

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-290

CORRESPONDENCE



Response to Telephone Amendment/ Patent Amendment

April 25, 2001

Michelle Dillahunt
Project Manager, Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT
AM

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Ms. Dillahunt:

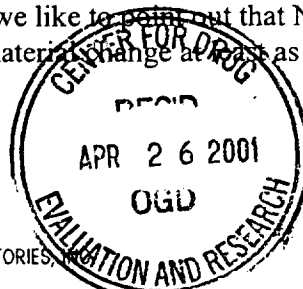
We wish to amend our Abbreviated New Drug Application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial. This is in reference to a telephone conversation on April 20, 2001 between Ms. Michelle Dillahunt and Mr. Robert West of the Agency and Ms. Pratima Patel of Ben Venue Laboratories, Inc.

FDA 356h form is provided.

As requested, a copy of Novartis Corporation's complaint for Patent 4,771,880 Infringement is provided in this amendment.

Novartis Corporation filed a legal action on May 8, 1998 regarding the infringement of Patent 4,771,880 in the United States District Court, of New Jersey. Therefore, Bedford Laboratories would like to request to the Agency that in accordance with 21 CFR 355 (j) (5) (B) (iii), full approval shall be made effective upon the expiration of the thirty-month period (November 8, 2000).

Title 21 CFR 314.94 (a)(12)(viii)(C)(1) requires that the sponsor of a pending ANDA submit an amended Patent Certification only if, "the applicant learns that the submitted certification is no longer accurate." An amended Patent Certification was not required, as Bedford Laboratories concluded that the original Paragraph IV Certification continued to be accurate. Specifically, our original Paragraph IV Certification concluded that the U.S. Patent 4,771,880 would not be infringed. Following the change in starting materials, that contention continues to be accurate. Also, we like to point out that Novartis (by its council) received actual notice of Bedford Laboratories' starting material change at least as early as October 19, 1999.



A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264



We trust this meets your approval. If you need any assistance in the review of this application, the phone numbers for contact are (440)-201-3333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in black ink, appearing to read "P. Patel for", written over the printed name.

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.

A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264

**RESPONSE TO
TELEPHONE
AMENDMENT**

ANDA 75-290

NDA ORIG AMENDMENT

N/A

From: Pratima Patel
Supervisor, Regulatory Affairs
Ben Venue Laboratories

☎ (440) 201-3469 (Direct)
(440) 232-2772 (Fax)

To: Robert West
Acting Deputy Director
OGD/CDER/FDA
Document Control Room,
Metro Park, North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

☎ (301) 827-5845
(301) 594-0183 (Fax)

Product: Pamidronate Disodium for Injection

Date: April 30, 2001

Comments: Enclosed, please find revised section of final printed package insert labeling of above mentioned drug product. Twelve copies of this revised package insert will be forwarded to you via FedEx.

Pages: 5 , including this cover sheet



Response to Telephone Amendment/ Chemistry Deficiencies

April 30, 2001

Robert West
Acting Deputy Director, HFD-601
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

NDA ORIG AMENDMENT
N/AM

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Mr. West:

We wish to amend our Abbreviated New Drug Application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial by providing revised final printed package insert labeling. This is in reference to a telephone conversation on April 27, 2001 between Mr. Robert West of the Agency and Ms. Pratima Patel of Ben Venue Laboratories, Inc.

FDA 356h form is provided.

As we have discussed, final printed package insert labeling has been revised by deleting the use of twelve copies of revised final printed package insert labeling are provided in this amendment for your review.

We trust this meets your approval. If you need any assistance in the review of this application, the phone numbers for contact are (440)-201-3469 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in cursive script, appearing to read "P. Patel".

Pratima Patel
Supervisor, Regulatory Affairs
Ben Venue Laboratories, Inc.

A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264

**RESPONSE TO
TELEPHONE
AMENDMENT****ANDA 75-290****NDA ORIG AMENDMENT***N/Am*

From: Pratima Patel
Supervisor, Regulatory Affairs
Ben Venue Laboratories

☎ (440) 201-3469 (Direct)
(440) 232-2772 (Fax)

To: Frank O. Holcombe, Jr. Ph.D.
Associate Director for Chemistry,
HFD-600
OGD/CDER/FDA
Document Control Room,
Metro Park, North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

☎ (301) 827-5845
(301) 594-0183 (Fax)

*REVISION
ACCEPTABLE
4/30/01*

Product: Pamidronate Disodium for Injection

Date: April 30, 2001

Comments: Enclosed, please find revised Compounding Instructions of the Master Batch Records, where the use of _____ has been deleted.
Hard copies of this document will be sent to you via FedEx.

Pages: 34 , including this cover sheet



February 28, 2001

Response to Telephone Amendment/
Chemistry Deficiencies

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT

N/AM

RE: **ANDA 75-290**
Product: **Pamidronate Disodium for Injection, 30 mg and 90 mg per vials**

Dear Sir:

We wish to amend our unapproved Abbreviated New Drug Application 75-290, Pamidronate Disodium for Injection, 30 and 90 mg per vials, by revising the Active Drug Specifications for Bioload test. This is in reference to the telephone conversation of February 28, 2001, between Mr. Shahid Ahmed of Ben Venue Laboratories and Dr. Rashmikanth Patel and Dr. David Gill of the Agency.

FDA form 356h is provided.

Attached, please find revised Active Drug Substance Specifications for the Agency's request, the Bioload Specifications have been revised as follows:

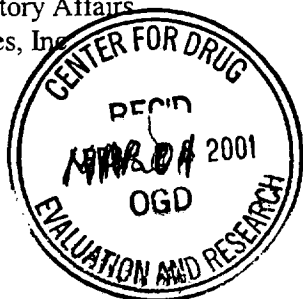
Bioload

Current USP

We trust this meets your approval. However, if the Agency needs any assistance in the review of this application, the phone numbers for contact are (440) 201-3333 (direct) and (440) 232-2772 (facsimile).

Sincerely,
for Bedford Laboratories™

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.



A DIVISION OF BEN VENUE LAB

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264



February 20, 2001

Michelle Dillahun
Project Manager, Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

MAIN CORRESP

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Ms. Dillahun:

We wish to amend our Abbreviated New Drug Application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial by providing following commitment. This is in reference to a voice mail message left for Shahid Ahmed of Ben Venue Laboratories, Inc. on February 20, 2001.

FDA 356h form is provided.

Bedford Laboratories commits to provide full cooperation to resolve any problem, which may arise during method validation testing as part of "Post-Approval" process for the above listed drug product.

We trust this meets your approval. If you need any assistance in the review of this application, the phone numbers for contact are (440)-201-3333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in black ink, appearing to read "P. Ahmed" or similar.

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.



A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264



January 18, 2001

Fax Amendment/Chemistry Deficiencies

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT
N/AM

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Sir:

We wish to amend our abbreviated new drug application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial in response to a telephone conversation between Ms. Michelle Dillahunty from the Agency and Ms. Pratima Patel from Ben Venue Laboratories Inc. on January 8, 2001.

FDA 356h form is provided in Attachment I.

The Final Product Certificates of Analysis for lots 985-35-108464 987-36-108466 have been revised to include the following:

1. Identification for the finished product
2. The time limit for the Completeness and Clarity of Solution
3. The specification has been revised to

The revised COAs are provided in Attachment II.

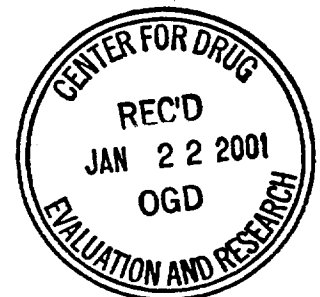
The final product specifications have been revised to clarify that the Total Impurities specification excludes e, and they are located in Attachment III.

The updated stability data is provided in Attachment IV.

If the Agency needs any assistance in the review of this application, the phone numbers for contact are (440)-201-3333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.



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December 5, 2000

Minor Amendment/Chemistry Deficiencies

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

NDA ORIG AMENDMENT

N/Ans
2/12/01
6/12/01
review
needed
for

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Sir:

We wish to amend our abbreviated new drug application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial by responding to your letter dated May 24, 2000.

FDA 356h form is provided in Attachment I.

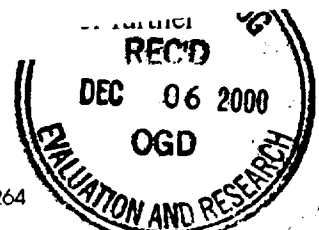
The number associated with the response given below corresponds to the number identifying the deficiencies in the communication.

1. The DMF holder has sent a response to the Agency concerning the deficiencies related to the active pharmaceutical ingredient on November 27, 2000. A copy of the letter from the DMF holder is provided in Attachment II.
2. The Loss on Drying Specifications for _____ is been tightened to not more than _____
Please refer to Attachment III for revised active drug substance specifications.
3. We acknowledged your comment. _____ protection is not required during the formulation of the drug product. However, _____ is to attain atmospheric pressure after _____ process has been completed; therefore, _____ is listed in the Composition Statement.
4. Before Ben Venue makes a decision to _____

OF A FEDERAL DEPARTMENT

A DIVISION OF BEN VENUE LABORATORIES, INC.

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026 710
12/7



5. The pH Specifications has been revised _____ ased on available data. Please refer to Attachment III for revised Finished Product and Stability Specifications.
6. We have tightened the _____ specification to _____ for Final Product Release testing. Revised Specifications are provided in Attachment III.
7. The proposed _____ release specifications for the drug product are revised per the Agency's comment. Please refer to Attachment III for revised Finished Product Specifications.
8. The Certificates of Analysis for BVL lot # 0985-35-108464 and 0987-36-108466 have been revised to include revised pH and _____ Specifications. Please refer to Attachment IV for revised Certificates of Analysis.
9. The proposed stability assay specifications have been to tightened to _____%. Please refer to Attachment III for revised Post-Approval Stability Protocol.
10. A 30 seconds reconstitution time has been included for the _____ for Finished Product and Stability Specifications. Please refer to Attachment III for revised Finished Product Specifications and Post-Approval Stability Protocol.

Also, the Specifications for active drug substance has been updated by including residual _____ content. Appropriate test method and method validation report is provided in Attachment VII.

B. In addition to,

1. Bedford Laboratories withdrawing the 60 mg/vial drug product form this Application.
2. Please refer to Attachment V for 18-months stability data for BVL lot # 0985-35-108464 and 0987-36-108466.
3. We acknowledged your comment. Please refer to Attachment VIII for revised drug substance and drug product stability specifications and all necessary current test methods.
4. Please refer to Attachment VI for the request for waiver *in vivo* studies.

If the Agency needs any assistance in the review of this application, the phone numbers for contact are (440)-232-3320, ext.3333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.



July 20, 2000

NEW CORRESP
NC

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

RE: **ANDA 75-290**
Product: **Pamidronate Disodium for Injection; 30 mg and 90 mg per vials**

Dear Sir:

We wish to amend our Abbreviated New Drug Application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial in accordance with 21 CFR 314.107 (f) (2).

FDA 356h form is provided in this amendment.

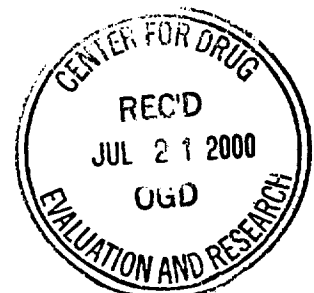
Bedford Laboratories™ is amending this application to notify the Agency indicating that Novartis Corporation has filed a legal action on May 8, 1998 regarding the infringement of Patent Number 4,711,880 (expiring July 29, 2005) in the United States District Court, in New Jersey.

If the Agency has any questions regarding this matter, the phone numbers for contact are (440)-232-3320, ext.3333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in cursive script, appearing to read "Shahid Ahmed".

Shahid Ahmed
Vice President, Regulatory Affairs
Ben Venue Laboratories, Inc.



A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264



NDA ORIG AMENDMENT
N/AC

November 16, 1999

**Major Amendment/Chemistry
and Labeling Deficiencies**

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

RE: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg and 90 mg per vials

Dear Sir:

We wish to amend our abbreviated new drug application 75-290, Pamidronate Disodium for Injection, 30 mg and 90 mg per vial by responding to your letter dated August 19, 1999. This is in reference to the telephone conversation with Michalle Dillahunt at the Agency and Shahid Ahmed of Ben Venue Laboratories on September 28, 1999.

FDA 356h form is provided in Attachment I.

The number associated with the response given below corresponds to the number identifying the deficiencies in the communication.

1.

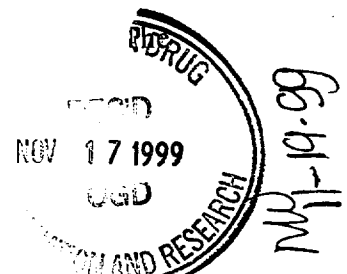
2.

3.

4.

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300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264





Office of Generic Drugs
ANDA 75-290

Pamidronate Disodium for Inj.
November 16, 1999

included in Attachment III.

5. F arc

REVISED.

6.

7.

B. In addition, we would like to acknowledge the following:

1. The deficiencies for will need to be resolved prior to approval of this drug product.
2. Response to labeling deficiencies are included in this amendment.
3. Sterility assurance information is pending review.
4. Method validation for this ANDA need to be completed prior to approval of this application.
5. Nine months stability data is provided in Attachment IV for your review. Also, the method validation for s provided in Attachment IV for your review. Please note that the stability data is updated with actual value of : ne Certificates of Analysis for finished product release have been updated to reflect this change and are provided in Attachment IV. Lastly, content has been corrected for both COAs.

Labeling Deficiencies:

We have updated package insert labeling to be consistent with reference listed drug's package insert labeling. Twelve copies of final printed package insert is provided in Attachment V. Also, side-by-side comparison of our proposed labeling with reference listed drug labeling, with all differences annotated is provided in this amendment.

Also, in Attachment VI, we have provided a revised Environmental Impact Analysis to reflect the current 21 CFR reference.



Office of Generic Drugs
ANDA 75-290

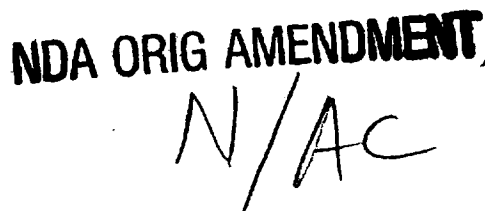
Pamidronate Disodium for Inj.
November 16, 1999

If the Agency needs any assistance in the review of this application, the phone numbers for contact are (440)-232-3320, ext.333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in black ink, appearing to read "Shahid Ahmed". The signature is fluid and cursive, with a long horizontal stroke at the end.

Shahid Ahmed
Director, Regulatory Affairs
Ben Venue Laboratories, Inc.



Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

Product: Pamidronate Disodium for Injection; 30 mg, 60 mg and 90 mg per vials

We wish to amend our abbreviated new drug application 75-290, Pamidronate Disodium for Injection, 30 mg, 60 mg and 90 mg per vial by responding to your letter dated July 14, 1998.

The number associated with the response given below corresponds to the number identifying the deficiencies in the communication.

1. The Component and Composition Section of the original application has been updated by [REDACTED]
2. The specification for Water [REDACTED] has been lowered to [REDACTED] for the active drug substance. The revised drug substance specification is provided in Attachment III.
3. The glass vials that have been and will be used for 30 mg, 60 mg and 90 mg Pamidronate Disodium for Injection are flint, not amber. The glass vial manufacturer, [REDACTED], has revised their statement to, "If amber glass, these containers are also in compliance....." Please refer to Attachment IV for the revised Certificates of Analysis for the glass vials were used.
4. Please refer to Attachment IV for revised Certificates of Analysis, which are updated to include for the test results of Powdered Glass and Arsenic test results. Again, the glass vials are flint; therefore, Light Transmission testing is not required.
5. [REDACTED]

300 Northfield Road • Bedford, Ohio 44146 • (440) 232-3320 • Fax (440) 232-6264

GENERIC DRUGS

Page(s) 2

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

3/12/99



2. Labeling deficiencies have been answered.
3. Sterility assurance information is pending review.
4. A satisfactory method validation for the drug substance and drug product is required by an Agency field laboratory at the appropriate time.

Labeling Deficiencies:

We have corrected the cited deficiencies for the all vial labels, carton labeling and package insert labeling. Twelve copies of final printed labels and labeling is provided in Attachment IX. Also, side-by-side comparison of our proposed labeling with our original application with all differences appropriately annotated.

Also, please refer to Attachment X for the filter validation report, which was conducted by our (refer to our commitment in the original application, Section XI).

At this time, Bedford Laboratories™ would like to amend this application with a new formulation of Pamidronate Disodium for Injection. Bedford Laboratories™ is not withdrawing the formulation submitted in the original application, but would like to include with a formulation which will utilize .o form the Pamidronate Disodium. This remains a product. (Please refer to Attachment XI and forward for documentation and data in support of these batches).

If the Agency needs any assistance in the review of this application, the phone numbers for contact are (440)-232-3320, ext.333 (direct) and (440)-232-2772 (fax).

Sincerely,
for Bedford Laboratories™

A handwritten signature in black ink, appearing to read "Shahid Ahmed", written over a horizontal line.

Shahid Ahmed
Director, Regulatory Affairs
Ben Venue Laboratories, Inc.



NAI
Proof of Notification
dt 5/5/98

April 14, 1998

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

NEW CORRESP

UC

Re: ANDA 75-290
Product: Pamidronate Disodium for Injection; 30 mg, 60 mg and 90 mg per vials

Dear Sir/Madame:

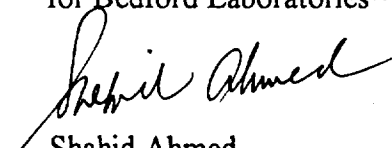
We wish to amend our unapproved Abbreviated New Drug Application, ANDA 75-290, for Pamidronate Disodium for Injection, 30 mg, 60 mg and 90 mg vials, in accordance with 21 CFR 314.94(a)(12)(I)(A)(4) and 21 CFR 314.95.

Bedford Laboratories™ is amending its application to certify that notice has been provided to the patent holder, Novartis Corporation, that Bedford Laboratories ANDA 75-290 for Pamidronate Disodium for Injection; 30 mg, 60 mg and 90 mg per vials was submitted and accepted for filing and review by the Agency. A copy of Bedford Laboratories™ Paragraph IV Certification was provided to the patent holder explaining the basis for our opinion that Patent Number 4,711,880 (expiring July 29, 2005) will not be infringed.

Additionally, please refer to the attached copy of the return receipt to document that the patent holder has received the Paragraph IV Certification notice.

If the Agency has any comment or further requests, or if we could be of any assistance in the review, we welcome direct and immediate telephone contact at (440) 232-3320, ext. 333.

Sincerely,
for Bedford Laboratories™


Shahid Ahmed
Director, Regulatory Affairs
Ben Venue Laboratories, Inc.

RECEIVED

APR 15 1998

GENERIC DRUGS

Madeline
4-21-98

A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (216) 232-3320 • Fax (216) 232-6264

ANDA 75-290

Bedford Laboratories
Division of Ben Venue Laboratories, Inc. FEB 17 1998
Attention: Shahid Ahmed
270 Northfield Road
Bedford OH, 44146
|||||

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.

Reference is also made to the telephone conversation dated February 13, 1998 and your correspondence dated February 13, 1998.

NAME OF DRUG: Pamidronate Disodium for Injection, 30 mg/vial,
60 mg/vial and 90 mg/vial

DATE OF APPLICATION: December 23, 1997

DATE (RECEIVED) ACCEPTABLE FOR FILING: December 29, 1997

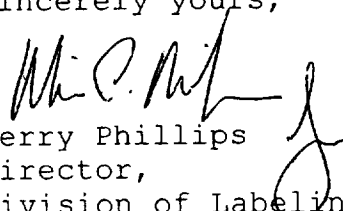
We will correspond with you further after we have had the opportunity to review your application.

Please identify any communications concerning this application with the number shown above.

Should you have questions concerning this application contact:

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

Sincerely yours,


Jerry Phillips
Director,
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research



OK to
File 2/17/98
S. Middleton

December 23, 1997

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park II
7500 Standish Place, Room 150
Rockville, MD 20855

Labeling review
completed
C. Hulequest
4/8/98

RE: Abbreviated New Drug Application
Product: Pamidronate Disodium for Injection; 30 mg, 60 mg and 90 mg per vials

Dear Sir/Madam:

In accordance with Section 505 (j)(1) of the Federal Food, Drug and Cosmetic Act, Bedford Laboratories™ is submitting in triplicate (an archival copy, a review copy and a field copy) an Abbreviated New Drug Application for Pamidronate Disodium for Injection, 30 mg, 60 mg and 90 mg per vials. Please note that the field copy is being sent directly to FDA District Office in Cincinnati, Ohio.

The drug product subject to this application will be manufactured by Ben Venue Laboratories, Inc.; located at 300 Northfield Road, Bedford, Ohio 44146.

This abbreviated new drug application contains the information required by Section 505 (j)(2)(A)(i), (ii)(I), (iv), (v) and (vi). The application is provided in the format suggested by your office, and contains a copy of the package insert of the "listed drug" (Novartis's Aredia®).

In accordance with Title 21 CFR 320.22 Bedford Laboratories™ requests a waiver of the requirements for submission of evidence demonstrating the *in vivo* bioavailability/bioequivalence for the drug product that is the subject of our application (Pamidronate Disodium for Injection, 30 mg, 60 mg and 90 mg per vials). The drug product is intended for intravenous administration and it contains the active ingredient in the same concentration as in the listed drug product.

Bedford Laboratories™ certifies that the methods used in, and the facilities and controls used for the manufacture, processing, packaging and holding of the drug product are in conformity with the cGMP in accordance with Title 21 CFR 210 and 211. Ben Venue's signed statement is provided in Section IX (MANUFACTURING FACILITY) Subsection 3 (cGMP Certification).

Three copies of analytical method which was used to test this product and an analytical method validation package are enclosed separately along with this application.

RECEIVED
GENERIC DRUGS

A DIVISION OF BEN VENUE LABORATORIES, INC.

300 Northfield Road • Bedford, Ohio 44146 • (216) 232-3320 • Fax (216) 232-6264



Office of Generic Drugs
December 23, 1997

Pamidronate Disodium for Inj.
Abbreviated New Drug Application

One copy of the Microbiological Validation, along with the drug product specification, stability protocol and the package insert is enclosed separately with this application. This drug product was lyophilized.

If the Agency needs any assistance in the review of this application, the phone numbers for contact are (440)-232-3320, ext.333 (direct) and (440)-439-6398 (fax).

Sincerely,

for Bedford Laboratories™

A handwritten signature in black ink, appearing to read "Shahid Ahmed", written over a horizontal line.

Shahid Ahmed
Director, Regulatory Affairs
Ben Venue Laboratories, Inc.