CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-841

ADMINISTRATIVE DOCUMENT(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Faulding Pharmaceutical Company	4/01/02
TELEPHONE NO. (Include Area Code)	**FACSIMILE (FAX) Number (Include Area Code)**
(201) 225-5546	(201)225-5530
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
Mack-Cali Centre II 650 From Road 2nd Floor Paramus, NJ 07652	

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 75-841

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Pamidronate Disodium Injection	N/A

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
(3-amino-1-hydroxypropylidene)bis,-disodium salt	N.A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Injection	3 mg/mL, 6 mg/mL, and 9 mg/mL; 10 mL Vials	Intravenous

(PROPOSED) INDICATION(S) FOR USE: In conjunction with adequate hydration is indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastasis. Indicated for the treatment of patients with modertae to severe Paget's disease of bone.

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, or 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug	Holder of Approved Application
Aredia Pamidronate Disodium Injection	Novartis Pharmaceutical Corporation

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OR PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION Amendment to Minor Amendment dated March 19, 2002.

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g., Final dosage form, Stability/testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

RECEIVED
APR 0 2 2002
OGD / CDER

This application contains the following items: *(Check all that apply)*

☐	1. Index	
☐	2. Labeling *(check one)*	☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50(c))	
☒	4. Chemistry section	
☒	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)	
☐	B. Samples (21 CFR 314.50(e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)	
☒	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)	
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)	
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))	
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)	
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	
☐	12. Case report forms (e.g., 21 CFR 314.50(f)(2); 21 CFR 601.2)	
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))	
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C.355(b)(2) or (j)(2)(A)	
☐	15. Establishment description (21 CFR Part 600, if applicable)	
☐	16. Debarment certification (FD&C Act 306(k)(1))	
☒	17. Field copy certification (21 CFR 314.50(k)(3))	
☐	18. User Fee Cover Sheet (Form FDA 3397)	
☐	19. Financial Information (21 CFR Part 54)	
☐	20. OTHER *(Specify)*	

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been review and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
for	Jatin J. Shah, Ph.D. Vice President, Scientific Affairs	4/01/02

ADDRESS *(Street, City, State, and ZIP Code)*	TELEPHONE NUMBER
Mack-Cali Centre II, 650 From Road, Second Floor, Paramus, NJ 07652	(201) 225-5546

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Redacted 34

Page(s) of trade secret and /or confidential commercial information

RECORD OF TELEPHONE CONVERSATION

I telephoned Dr. Shah of Faulding in reference to ANDA 75-841 to request a method validation commitment.

Dr. Shah agreed to fax the method validation and follow up with a hard copy.

APPEARS THIS WAY
ON ORIGINAL

DATE
April 16, 2002

ANDA NUMBER
75-841

IND NUMBER

TELECON

INITIATED BY

X **SPONSOR**

FDA

PRODUCT NAME
Pamidronate Disodium Injection,
3 mg/mL,
6 mg/mL, 9 mg/mL

FIRM NAME
Faulding Pharmaceutical Co.

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Jatin Shah
Susan Hamet

TELEPHONE NUMBER
(201)225-5546

SIGNATURE
M. Dillahunt
M Dillahunt

V:\FIRMSAM\FAULDING\TELECONS\75841.tcon4.doc
CC: ANDA 75-841
Chem Div I, T-con Notebook

Redacted 2

Page(s) of trade secret and /or confidential commercial information

RECORD OF TELEPHONE CONVERSATION

The firm received a minor deficiency letter dated December 19, 2001, for ANDA 75-841, Pamidronate Injection. The firm is requesting a telecon for clarification of the deficiencies. (see attached fax)

Faulding stated that the current methodology and technology cannot differentiate unbound drug from drug-metal complexes. They had tried several methods, including MS among other procedures. Dr. Schwartz indicated that Faulding should provide the Agency with a synopsis of their attempts to differentiate the bound from unbound drug in their response to the 12/19/01 deficiency letter.

[redacted] discussed in detail the theoretical potential for Pamidronate Disodium to bind with metal ions and particularly [redacted] in aqueous solution.

After much discussion by the attendees, it was decided that Faulding should make an effort to establish a limit of [redacted] based on the levels seen in the upcoming stability samples) of [redacted] but not more than [redacted] They should also submit their theoretical arguments as to why the chemistry of [redacted] in the Faulding formulation is unlikely to form complexes with the drug.

In addition, since FDA had based deficiencies for [redacted] as a "worst case" situation, and Faulding could not meet the recommended [redacted] specification of nmt [redacted] they should develop, validate and evaluate additional tests for [redacted] in the drug product and set limits consistent with their data (with the expectation that the levels of [redacted] will be below those seen for [redacted] in the drug product) and would likely meet NMT [redacted] limits.

Mr. Smela also informed the firm that after the application is approved and additional data are generated, they may submit a supplement to their application to delete some of the additional testing if the data support it.

DATE
February 28, 2002

ANDA NUMBER
75-841

IND NUMBER

TELECON

INITIATED BY

X **SPONSOR**

FDA

PRODUCT NAME
Pamidronate Disodium Injection,
3 mg/mL,
6 mg/mL, 9 mg/mL

FIRM NAME
Faulding Pharmaceutical Co.

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Jatin Shah, Ph.D. Vice-President, Scientific Affairs
Hugh Burrill, Ph.D. Vice-President, Research and Development
[redacted]
Consultant Services
[redacted]
Consultant Services

TELEPHONE NUMBER
(201)225-5546

SIGNATURE
K.Furnkranz 3/11/02
M.Smela 3/1/02
P.Schwartz 3/4/02
M.Dillahunt 3/11/02

V:\FIRMSAM\FAULDING\TELECONS\75841.tcon2.doc
CC: ANDA 75-841
Chem Div I, T-con Notebook

RECORD OF TELEPHONE CONVERSATION

Gordon Johnston called back to follow up on the 2/28/02 telephone discussion regarding the Faulding ANDA 75-841, Pamidronate Injection.

Gordon indicated that the firm has just about completed their work in response to our requests (refer to the 2/28/02 telecon).

He noted that the other metals that have been investigated as leachables that could potentially bind to the drug product [redacted] were found at low levels (below those levels previously determined for [redacted]. However, after further testing of current stability samples, Faulding does not feel that it will be possible to lower the [redacted] limit to [redacted]. They are considering lowering slightly to [redacted] or leaving the limit at [redacted] He asked how we would react to that.

I indicatd that those possibilities were discussed during the telecon, and we would have to evaluate the data and Faulding's response and make a decision as to the adequacy of the firm's response.

Mr Johnston asked what our turnaround time was on MINOR Amendments, and I indicated that we are obligated to turn around MINOR amendments within 30 days.

He indicated that they would be submitting their ANDA Amendment shortly.

DATE
March 13, 2002

ANDA NUMBER
75-841

IND NUMBER

TELECON

INITIATED BY

X SPONSOR

FDA

PRODUCT NAME
Pamidronate Disodium Injection,
3 mg/mL,
6 mg/mL, 9 mg/mL

FIRM NAME
Faulding Pharmaceutical Co.

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
[redacted]
Consultant Services

TELEPHONE NUMBER
(201)225-5546

SIGNATURE
K.Furnkranz
3/18/02

V:\FIRMSAM\FAULDING\TELECONS\75841.tcon03/13/02.doc
CC: ANDA 75-841
Chem Div I, T-con Notebook

HNDA 15-541

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: June 27, 2002

FROM: Gary Buehler
Director
Office of Generic Drugs

Robert Rupp for 6/27/2002

TO: Record

SUBJECT: Pamidronate Approval

Issues were raised regarding the labeling of generic pamidronate products, the "sameness" of the active ingredients in the generic products, inactive ingredients and about the potential for a solution of pamidronate disodium to complex with a glass vial. The Office of Generic Drugs' decision making on many of those issues was fully addressed in a letter to the innovator firm, Novartis, dated June 27, 2002. Further information is contained in this memo.

Labeling

The reference listed drug for pamidronate disodium injection, Aredia, had a labeling change approved after the approval of an abbreviated new drug application (ANDA) for the drug product. The generic firm is now able to market the product because of a court decision rendered in a case involving another generic applicant for the product. The attorney representing the innovator firm, Novartis, has questioned whether the generic drug product may be marketed with labeling that does not include the changes recently approved for Aredia. These changes have received three years Waxman-Hatch exclusivity and, thus, if it were necessary to include the protected labeling, the generic product could not be marketed.

The new innovator labeling includes changes to allow administration of the product to patients with hypercalcemia of malignancy (HCM) over 2 – 24 hours rather that over 24 hours as recommended previously.

Prior to Novartis' attorney raising the question about the labeling, the Office of Generic Drugs' (OGD) labeling reviewer had sought the input of the appropriate reviewing medical officer, Eric Colman, M.D., in the Division of Metabolic and Endocrine Drug Products. The conclusion of Dr. Colman is that the previous labeling carried by the generic product is not less safe than the revised labeling now on the innovator product.

The medical officer indicated that the change was apparently initiated by Novartis to allow more direct competition with a similar product that had entered the market with a

shorter administration time. His review of the supplement found there was no head-to-head comparison of the product administered over 2 hours to administration over 24 hours. Data was compared from two different studies, known as a cross study comparison. A comparison of data from patients treated with pamidronate over 24 hours to the patients treated over 2 hours indicated the safety profiles, in particular renal safety, are similar for these dosing regimens. In addition published reports from the literature support the relative efficacy and safety of pamidronate when infused over 2 – 24 hours. In addition, data from the clinical trials that supported the approval of the NDA showed "there is no evidence from the three studies that the risk for renal injury is appreciably altered when subjects receive 90 mg vs 60 mg or 30 mg or when the infusion time is reduced from 24 to 4 hours."

There was, in fact, concern that infusion of Aredia over a shorter time period could be a safety concern by increasing the risk for renal toxicity, or other adverse events. This was pointed out in the Discussion section in the Medical Officer's Review of the Novartis labeling supplement. The review stated the 2-hour data in the supplement for the labeling change "...provides reassurance that, compared with the 24-hour regimen, the 2-hour infusion does not increase the risk for renal toxicity, or other significant adverse events." It could be asserted that the generic product labeling indicating infusion of 24-hours could be safer since the labeling state "longer infusions may reduce the risk for renal toxicity, particularly in patient with pre-existing renal insufficiency."

With this information from the medical officer, OGD has determined that it is not inappropriate to allow marketing of a generic pamidronate disodium injection without the recently approved change in the innovator labeling. Information changed in the innovator labeling will not be included in the ANDA labeling.

Drug Product Interaction With Glass Vial

Novartis provided information on April 22, 2002, that, in the firm's opinion demonstrated and documented the interaction of solution with its glass packaging. Further, the need for clinical studies was suggested. The data submitted was from testing done with a marketed product purchased in Australia from a subsidiary of Faulding (one of the generic firms seeking approval in the US). The data presented was of limited value since, as Novartis acknowledged, some of the products had exceeded expiration dating. It would be expected that there could be changes in a product that was past its expiration dating. Also, the firm stated that on accelerated stability with high heat the ——— levels are high. Any generic product will carry storage conditions to prevent exposure of the product to high heat.

Months prior to the receipt of the Novartis communication OGD reviewers were aware of the potential for the solution to leach mineral and metals from the glass container. The reviewers determined that seeking information regarding the levels of ——— in the finished drug product would provide an indication of the extent of the leaching. Further, the generic firms should have a method to detect dissolved ——— versus undissolved ——— from ——— vials. Work was done by OGD staff to

calculate the potential levels of the leached materials and then to determine what specifications were appropriate. Firms were required to submit stability data to support the limits or justify with comparison data for the reconstituted reference listed drug.

The subsequent potential for binding of the drug with metals was an issue raised in the review of the ANDAs. Again, firms were required to set appropriate specifications supported with stability data or with the limits justified with comparison data on bound versus unbound drug for the constituted reference listed drug. During the review of one ANDA, the sponsor noted that the current methodology and technology could not differentiate unbound drug from drug-metal complexes. It was recommended that the firm make an effort to establish a limit of ——— based on the levels seen in the stability samples. The scientific rationale for their position that the chemistry of ——— in the formulation is unlikely to form complexes should also be presented.

Since there was question about the product meeting the ——— specification, tests should be developed and validated to determine levels of ——————————————— ——— in the drug product. Appropriate limits were to be established.

Adequate controls were put into place by the ANDA applicants and data presented to OGD show that the proposed products submitted in the ANDAs met the set specifications prior to approval.

Gary J. Buehler

q:\issues\pamidronate\memofile

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-841

CORRESPONDENCE

VIA UPS OVERNIGHT COURIER

February 28, 2000

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

Re: Abbreviated New Drug Application
Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL Vials

Original Application

Dear Mr. Sporn:

In accordance with the regulations, as promulgated under Section 505(j) of the Federal Food, Drug and Cosmetic Act, as amended, Whitney is submitting this Abbreviated New Drug Application (ANDA) for Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials.

The reference listed drug Aredia® (Pamidronate Disodium) Injection, 30 mg/vial, 60 mg/vial and 90 mg/vial is available as lyophilized powder manufactured by Novartis Pharmaceutical Corporation.

Whitney's proposed Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials is an aqueous sterile solution for intravenous injection. Its composition is qualitatively and quantitatively the same as the multidose reference listed drug product.

Whitney's ANDA for ready-to-use solution of Pamidronate Disodium Injection is submitted based on Faulding Pharmaceutical Company's approved suitability petition (Docket No. 99P-2252/CP1).

The Archival, Review and Field copies of this Abbreviated New Drug Application have been prepared in accordance with the Guidance for Industry on Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application. This application is contained in three volumes and contains sterility assurance information. For ease of review, an additional copy of Section XXII, Sterilization Assurance Information and Data, is provided as a separate volume.

If you have any questions concerning this submission, please contact me at (703) 714-9581.

Sincerely,

Whitney Pharmaceuticals Inc.

Jatin Shah, Ph.D.
President

Whitney Pharmaceuticals Inc. ■ 8300 Boone Blvd., Suite 533 ■ Vienna, VA 22182
Telephone (703) 714-9581 ■ Facsimile (703) 714-9582

ANDA 75-841

Whitney Pharmaceuticals Inc.
Attention: Jatin Shah
8300 Boone Boulevard
Suite 533
Vienna, VA 22182

MAY 30 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: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL, 9 mg/mL; 10 mL vials

DATE OF APPLICATION: February 28, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: April 19, 2000

You have filed a Paragraph IV patent certification, in accordance with 21 CFR 314.94(a)(12)(i)(A)(4) and Section 505(j)(2)(A)(vii)(IV) of the Act. Please be aware that you need to comply with the notice requirements, as outlined below. In order to facilitate review of this application, we suggest that you follow the outlined procedures below:

CONTENTS OF THE NOTICE

You must cite section 505(j)(2)(B)(ii) of the Act in the notice and should include, but not be limited to, the information as described in 21 CFR 314.95(c).

SENDING THE NOTICE

In accordance with 21 CFR 314.95(a):

Send notice by U.S. registered or certified mail with return receipt requested to each of the following:

1) Each owner of the patent or the representative designated by the owner to receive the notice;

2) The holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval.

3) An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

DOCUMENTATION OF NOTIFICATION/RECEIPT OF NOTICE

You must submit an amendment to this application with the following:

In accordance with 21 CFR 314.95(b), provide a statement certifying that the notice has been provided to each person identified under 314.95(a) and that notice met the content requirements under 314.95(c).

In accordance with 21 CFR 314.95(e), provide documentation of receipt of notice by providing a copy of the return receipt or a letter acknowledging receipt by each person provided the notice.

A designation on the exterior of the envelope and above the body of the cover letter should clearly state "PATENT AMENDMENT". This amendment should be submitted to your application as soon as documentation of receipt by the patent owner and patent holder is received.

DOCUMENTATION OF LITIGATION/SETTLEMENT OUTCOME

You are requested to submit an amendment to this application that is plainly marked on the cover sheet "PATENT AMENDMENT" with the following:

If litigation occurs within the 45-day period as provided for in section 505(j)(4)(B)(iii) of the Act, we ask that you provide a copy of the pertinent notification.

Although 21 CFR 314.95(f) states that the FDA will presume the notice to be complete and sufficient, we ask that if you are not sued within the 45-day period, that you provide a letter immediately after the 45 day period elapses, stating that no legal action was taken by each person provided notice.

You must submit a copy of a court order or judgement, or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information. We ask that this information be submitted promptly to the application.

If you have further questions you may contact Nasser Mahmud, Chief, Regulatory Support Branch, at (301)827-5862.

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

cc: ANDA 75-841
DUP/Jacket
Division File
Field Copy
HFD-610/R.West
HFD-610/P.Rickman
HFD-92
HFD-615/M.Bennett
HFD-600/

Endorsement:
HFD-615/NMahmud, Chief, RSB _____ date 5/30/00
HFD-615/EThomas, CSO _____ date 5/25/00
Word File V:\Firmsnz\whitney\ltrs&rev\75841.ack
FT/mjl/5/22/00
ANDA Acknowledgment Letter!

FOXKISER
750 17TH STREET, N. W.
SUITE 1100
WASHINGTON, D. C. 20006
(202) 778-2300

NEW CORRESP
NC

August 28, 2000

Whitney sued w/in 45 days.
CA # 00-CV-3584
9/21/00

Hand-Delivered

Mr. Gary Buehler
Acting Director
Office of Generic Drugs, HFD-600
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place, Suite 286-N
Rockville, Maryland 20855

Re: Novartis Corporation v. Faulding Inc., Faulding Pharmaceutical Co., and Whitney Pharmaceuticals Inc., Civil Action No. 2:00cv03584, U.S. District Court For The District Of New Jersey, Whitney Pharmaceuticals ANDA No. 75-841

Dear Mr. Buehler:

On behalf of Novartis Corporation, the purpose of this letter is to inform the Office of Generic Drugs that Novartis Corporation, on July 24, 2000, filed a patent infringement lawsuit against Faulding Inc., Faulding Pharmaceutical Company, and Whitney Pharmaceuticals Inc., in the U.S. District Court for the District of New Jersey, Novartis Corporation v. Faulding Inc., Faulding Pharmaceutical Co., and Whitney Pharmaceuticals Inc., Civil Action No. 2:00cv03584, in response to Whitney Pharmaceuticals' Notice of Paragraph IV Patent Certification, dated June 6, 2000, covering Whitney's 505(j) application, ANDA No. 75-841, which the Notice states is for "pamidronate disodium injection 30 mg vials, 60 mg vials, and 90 mg vials."

Enclosed for the Office's reference is a copy of the Complaint that was filed in the above-referenced action.

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
AUG 30 2000
OGD

Please feel free to contact me, on (202) 778-2354, if you have any questions or require additional information in connection with this matter.

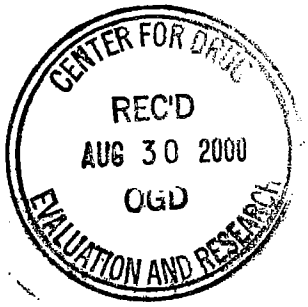
Respectfully Submitted,

John M. Engel

John M. Engel

Enclosure

cc: Document and Records Section (*via* First Class Mail)
12229 Wilkins Avenue
Rockville, Maryland 20852



NEW CORRESP
NC

UPS OVERNIGHT COURIER

October 25, 2000

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

RE: **ANDA 75-841 for Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL, 9 mg/mL; 10 mL Vials**

Dear Mr. Buehler:

Reference is made to our February 28, 2000 submission of an Abbreviated New Drug Application, ANDA #75-841, Pamidronate Disodium Injection. Further reference is made to our June 20, 2000 patent amendment submitted in accordance with 21 CFR 314.95(b) and 21 CFR 314.95(e), which included the following:

- Certification from Whitney Pharmaceutical Inc. that Novartis Pharmaceuticals Corporation, the holder of the approved application for the listed drug and owner of U.S. patent #4,711,880 (the subject of our Paragraph IV certification), was sent notice of patent certification;

- Documentation of receipt of this notice (a copy of the certified mail return receipt) from Novartis Pharmaceuticals Corporation, dated June 9, 2000.

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 27 2000
OGD

Whitney Pharmaceuticals Inc. ■ 8300 Boone Blvd., Suite 533 ■ Vienna, VA 22182
Telephone (703) 714-9581 ■ Facsimile (703) 714-9582

In accordance with current procedures pertaining to the notice requirements associated with Paragraph IV patent certifications, please be informed that Whitney Pharmaceuticals Inc. has received "Notice of Voluntary Dismissal" of the suit, dated October 3, 2000. A copy of the Notice of Voluntary Dismissal has been enclosed.

Accordingly, it is Whitney's opinion that the subject Abbreviated New Drug Application is eligible for final approval upon successful completion of the review process.

If there are any questions concerning this amendment, please contact the undersigned at (703) 714-9581.

Sincerely,

Jatin J. Shah

Jatin Shah, Ph.D.
President , Whitney Pharmaceutical Inc.

Whitney Pharmaceuticals Inc. ■ 8300 Boone Blvd., Suite 533 ■ Vienna, VA 22182
Telephone (703) 714-9581 ■ Facsimile (703) 714-9582

NEW CORRESP

NC

CORRESPONDENCE TO FILE

UPS OVERNIGHT COURIER

November 16, 2000

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

RE: Ownership Transfer of ANDA No. 75-841 for Pamidronate Disodium for Injection, 30 mg, 60 mg, and 90 mg.

Dear Mr. Buehler:

In accordance with the provisions of 21 CFR 314.72, we are notifying you of a change in ownership of ANDA 75-696. Effective as of the close of business on November 14, 2000, the ANDA ownership and all rights thereto were transferred from Whitney Pharmaceuticals Inc. to:

Point Holdings Inc.
529 Fifth Avenue
New York, NY 10017

Point Holdings Inc. has been provided with the original application and records required to be kept under 21 CFR 314.81.

If you have any further questions, please contact the undersigned at 908-931-3807.

Sincerely,

WHITNEY PHARMACEUTICALS INC.

Jatin Shah, Ph.D., President

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
NOV 20 2000
OGD

Whitney Pharmaceuticals Inc. ■ 8300 Boone Blvd., Suite 533 ■ Vienna, VA 22182
Telephone (703) 714-9581 ■ Facsimile (703) 714-9582

POINT HOLDINGS INC.

529 FIFTH AVENUE
NEW YORK, NY 10017
TELEPHONE: (212) 878-1794
FACSIMILE: (212) 681-4375

CORRESPONDENCE TO FILE

USP OVERNIGHT COURIER

November 16, 2000

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

NEW CORRESP
NC

RE: Appointment of Official Regulatory Agent and Confirmation of Ownership Transfer for of ANDA No. 75-841 for Pamidronate Disodium for Injection, 30 mg, 60 mg, and 90 mg.

Dear Mr. Buehler:

Point Holdings Inc. hereby submits this correspondence to confirm that our firm has obtained the ownership of ANDA 75-841 for Pamidronate Disodium for Injection, 30 mg, 60 mg, and 90 mg, effective November 14, 2000. Appended is a letter from Whitney Pharmaceuticals Inc. confirming this ownership transfer.

Pursuant to 21 CFR 314.72, please note the following:

1. A complete copy of ANDA 75-841, including records that are required to be kept under 21 CFR 314.81, is in the possession of Point's regulatory agent (agent assignment details are noted further in this correspondence).

2. Point Holdings Inc. commits to all agreements, promises, and conditions made by the former owner of ANDA 75-841, and contained in the application.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
NOV 21 2000
OGD

In addition, please be advised that Point Holdings Inc. as holder of ANDA 75-841 hereby appoints Faulding Pharmaceutical Company as the official regulatory agent. In this capacity, Point Holdings Inc. authorizes Faulding Pharmaceutical Company to represent us in all regulatory matters pertaining to the subject ANDA. The pertinent information is as follows:

Address: Faulding Pharmaceutical Co.
200 Elmora Avenue
Elizabeth, New Jersey 07207

Contact: Jatin Shah, Ph.D.
Vice President, Scientific Affairs

Phone: (908) 931-3807
Fax: (908) 709-4150

Point Holdings Inc. trusts that the information contained in this correspondence is complete and in order. Should you have any questions regarding this matter of ownership transfer, please contact the undersigned at (908) 659-2575.

Sincerely,

POINT HOLDINGS INC.

Andrew M. Berdon
Corporate Secretary

POINT HOLDINGS INC.
529 FIFTH AVENUE
NEW YORK, NY 10017
TELEPHONE: (212) 878-1794
FACSIMILE: (212) 681-4375

POINT HOLDINGS INC.

529 FIFTH AVENUE
NEW YORK, NY 10017
TELEPHONE: (212) 878-1794
FACSIMILE: (212) 681-4375

CORRESPONDENCE TO FILE

UPS OVERNIGHT COURIER

December 8, 2000

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

NEW CORRESP
NC

RE: Clarification of Appointment of Official Regulatory Agent and Confirmation of Ownership Transfer of ANDA No. 75-841 for Pamidronate Disodium Injection, 30 mg, 60 mg, and 90 mg.

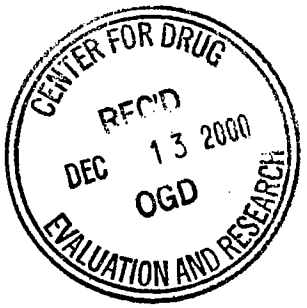
Dear Mr. Buehler:

Pursuant to the telephone request on December 1, 2000 from Ms. Regina Warren, this letter clarifies the appointment of Faulding Pharmaceutical Co. as regulatory agent and Point Holdings Inc. as owner of ANDA 75-841 for Pamidronate Disodium Injection, 30 mg, 60 mg, and 90 mg. The information in this letter supplements the information in our letter of November 16, 2000 and corrects the address of our regulatory agent.

1. We have enclosed a copy of the FDA Form 356(h) as requested.

2. In addition, please be advised that the proper contact information for our regulatory agent, Faulding Pharmaceutical Co., is as follows:

Address: Faulding Pharmaceutical Co.
11 Commerce Drive
Cranford, New Jersey 07016



Contact: Jatin Shah, Ph.D.
Vice President, Scientific Affairs

Phone: (908) 931-3807
Fax: (908) 709-4150

Point Holdings Inc. trusts that the information contained in this correspondence is complete and in order. Should you have any questions regarding this matter of ownership transfer, please contact the undersigned at (908) 659-2411 or our regulatory agent at the phone number provided above.

Sincerely,

POINT HOLDINGS INC.

Andrew M. Berdon
Corporate Secretary

POINT HOLDINGS INC.
529 FIFTH AVENUE
NEW YORK, NY 10017
TELEPHONE: (212) 878-1794
FACSIMILE: (212) 681-4375

ANDA 75-841

Faulding Pharmaceuticals Co.
Agent for: Point Holding Inc.
Attention: Jatin Shah, Ph.D.
11 Commerce Drive
Cranford, NJ 07016

JAN 3 2001

Dear Sir:

We acknowledge receipt of your communication dated November 16, (2 submissions) and December 8, 2000, submitted as required by the provisions of Regulation 21 CFR 314.72(a) and Section 505(k) of the Federal Food, Drug and Cosmetic Act for Pamidronate Disodium Injection, 30 mg/vial, 60 mg/vial, and 90 mg/vial.

Your letter details the transfer of ownership of the ANDA, from Whitney Pharmaceuticals, Inc. to Point Holding Inc. We also acknowledge your request that Faulding Pharmaceutical Co. serve as regulatory agent for Point Holdings Inc.

Pursuant to 21 CFR 314.72(b), the new owner shall advise FDA about any change in the conditions of the pending application.

The material submitted is being retained as part of your application.

Sincerely yours,

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

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

January 12, 2001

Attn: Michelle Dillahunt, Project Manager
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: ANDA # 75-841 – Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL Vials

Dear Ms. Dillahunt:

As per our telephone conversation on January 11, 2001, below is the question for which Faulding is seeking advise/clarification from the FDA. This question is from the major deficiency letter issued by the agency for Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL Vials (ANDA # 75-841).

Comment 10:
Please establish release and stability specifications for leached ——— ——— in the drug product and provide data from your 3 months accelerated stability samples using a validated analytical method. For stability, annual testing for ———, would be acceptable.

We would like to request clarification if the question should actually refer to '———' instead of '———' since ——— may leach out of the glass vial. Please note that Faulding uses ——— glass vials for this product to reduce/eliminate leaching.

We are looking forward to clarification for this comment as soon as possible so that we can respond to this major deficiency letter as soon as possible. Please call me at (908) 931-3806 if you need additional information.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

We are aware that the solution may leach minerals and metals from the glass. We are looking for ——— to get an idea of how much leaches. They should have a method to detect dissolved ——— from (———) vs. undissolved ——— from ——— vials. We do not object and also encourage to test for ——— or any other glass constituents that can be

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

MICROBIOLOGY AMENDMENT

March 30, 2001

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

ORIG AMD DRAFT

AS

RE: ANDA 75-841 – Pamidronate Disodium Injection
3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency letter dated February 22, 2001, in which you requested MICROBIOLOGY information.

For ease of review we have arranged the amendment as follows:

1. Form FDA 356h
2. Microbiology: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses
3. Field Copy Certification

We have provided an archival copy, a review copy and a field copy for this response. We are looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

MICROBIOLOGY AMENDMENT

April 4, 2001

NC

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

NEW CORRESP

RE: ANDA 75-841 – Pamidronate Disodium Injection
3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is the authorized U.S. agent for Point Holdings' Inc. ANDA for Pamidronate Disodium Injection (ANDA # 75-841). On behalf of Point Holdings, Inc., Faulding Pharmaceutical Co. has submitted a microbiology deficiency response on March 30, 2001. The FDA Form 356h provided in this submission contained some incorrect information.

With this correspondence we are providing the corrected FDA Form 356h for the microbiology response amendment. Please disregard the previous FDA Form 356h and replace it with the one attached.

We are providing an archival copy, a review copy and a field copy of this correspondence. Faulding apologizes for the error and is looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

MAJOR AMENDMENT

April 6, 2001

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

ORIG AMENDMENT
N/AC

RE: ANDA 75-841 – Pamidronate Disodium Injection
3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is the authorized U.S. agent for Point Holdings' Inc. ANDA for Pamidronate Disodium Injection (ANDA # 75-841). On behalf of Point Holdings, Inc., Faulding Pharmaceutical Co. is responding to your deficiency letter dated October 31, 2000, in which you requested CHEMISTRY and LABELING information.

For ease of review we have arranged the amendment as follows:

1. Table of Contents
2. Table of Attachments
3. Form FDA 356h
4. Chemistry: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses
5. Field Copy Certification
6. Labeling: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses

We have provided an archival copy, a review copy and a field copy for this response. We are looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H. Maaser

CENTER FOR DRUG EVALUATION AND RESEARCH
APR 0 9 2001
OGD

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

Amendment to Method Validation Package

April 10, 2001

Mr. Gary Buehler, Acting Director
FDA, CDER
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NC
NEW CORRESP

Re: ANDA Method Validation Amendment (ANDA # 75-841)
Pamidronate Disodium Injection
3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

In response to a major chemistry deficiency received on October 31, 2000 from the Food and Drug Administration, Center for Drug Evaluation, a method using ' was developed and validated for the analysis of . in Pamidronate Disodium Injection. The above work has been carried out by ' Additionally, changes have been made in the drug substance and final drug product specifications.

Faulding would like to amend the original Method Validation Package, submitted to the FDA on April 19, 2000 to include the revised specifications, the new methods and method validation reports for each method. The response to the major deficiency letter has been submitted to the FDA Center on April 6, 2000.

Copies of the revised drug product and drug substance specifications are provided in **Attachments 1** and **2**, respectively. The new methods and the validation reports are provided in **Attachment 3**.

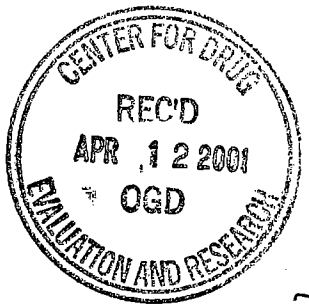
This amendment to the Methods Validation Package is paginated consecutively in the bottom right corner of each page. Page numbers found in the center of each page provide information as to where this information is located in the amendment filed to our original ANDA on April 6, 2001, in response to FDA's deficiency letter of October 31, 2000.

If you require any additional information, please contact me at (908) 931-3806.

Sincerely,

H. Maas

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150



4-18-01

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

200 Elmora Avenue
Elizabeth
New Jersey 07207
United States

Telephone
+1 908 527 9100
Facsimile
+1 908 527 0649

www.faulding.com

VIA UPS OVERNIGHT COURIER

AMENDMENT TO MAJOR AMENDMENT APRIL 6, 2001

August 7, 2001

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

ORIG AMENDMENT

NIAC

RE: ANDA 75-841 – Pamidronate Disodium Injection 3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is the authorized U.S. agent for Point Holdings' Inc. ANDA for Pamidronate Disodium Injection (ANDA # 75-841). On behalf of Point Holdings, Inc., Faulding Pharmaceutical Co. had submitted a major amendment (Chemistry and Labeling) on April 6, 2001 in response to your deficiency letter dated October 31, 2000.

Faulding Pharmaceutical Co. would like to amend their April 6, 2001 response as outlined below.

Faulding wishes to include an additional Batch Record providing for an increase in batch size for the proposed commercial batches of Pamidronate Disodium Injection for 3 mg/mL and 9 mg/mL strengths. The following table lists the original batch sizes included in the ANDA and the new proposed batch sizes:

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
AUG 0 6 2001
OGD

Table 1: Proposed Batch Sizes

Strength	Proposed Batch Size	
	Original ANDA	New
3 mg/mL	[redacted]	[redacted]
6 mg/mL	[redacted]	No Changes
9 mg/mL	[redacted]	[redacted]

The table below describes the relationship between the exhibit batch sizes submitted in the ANDA for the 3 mg/mL and 9 mg/mL presentations and the proposed commercial batch sizes. Based on the information provided in the table, the exhibit batches still comply with Policy & Procedure Guide #22-90 that requires ANDA drug products to be supported by an exhibit batch of at least ——— of the proposed commercial batch size.

Table 2: Exhibit vs Proposed Commercial Batch Sizes

Presentation	3 mg/mL (10 mL vial)	9 mg/mL (10 mL vial)
Exhibit Batch #s	J02 4935R	J02 4945R
Exhibit Batch Size[1] (E)	1206	1251
Exhibit Batch Volume		
Commercial Batch Size[2] (C)		
Commercial Batch Volume		
E relative to C (%)		

1. Units filled satisfactorily
2. Estimated yield (single units)

Copies of the BRF000 for the new batch sizes are provided in Attachment 1. We are providing an archival copy, a review copy and a field copy of this amendment to our submission of April 6, 2001. We are looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H Maas

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

VIA UPS OVERNIGHT COURIER

FIELD COPY

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520

www.faulding.com

April 1, 2002

Douglas I. Ellsworth
District Director
New Jersey District Office
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

SUBJECT: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials
ANDA # 75-841

AMENDMENT TO MINOR AMENDMENT DATED MARCH 19, 2002 FOR A PENDING ABBREVIATED NEW DRUG APPLICATION

Dear Mr. Ellsworth:

Pursuant to 21 CFR 314.96(b), Faulding Pharmaceutical Co. herewith submits a field copy of the Amendment dated April1, 2002 to the Minor Amendment dated March 19, 2002 to the above referenced ANDA. Faulding certifies that the Field copy of the amendment is a true copy of the CMC section contained in the Archival and Review Copies of the amendment.

If you have any questions regarding these submissions, please do not hesitate to contact me at the phone number provided below.

Sincerely,

for Jatin J. Shah, Ph.D
Vice President, Scientific Affairs
Tel.: (201) 225-5546
Fax: (201) 225-5530
Enclosure

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520

www.faulding.com

VIA UPS OVERNIGHT COURIER

FIELD COPY

March 19, 2002

Douglas I. Ellsworth
District Director
New Jersey District Office
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

SUBJECT: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials
ANDA # 75-841

MINOR AMENDMENT TO PENDING ABBREVIATED NEW DRUG APPLICATION
RESPONSE TO CHEMISTRY DEFICIENCIES

Dear Mr. Ellsworth:

Pursuant to 21 CFR 314.96(b), Faulding Pharmaceutical Co. herewith submits a field copy of the Amendment dated March 19, 2002 to the above referenced ANDA. Faulding certifies that the Field copy of the amendment is a true copy of the CMC section contained in the Archival and Review Copies of the amendment.

If you have any questions regarding these submissions, please do not hesitate to contact me at the phone number provided below.

Sincerely,

Jatin J. Shah, Ph.D
Vice President, Scientific Affairs
Tel.: (201) 225-5546
Fax: (201) 225-5530

VIA UPS OVERNIGHT COURIER

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520

www.faulding.com

March 19, 2002

Faulding
A World of Health

Mr. Gary Buehler
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 150
Document Control Room
7500 Standish Place
Rockville, Maryland 20855

ORIG AMENDMENT

SUBJECT: **ANDA # 75-841 - Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials**

MINOR AMENDMENT TO PENDING ABBREVIATED NEW DRUG APPLICATION RESPONSE TO CHEMISTRY DEFICIENCIES

Dear Mr. Buehler:

Reference is made to the subject original ANDA dated February 28, 2000, and to the Agency's letter dated December 19, 2001. Reference is also made to Faulding's gratuitous letter dated February 22, 2002 requesting a teleconference to discuss a proposed alternative approach toward addressing issues raised in the Agency's letter dated December 19, 2001, and to the ensuing teleconference with the Office of Generic Drugs on February 28, 2002.

Faulding herewith is responding to the FDA letter dated December 19, 2001. In that regard, we have restated the Agency's comments in bold type followed by our responses. For clarification and ease of review the response has been formatted to include the following:

1. Table of Contents
2. Table of Attachments
3. FDA Form 356h
4. Response to Chemistry Deficiencies
5. Field Copy Certification

We trust that we have addressed the Agency's concerns. Please contact the undersigned if you have any questions regarding this amendment.

Sincerely,

Jatin J. Shah
Vice President, Scientific Affairs

Enclosure
Cc: New Jersey District Office

RECEIVED
MAR 2 0 2002
OGD / CDER

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

Faulding
A World of Health

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520
www.faulding.com

March 19, 2002

VIA FACSIMILE TRANSMISSION

Mr. Gary Buehler, R.Ph.
Director, Office of Generic Drugs
Center for Drug Evaluation Research
Food and Drug Administration
Metro Park North II, HFD 600
7500 Standish Place
Rockville, Maryland 20855

ML
P.M.P
3/27/01

NEW CORRESP
NC

RE: ANDA 75-841
Pamidronate Disodium Injection
Relinquish 180-day Exclusivity

Dear Mr. Buehler:

Faulding Pharmaceuticals (Faulding) has a pending ANDA (75-841) for Pamidronate Disodium Injection. Faulding believes that it was the first applicant to file a substantially complete ANDA for this product with a paragraph IV patent certification in accord with 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act.

Pursuant to 21 CFR 314.96(a), Faulding Pharmaceuticals hereby relinquishes its eligibility for 180-day exclusivity with respect to Pamidronate Disodium Injection. By relinquishing eligibility for 180-day exclusivity Faulding Pharmaceuticals recognizes and intends that this relinquishment will apply to all subsequently filed ANDAs for Pamidronate Disodium Injection and that the FDA may approve any such ANDAs without regard to the 180-day exclusivity. 21 USC 355(j)(5)(B)(iv).

Faulding believes that this letter hereby allows any subsequent ANDA for Pamidronate Disodium Injection to be approved immediately.

Please contact me directly at 2021-225-5546 or 908-403-2322 should there be any questions.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs

RECEIVED
MAR 21 2002
OGD / CDER

3/21/02

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

March 19, 2002

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States
Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520
www.faulding.com

VIA FACSIMILE TRANSMISSION

Mr. Gary Buehler, R.Ph.
Director, Office of Generic Drugs
Center for Drug Evaluation Research
Food and Drug Administration
Metro Park North II, HFD 600
7500 Standish Place
Rockville, Maryland 20855

RE: ANDA 75-841
Pamidronate Disodium Injection
Relinquish 180-day Exclusivity

Dear Mr. Buehler:

Faulding Pharmaceuticals (Faulding) has a pending ANDA (75-841) for Pamidronate Disodium Injection. Faulding believes that it was the first applicant to file a substantially complete ANDA for this product with a paragraph IV patent certification in accord with 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act.

Pursuant to 21 CFR 314.96(a), Faulding Pharmaceuticals hereby relinquishes its eligibility for 180-day exclusivity with respect to Pamidronate Disodium Injection. By relinquishing eligibility for 180-day exclusivity Faulding Pharmaceuticals recognizes and intends that this relinquishment will apply to all subsequently filed ANDAs for Pamidronate Disodium Injection and that the FDA may approve any such ANDAs without regard to the 180-day exclusivity. 21 USC 355(j)(5)(B)(iv).

Faulding believes that this letter hereby allows any subsequent ANDA for Pamidronate Disodium Injection to be approved immediately.

Please contact me directly at 2021-225-5546 or 908-403-2322 should there be any questions.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520

www.faulding.com

March 22, 2002

Faulding
A World of Health

Document Control Staff
Office of Generic Drugs
Center for Drug Evaluation Research
Food and Drug Administration
Metro Park North II, HFD 600
7500 Standish Place
Rockville, Maryland 20855

NC

NEW CORRESP

RE: ANDA 75-841
Pamidronate Disodium Injection
Relinquish 180-day Exclusivity

Dear Document Control Staff,

On March 19, 2002 the attached Administrative Amendment was sent to Mr. Gary Buehler. As required, the originals of the letter and Form 356(h) were sent via Federal Express that evening, as the Archival File.

In review of our files, we noticed the document was not sent in duplicate. Therefore, please accept the attached copy of the above stated amendment and Form 356(h) dated March 19, 2002 as your Review File copy.

We are sorry for the confusion this may have caused. Should you have any questions, please do not hesitate to call.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs

Tel: (201) 225-5546
Fax: (201) 225-5530

Enc.

RECEIVED

MAR 2 5 2002

OGD / CDER

VIA UPS OVERNIGHT COURIER

ORIGINAL

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

A World of Health

650 From Road
Mack-Cali Centre II
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5520

www.faulding.com

April 1, 2002

Mr. Gary Buehler
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 150
Document Control Room
7500 Standish Place
Rockville, Maryland 20855

SUBJECT: **ANDA # 75-841 - Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL; 10 mL vials**

AMENDMENT TO MINOR AMENDMENT DATED MARCH 19, 2002

NEW CORRESP

Dear Mr. Buehler:

Reference is made to the subject original ANDA dated February 28, 2000, and to the Minor Amendment dated March 19, 2002, submitted in response to the Agency's letter dated December 19, 2001. In that Amendment, method validation information was provided to support additional analytical testing involving four metal ions. The method validation information was furnished in two separate reports. The purpose of this submission is to provide additional information for clarification (i.e., a bridging report summary) to support minor differences noted in the two reports. The additional information is being submitted as part of a revised study report that is intended to replace pages 51-77 of the above referenced Minor Amendment dated March 19, 2002.

Please contact the undersigned if you have any questions regarding this amendment.

Sincerely,

for Jatin J. Shah
Vice President, Scientific Affairs

Enclosure
Cc: New Jersey District Office

RECEIVED
APR 0 2 2002
OGD / CDER

Faulding Pharmaceutical Company
A division of Mayne Nickless

Faulding

Mack-Cali Centre II
650 From Road
2nd Floor
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5510
www.faulding.com

VIA UPS OVERNIGHT COURIER

TELEPHONE AMENDMENT

NC

NEW CORRESP

April 16, 2002

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

RE: ANDA 75-841 – Pamidronate Disodium Injection
3 mg/mL, 6 mg/mL and 9 mg/mL, 10 mL Vials

Dear Mr. Buehler:

Reference is made to the request today from Project Manager, Michelle Dillahunt regarding the method validation commitment.

Faulding hereby commits to resolve any issues identified in the methods validation process after approval. A Field Copy Certification of this amendment is provided in accordance with 21 CFR 314.96.

FDA Form 356(h) immediately follows this letter.

Should you have any questions concerning this submission, please contact me directly.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs
Tel: (201) 225-5546
Fax: (201) 225-5530

RECEIVED
APR 17 2002
OGD / CDER

ANDA 75-841

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

TO: APPLICANT: Faulding Pharmaceutical Company

TEL: ~~732-465-3888~~ 201-225-5504

FAX: ~~732-465-388~~5 201-225-5530

ATTN: ~~Jatin j. Shah, Ph.D.~~ STEVE RICARDSON

PROJECT MANAGER: 301-827-5848

FROM: Peter Chen

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated February 28, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Pamidronate Disodium Injection, 3 mg/mL (packaged in 30 mg/10 mL single-use vials), 6 mg/mL (packaged in 60 mg/10 mL single-use vials), and 9 mg/mL (packaged in 90 mg/10 mL single-use vials).

We are pleased to inform you that this application is APPROVED!