC deficiencies related to labeling in the How Supplied section of the packaging insert, carton label, and blister label, see pages 16 to 20 of CMC (review # 2). In addition, the . in batches submitted for stability studies, tests for requalification for mesna drug substance, and reprocessing for mesna tablets deficiencies have been communicated to the applicant on 13-MAR-2002 via facsimile by Debra Vause, Project Manger. These responses and revisions can be submitted as post-marketing commitments.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

The applicant should revise their regulatory specifications to include recommended specification for dissolution for mesna tablets. They should provide full accountability and reconciliation for . batches used in their stability studies. The requalification procedures for mesna should be revised to include full testing as outlined in their regulatory specifications and any reprocessing of mesna tablets should notify the Agency.

NDC numbers should appear in the How Supplied section of the labeling and in the carton label. ASTA Medica should be replaced by Baxter Oncology GmbH, since ownership was transferred as of January 1, 2002. In addition, the blister label need to be revised.

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Mesnex (mesna) 400 mg immediate release Tablets are supplied as a white, oblong, scored biconvex film-coated tablets with the imprint M4. Mesnex Tablets are made by method. Mesnex is a detoxifyng agent to inhibit the hemorrhagic cystitis induced by ifosfamide.

The active ingredient mesna is a synthetic sulfhydryl compound identified chemically as sodium-2-mercaptoethanesulfonate.

B. Description of How the Drug Product is Intended to be Used

The drug product is intended to be used orally. The maximum recommended daily dose is 400 mg.

C. Basis for Approvability or Not-Approval Recommendation

NDA 20-855 is recommended for approval from a CMC perspective. Chemistry review #1 on 25-Mar-1998 recommended Not Approvable. However, the information provided in the 24-AUG-2001 amendment has responded to the major CMC concerns. The comments cited in this review are for minor changes.

III. Administrative

A. Reviewer's Signature

Josephine Jee /S/

B. Endorsement Block

ChemistName/Date: Josephine Jee/28-FEB-2002
Revised : Josephine Jee/07-MAR-2002, 11-MAR-2002, 14-MAR-2002, 19-MAR-2002
ChemistryTeamLeaderName/Date: Richard Lostritto
ProjectManagerName/Date: Debra Vause

C. CC Block

cc:
Org. NDA 20-855 Amendment
HFD-150/Division File
HFD-150/J.Jee/2/28/02
HFD-150/D.Vause
HFD-150/R.Lostritto
HFD-810/J.Simmons
R/D Init by:
filename: **NDA20-855REV#2.001.doc**

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/s/

Josephine Jee
3/19/02 03:50:25 PM
CHEMIST

Richard Lostritto
3/19/02 11:01:29 PM
CHEMIST

DIVISION OF ONCOLOGY DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-855 **CHEM. REVIEW #:** 1 **REVIEW DATE:** 3/23/98

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	March 20, 1997	March 25,1997	April 7, 1997
Original	May 16, 1997	May 19 1997	May 27, 1997
Original	Sept. 17, 1997	Sept. 22, 1997	Sept. 23, 1997
Original	Dec. 16, 1997	Dec. 17, 1997	Dec. 22, 1997
Original	Feb. 23, 1998	Feb. 24, 1998	Feb. 26, 1998

NAME & ADDRESS OF APPLICANT: ASTA Medica, inc.
Continental Plaza
401 Hackensack Ave.
Hackensack, N. J. 07601

DRUG PRODUCT NAME

Proprietary: Mesnex (US) and Uromitexan™ (Germany & Canada).

Nonproprietary/USAN: Sodium-2-mercaptoethane sulfonate

Code Name/#: UCB 3983, and Asta-D-7093

Chem.Type/Ther.Class: [redacted]

CAS: 19767-45-4

PHARMACOL. CATEGORY/INDICATION:

DOSAGE FORM: Tablets
STRENGTHS: 400 mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: X Rx __ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Sodium-2-mercaptoethanesulfonate M.W.: 164.18

$[HS\text{-}CH_2\text{-}CH_2\text{-}SO_3^-]\ Na^+$

RELATED DOCUMENTS:

Related Doc. #	Holder/Applicant	Subject	Status
IND [redacted]	ASTA Medica	Mesna Tablets	current IND
NDA19,884	ASTA Medica	Mesnex Inj.	Approved

SUPPORTING DOCUMENTS:

Support Doc. #	Holder/ Applicant	Content/ Item	Status	Review Date	Letter Date
DMF [redacted] (Type II)	[redacted]	[redacted]	Deficient	3/11/98	3/11/98
DMF [redacted] (Type III)	[redacted]	[redacted]	Satisfactory		
DMF [redacted] (Type I)	[redacted]	[redacted]	Satisfactory		

CONSULTS:

Consult Type	Status	Comments
Trademark - Lab. & Nomenclature	Acceptable	O.K. on 6/23/97 by D. Boring
Env. Assess.	7/10/97	2/23/98 ASTA requested the withdrawal of the orig. EA and replace with a claim for categorical exclusion under 21 CFR section 25.31 (a).

REMARKS/COMMENTS:
See below for comments.

CONCLUSIONS & RECOMMENDATIONS:
This application can be considered Approvable from a CMC point of view only if the remaining deficiencies can be addressed satisfactorily. The CMC deficiencies are listed in the List of Chemistry deficiencies and comments.

cc:
Org. NDA 20-855
HFD-150/Division File
HFD-150/JJee/3-18-98
HFD-150/JJee/3-23-98 3/23/98
HFD-150/RWood
HFD-150/PGuinn
HFD-150/DPeace
R/D Init by: S 3-23-98

S

Josephine M. Jee, Review Chemist

filename: 20855.r1d

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CHEMISTRY REVIEW

Division of Oncology Drug Products

TYPE AND NUMBER OF APPLICATION : NDA 20-855 - Labeling Review 1
LABELING SUB. : 2/24/98 CDER DATE: 2/24/98 ASSIGNED DATE: 2/24/98

STATUS OF APPLICATION: Active
NAME OF SPONSOR: **ASTA MEDICA**
PRODUCT NAME: Mesnex® (mesna) Tablets
Proprietary: Mesnex
Nonproprietary: mesna
CHEMICAL STRUCTURE: $C_2H_5NaO_3S_2$

$HS\text{-}CH_2\text{-}CH_2SO_3^-Na^+$

DOSAGE FORM, STRENGTH, AND ROUTE OF ADMINISTRATION:
Tablets, 400 mg Oral
PROPOSED MARKETING STATUS: Rx
PHARMACOL. CATEGORY/ INDICATION:

Package Insert:

Description section
Adequate.

DOSAGE AND ADMINISTRATION
Adequate.

HOW SUPPLIED

a. Please provide full description of tablets (e.g., color, shape, coating, scoring, and imprint) to facilitate identification of the drug product, according to 21 CFR 201.57 (k) (3).

b. National Drug Code for mesna tablets should be included in the "How Supplied" section according to 21 CFR 201.57 (k) (3).

Unit Dose Label:

1. The label of the actual unit dose container must state the dosage form (e.g., Tablet).

2. The established name (mesna) and 400 mg Tablet should be printed in letters that are at least half as large as the letters comprising the proprietary name. The established name should precede the manufacturer name (ASTA Medica).

Outer package (box label):

The outer package from which the blister pack is dispensed should bear the following information:

1. The number of tablets should be clearly displayed (e.g., 10 400 mg Tablets should be replaced by 10 x 400 mg Tablets).

2. The declared amount, 400 mg, should follow (mesna) Tablets.

3. Expiration date should appear on the carton or box label as provided for in 21 CFR 201.17 and 211.137.

4. The lot or control number should appear on the carton or box label as provided for in 21 CFR 201.100 (b) and 211.130.

5. The line under MESNEX should be deleted.

6. Under Dosage, please delete the information provided after package insert.

5. The NDC number shall appear prominently in the top third of the principal display panel of the label as provided for in 21 CFR 207.35.

6. We recommend the following order when providing information for the box label:

Front panel:
- i. The number of tablets (e.g., 10 X 400 mg tablets)
- ii. NDC number
- iii. Proprietary name (MESNEX) - remove the line under MESNEX
- iv. Established name
- v. Declared amount, 400 mg.
- vi. For oral administration
- vii. Dosage statement
- viii. Storage conditions
- ix. Caution statement
- x. Names of distributor and manufacturer

Top panel:
- i. Lot or control number and expiration date
- ii. The number of tablets should be written as 10 x 400 mg tablets
- iii. NDC number
- iv Proprietary name (MESNEX®) - remove the line under MESNEX®
- v. Established name
- vi. Declared amount
- vii. Name of distributor

Side panel:

i. The number of tablets (e.g., 10 X 400 mg tablets)
ii. NDC number
iii. Proprietary name (MESNEX) - remove the line under MESNEX
iv. Established name
v. Each tablet contains 400 mg of mesna
vi. For oral administration
vii. Dosage statement
viii. Storage conditions
ix. Caution statement
x. Names and addresses of distributor and manufacturer

Please send samples of your final unit dose label and box label.

JS

Review Chemist, DNDC I, (HFD-150)

cc:
ORIG. NDA20-855
HFD-150/Div. File
HFD-150/JJee/ 2/26/98
HFD-150/ JJee 3/3/98
HFD-150/RWood
HFD-150/PGuir-
R/D Init. by:
Doc. #: 20855lap.rev

JS 3-4-98

MESNA TABLETS

Application Summary - Package Insert and Patient Package Insert

Contained in this section is the approved Package Insert for Mesnex® Injection which has been modified to include information on the tablets and the intravenous plus oral dosing schedule. The changed areas are in bold and references provided. We are also providing a draft Patient Package Insert.

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CDER Establishment Evaluation Report for March 16, 1998

Application: **NDA 20855/000**
Stamp: **25-MAR-1997** Regulatory Due: **25-MAR-1998**
Applicant: **ASTA MEDICA (US)**
401 HACKSENSACK AVE
HACKENSACK, NJ 07601

Priority: **3S** Org Code: **150**
Action Goal: District Goal: **23-NOV-1997**
Brand Name: **MESNEX (MESNA) 400MG TABS**
Established Name:
Generic Name: **MESNA**
Dosage Form: **TAB (TABLET)**
Strength: **400 MG**

FDA Contacts:			
	L. VACCARI	**(HFD-150)**	**301-594-2473 , Project Manager**
	J. JEE	**(HFD-150)**	**301-594-2473 , Review Chemist**
	R. WOOD	**(HFD-150)**	**301-594-2473 , Team Leader**

Overall Recommendation:

ACCEPTABLE on 20-FEB-1998 by M. EGAS (HFD-322) 301-594-0095

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **19-FEB-1998**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: [redacted]

Establishment: **9611095**
ASTA MEDICA AG
D-4802, WERK KUENSEBECK, KANS
HALLE-KUENSEBECK, , GM
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **06-JUN-1997**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: [redacted]

Establishment: [redacted]
DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **20-FEB-1998**
Decision: **ACCEPTABLE**

Responsibilities: [redacted]

Reason: **DISTRICT RECOMMENDATION**

Establishment: [redacted]

DMF No: [redacted]
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **06-JUN-1997**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: [redacted]