CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-019

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 76-019

3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories, Inc.
Attention: Jonathan Dohnalek
200 Abbott Park Road
Dept. 0389, Bldg AP30-1
Abbott Park, IL 60064-6157

4. LEGAL BASIS FOR SUBMISSION
Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 500MG/VIAL
Application Number: 16-267
Approved prior to Jan 1, 1982
Reference Listed Drug: Yes

There are no unexpired patents for this product.
There is no unexpired exclusivity for this product.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Deferoxamine Mesylate for Injection USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
31-OCT-2000: Original Submission

FDA:
08-DCE-2000: Acknowledgement Letter

10. PHARMACOLOGICAL CATEGORY
Iron-chelating agent

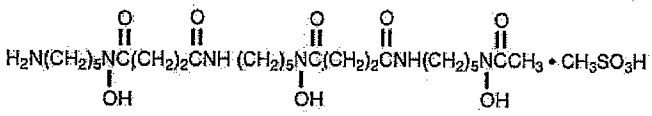
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Lyophilized Powder for Injection; subcutaneous, I.M. or I.V.

14. POTENCIES
500 mg/vial

15. CHEMICAL NAME AND STRUCTURE
Butanediamide, N'-[5-[[4-[[5-(acetylhydroxyamino)pentyl]-amino]-1,4-dioxobutyl]hydroxyamino)pentyl]-N-5-aminopentyl)-N-hydroxy-,monomethanesulfonate.
MW: 656.79



16. RECORDS AND REPORTS
Labeling Review-Deficient 1/3/01
Bio Review-Acceptable 1/10/01

17. COMMENTS
EER found Acceptable.
Bio Division approved Bio Waiver.
1st Labeling Review found deficiencies.
Micro Review is pending.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend Minor Amendment

19. REVIEWER: D. Roselle, Ph.D.
DATE COMPLETED: 20-MAR-2001

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1. CHEMISTRY REVIEW NO. 2

2. ANDA # 76-019

3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories
Attention: Jonathan Dohnalek
200 Abbott Park Road, D-389, J45/2
Abbott Park, IL 60064-6133

4. LEGAL BASIS FOR SUBMISSION
Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 500MG/VIAL
Application Number: 16-267
Approved prior to Jan 1, 1982
Reference Listed Drug: Yes

Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 2 G/VIAL
Application Number: 16-267
Approved prior to May 25, 2000
Reference Listed Drug: Yes

There are no unexpired patents for this product.
There is no unexpired exclusivity for this product.

5. SUPPLEMENT(s) N/A 6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Deferoxamine Mesylate for Injection USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
31-OCT-2000: Original Submission
07-NOV-2001: Major Amendment - 2 g/vial New Strength
30-JAN-2002: Amendment - Requested Information
12-APR-2002: Label Amendment

FDA:
08-DEC-2000: Acknowledgement Letter
11-MAY-2001: Minor Deficiency Letter
12-JUN-2001: Micro Deficiency Letter

10. PHARMACOLOGICAL CATEGORY
Iron-chelating agent

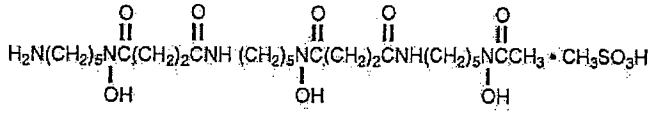
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Lyophilized Powder for Injection; subcutaneous, I.M. or I.V.

14. POTENCIES
500 mg/vial & 2 g/vial

15. CHEMICAL NAME AND STRUCTURE
Butanediamide, N'-[5-[[4-[[5-(acetylhydroxyamino)pentyl]-amino]-1,4-dioxobutyl]hydroxyamino)pentyl]-N-5-aminopentyl)-N-hydroxy-,monomethanesulfonate.
MW: 656.79



16. RECORDS AND REPORTS
Labeling Review
Bio Waiver
Chemistry Review 1

17. COMMENTS
EER found Acceptable.
Bio Waivers granted for 500 mg & 2 g configurations.
Labeling Division approved final labeling (500 mg & 2 g).
Micro found acceptable: June 7, 2002
Testing needed to address potential adverse reactions (GJSmith)

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend Not Approvable - Major

19. REVIEWER:
D. Roselle, Ph.D.

DATE COMPLETED:
21-FEB-2002/27-JUN-2002

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1. CHEMISTRY REVIEW NO. 3

2. ANDA # 76-019

3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories
Attention: Jonathan Dohnalek
200 Abbott Park Road, D-389, J45/2
Abbott Park, IL 60064-6133

4. LEGAL BASIS FOR SUBMISSION
Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 500MG/VIAL
Application Number: 16-267
Approved prior to Jan 1, 1982
Reference Listed Drug: Yes

Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 2 G/VIAL
Application Number: 16-267
Approved prior to May 25, 2000
Reference Listed Drug: Yes

There are no unexpired patents for this product.
There is no unexpired exclusivity for this product.

5. SUPPLEMENT(s) N/A 6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Deferoxamine Mesylate for Injection USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
31-OCT-2000: Original Submission
07-NOV-2001: Major Amendment - 2 g/vial New Strength
30-JAN-2002: Amendment - Requested Information
12-APR-2002: Label Amendment
25-NOV-2002: New Correspondence
20-DEC-2002: Major Amendment
(Refer to Section No. 25)

FDA:
08-DEC-2000: Acknowledgement Letter
11-MAY-2001: Minor Deficiency Letter
12-JUN-2001: Micro Deficiency Letter
16-JUL-2002: Major Deficiency Letter

10. PHARMACOLOGICAL CATEGORY
Iron-chelating agent

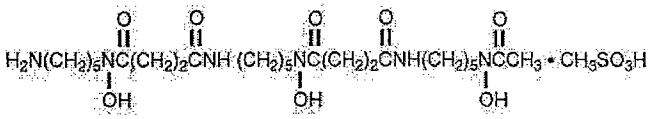
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Lyophilized Powder for Injection; subcutaneous, I.M. or I.V.

14. POTENCIES
500 mg/vial & 2 g/vial

15. CHEMICAL NAME AND STRUCTURE
Butanediamide, N'-[5-[[4-[[5-(acetylhydroxyamino)pentyl]-amino]-1,4-dioxobutyl]hydroxyamino)pentyl]-N-5-aminopentyl)-N-hydroxy-,monomethanesulfonate.
MW: 656.79



16. RECORDS AND REPORTS
Labeling & Micro Review
Bio Waiver
Chemistry Review 1 & 2

17. COMMENTS
EER found Acceptable: 21-DEC-2000
(FUR submitted 30-APR-2003).
Bio Waivers granted for 500 mg & 2 g configurations.
Labeling Division approved final labeling (500 mg & 2 g).
Micro found acceptable: 16-APR-2003
API testing needed to address potential adverse reactions.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend Minor Amendment

19. REVIEWER: D. Roselle, Ph.D.
DATE COMPLETED: 28-APR-2003

APPEARS THIS WAY
ON ORIGINAL

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ANDA: 76-019 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Deferoxamine Mesylate for Injection USP,
500 mg/vial and 2 g/vial

Reference is made to your amendment dated July 1, 2003. Review indicates that the protocol with the proposed method as described in your amendment should be suitable without further revision. Please note that final determination will be dependent upon acceptable review of the completed package. Your response shall be considered a Minor amendment.

Sincerely yours,

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

1. CHEMISTRY REVIEW NO. 4

2. ANDA # 76-019

3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories
Attention: Jonathan Dohnalek
200 Abbott Park Road, D-389, J45/2
Abbott Park, IL 60064-6133

4. LEGAL BASIS FOR SUBMISSION
Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 500MG/VIAL
Application Number: 16-267
Approved prior to Jan 1, 1982
Reference Listed Drug: Yes

Proprietary Name: DESFERAL
Applicant: NOVARTIS
Strength: 2 G/VIAL
Application Number: 16-267
Approved prior to May 25, 2000
Reference Listed Drug: Yes

There are no unexpired patents for this product.
There is no unexpired exclusivity for this product.

5. SUPPLEMENT(s) N/A 6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME Deferoxamine Mesylate for Injection USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:
Firm:
31-OCT-2000: Original Submission
07-NOV-2001: CMC Major Amendment - 2 g/vial New Strength
30-JAN-2002: Amendment - Requested Information
12-APR-2002: Label Amendment
25-NOV-2002: New Correspondence
20-DEC-2002: Major Amendment
(Refer to Section No. 25)
30-OCT-2003: CMC Amendment (Extends Expiration Period)
(Refer to Section No. 29)
07-JAN-2004: Micro Amendment
05-FEB-2004: Commitment for tentative 30 months expiration

FDA:
08-DEC-2000: Acknowledgement Letter
11-MAY-2001: Minor Deficiency Letter
12-JUN-2001: Micro Deficiency Letter
16-JUL-2002: Major Deficiency Letter
23-JUL-2003: Minor Deficiency Letter

10. PHARMACOLOGICAL CATEGORY
Iron-chelating agent

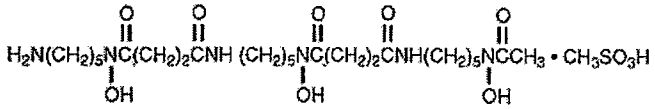
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Lyophilized Powder for Injection; subcutaneous, I.M. or I.V.

14. POTENCIES
500 mg/vial & 2 g/vial

15. CHEMICAL NAME AND STRUCTURE
Butanediamide, N'-[5-[[4-[[5-(acetylhydroxyamino)pentyl]-amino]-1,4-dioxobutyl]hydroxyamino)pentyl]-N-5-aminopentyl)-N-hydroxy-,monomethanesulfonate.
MW: 656.79



16. RECORDS AND REPORTS
Labeling & Micro Reviews
Bio Waivers
Chemistry Reviews 1, 2 & 3

17. COMMENTS
EER Acceptable: 21-DEC-2000
Bio Waiver (500 mg): 10-JAN-2001
Bio Waiver (2 g): 20-FEB-2002
Labeling Approval (500 mg & 2 g): 15-MAY-2002
Micro Acceptable (Initial): 7-JUN-2002
Micro Acceptable ([redacted] : 17-APR-2003
Micro Acceptable [redacted] : 22-JAN-2004

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend Approval

19. REVIEWER: D. Roselle, Ph.D.

DATE COMPLETED: 05-FEB-2004

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