CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020560/S013

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

NDA 20-560 FOSAMAX®
Alendronate sodium
Patent Information

Item 13

PATENT AND EXCLUSIVITY INFORMATION
MERCK RESEARCH LABORATORIES

1.	Active Ingredient	Alendronate sodium
2.	Dosage	5 mg and 10 mg
3.	Trade Name	FOSAMAX®
4.	Dosage Form Route of Administration	Tablet Oral
5.	Applicant Firm Name	Merck Research Laboratories
6.	NDA Number	20-560
7.	Approval Date	
8.	Exclusivity - Date First ANDA Could Be Submitted	Three (3) years from this NDA approval date or five (5) years from September 29, 1995 (September 29, 2000)
9.	Applicable Patent Numbers	US Patent 4,621,077 Expires August 6, 2007 US Patent 5,358,941 Expires December 2, 2012 US Patent 5,681,590 Expires December 2, 2012 US Patent 5,804,570 Expires February 17, 2015 US Patent 5,849,726 Expires June 6, 2015

EXCLUSIVITY SUMMARY FOR NDA # 20-560 SUPPL # 013

Trade Name: Fosamax Generic Name: aledronate sodium tablets

Applicant Name Merck_____ HFD # 510

Approval Date If Known _____

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES /___/ NO /_x__/

b) Is it an effectiveness supplement?

Labeling supplement YES /_x__/ NO /___/

If yes, what type? (SE1, SE2, etc.) SE8

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES /_x__/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

_____

_____

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

This was a labeling supplement providing longer term clinical efficacy and safety data to support the use of the Fosamax in the treatment of postmenopausal osteoporsis from three years for up to five years treatment. The labeling changes in the Clinical section of the package insert were supported by data from two clinical studies which included data of alendronate on changes in bone mineral density (BMD) and biochemical markers of bone turnover.

cc: Original NDA Division File HFD-93 Mary Ann Holovac

d) Did the applicant request exclusivity?

YES /___/ NO /__x_/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

No. Not applicable

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /___/ NO /_x__/

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /_x__/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /_x__/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 20-960 Fosamax

NDA# _____ _____

NDA# _____ _____

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/
Not Applicable

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1: Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /_x__/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /_x__/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /_x__/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /_x__/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Study Protocol 035

Study Protocol 037

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /_x__/

Investigation #2 YES /___/ NO /_x__/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

_____ _____

_____ _____

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /_x__/

Investigation #2 YES /___/ NO /_x__/

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

_____ _____

_____ _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

___Study #1 Protocol 035_____ _____

___Study #2 Protocol 037_____ _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !

IND # [redacted] YES /_x__/ ! NO /___/ Explain: _____

!

! _____

Investigation #2 !

!

IND # [redacted] YES /_x__/ ! NO /___/ Explain: _____

_____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1 !

!

YES /___/ Explain _____ ! NO /___/ Explain _____

!

_____ ! _____

!

_____ ! _____

!

!

Investigation #2 !

!

YES /___/ Explain _____ ! NO /___/ Explain _____

! _____

_____ !

! _____

_____ !

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /_x__/

If yes, explain: _____

_____

/S/ [redacted] 6-7-99

Signature Date

Title: Regulatory Project manager

/S/ [redacted] 6/7/99

Signature of Office/ Division Director Date

APPEARS THIS WAY ON ORIGINAL

cc: Original NDA Division File HFD-93 Mary Ann Holovac

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	20560	**Trade Name:**	FOSAMAX (ALENDRONATE SODIUM)10+40MG TABS
Supplement Number:	13	**Generic Name:**	ALENDRONATE SODIUM
Supplement Type:	SLR	**Dosage Form:**	TAB
Regulatory Action:	AP	**Proposed Indication:**	

ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?
NO, No waiver and no pediatric data

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days)____Children (25 Months-12 years)
____Infants (1-24 Months) ____Adolescents (13-16 Years)

Label Adequacy	Does Not Apply
Formulation Status	-
Studies Needed	-
Study Status	-

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:
The indication is to prevent and treat osteoporosis in postmenopausal women.

The indication is to treat postmenopausal women

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, RANDY HEDIN

/S/ [redacted]
Signature

6/4/99
Date

Michelle W. Kloss, Ph.D.
Director
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486-0004
Fax 610 397 2516
Tel 610 397 2905
215 652 5000

June 5, 1998

MERCK
Research Laboratories

Solomon Sobel, M D., Director
Division of Metabolism and Endocrine Drug Products
HFD-510, Room 14B-04
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-560: FOSAMAX™ (Alendronate Sodium Tablets)
Supplemental New Drug Application

Dear Dr. Sobel:

Pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act and in accordance with Title 21 of the Code of Federal Regulations, Merck Research Laboratories (MRL) is submitting a Supplemental New Drug Application (sNDA) for FOSAMAX™ (alendronate sodium tablets).

This submission supplements the approved Original New Drug Application for use of FOSAMAX in the treatment of postmenopausal osteoporosis. The approved application provided results from a clinical development program with FOSAMAX that included clinical efficacy and safety documentation from Protocols 035 and 037, which were 3-year, double-blind studies. This supplemental application provides longer-term clinical efficacy and safety documentation from 2-year extensions (Years 4 and 5) of Protocols 035 and 037.

This application is formatted as required in Title 21, paragraph 314.50 of the Code of Federal Regulations. It consists of a complete "archival" copy (blue binders), comprising 8 volumes, and review copies for each of the three (3) technical sections (one technical review copy for each Item) as described in the Statement of Organization, which is attached to this letter.

In accordance with the Food and Drug Administration Modernization and Accountability Act of 1997 (FDAMA); User Fee I.D. [redacted] was sent to the [redacted] on May 21, 1998.

This sNDA is being provided in both paper copy and electronic format, with the exception of Items 11 and 12 (Case Report Tabulations and Case Report Forms), which are being provided in electronic format only (see attached "Statement of Organization").

Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment for this supplemental application under 21 CFR §25.31(b). The description of the proposed action is included in volume two of this submission.

This application is also being submitted electronically in accordance with the Guidance for Industry - Archiving Submissions in Electronic Format - NDAs, published September, 1997.

This sNDA is being submitted in the following formats:

FORMAT	INFORMATION INCLUDED	MEDIA FORMAT	DATE OF SUBMISSION
Paper	(all information except CRTs and CRFs)	Paper	June 5, 1998
Electronic Archival Files	sNDA Table of Contents, Case Report Tabulations, Case Report Forms	CD Serial number: 7279 2012 0410	June 5, 1998
Electronic Submission	(all information)	CD	June 5, 1998 (to Technology Services Support Staff)

As noted in the Guidance document, this letter is being included as *cover.pdf* and includes:

- Appropriate regulatory information
- A description of the submission
- A description of which portions of the submission are presented only in paper, only in electronic format, or both paper and electronic format *(see above)*
- A description of the electronic submission including the contents of the media, their number and format, a description of the file types and the total size of the submission

  The electronic archival files for Case Report Tabulations and Case Report Forms are provided on 1 CD. The files are provided in .PDF and .PDF catalogue index format. The total file size is approximately 204 MB.
- Verification that the submission is virus free with a description of the software used to check the files for viruses

  Merck Research Laboratories (MRL) has employed Norton anti-virus (NAV) software and has scanned all files. No viruses were detected.
- A description of any deviation from the specifications in the guidance document

  There are no deviations from the specifications as noted in the guidance document.

MRL will work with the FDA to arrange orientation to the electronic submission for all interested Agency reviewers.

As required by §306(k)(1) of 21 U.S.C. 335a(k)(1), we hereby certify that, in connection with this application, Merck & Co., Inc., did not and will not use in any capacity the services of any debarred under sections 306(a) or (b) of the Act.

MRL would like to meet with the FDA approximately 90 days following receipt of this application. The purpose of this meeting will be to discuss the general progress and status of the review of this application and to determine if there are any important deficiencies identified at that time. MRL will contact the FDA to arrange for this meeting.

We consider the filing of this Supplemental New Drug Application to be a confidential matter and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining written permission from Merck & Co., Inc.

If you have any questions or need further information, please contact Michelle W. Kloss, Ph.D. (610/397-2905) or, in my absence, Larry P. Bell, M.D., (610/397-2310)

Sincerely, yours,

Michelle W. Kloss

Michelle W. Kloss, Ph.D.
Director
Regulatory Affairs

Q:RC\MK-0217\35_37COV

Attachment

Federal Express #1

Desk Copy
Mr. Randy Hedin, HFD-510, Room 14B-04 - Federal Express #1

Ms. Debra Pagano (Volumes 1,2)
Philadelphia District Office
Food & Drug Administration
U.S. Custom House Room 900
2nd and Chestnut Street
Philadelphia, Pennsylvania 19106-2973 - Federal Express #2

Supplemental New Drug Application

NDA 20-560

FOSAMAX™
(Alendronate Sodium Tablets)

STATEMENT OF ORGANIZATION

This application is formatted as required in Title 21, paragraph 314.50 of the Code of Federal Regulations. It consists of a complete "archival" copy (Blue Binders), comprising 8 volumes and three "review" copies as follows:

ITEM	DESCRIPTION	BINDER COLOR	TOTAL VOLUMES
4	Chemistry, Manufacturing and Control Documentation	Red	1
8	Clinical Documentation	Light Brown	2
10	Statistical Documentation	Green	2

In addition to the specific technical item, each review copy also includes, in the appropriate color binder and Volume 1 containing Item 1 (the overall Index to the Contents of the Application) and Item 2 (Labeling). The total number of volumes contained in this submission, therefore, is 16 volumes.

The information for Item 11 (Case Report Tabulations) and Item 12 (Case Report Forms) is only being provided in electronic format only. Item 11 and Item 12 are each represented in the archival copy of this supplemental application by one volume which includes the complete tables of contents for the corresponding section.

SE1-013

BS

Larry P. Bell, M.D.
Senior Director
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2310
215 652 5000
Email larry_bell@merck.com

ORIGINAL NDA SUPPL AMENDMENT
These copies are
OFFICIAL FDA Copies
not desk copies.

August 10, 1998

MERCK
Research Laboratories

Mr. David M. Moss
Director, Technology Support Service Staff
HFD-73, Room 8B-45 (CDER)
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-560/S-013: FOSAMAX™
(Alendronate Sodium Tablets)

Response to Request for Information----Statistical Electronic Submission

Dear Mr. Moss:

Reference is made to the supplemental New Drug Application (sNDA) cited above submitted both in hard copy and electronically on June 5, 1998. Reference is also made to a July 8, 1998 telephone conversation between Mr. Randy Hedin (FDA) and Dr. Michelle Kloss (MRL) during which the Agency requested that MRL provide the SAS datasets and the statistical programs for the efficacy data from this supplement to facilitate the review of the application.

With this submission, we are providing the requested information. Accompanying this letter is one (1) CD (serial no. 8086 2047 1070) containing the SAS datasets and statistical programs for the efficacy data from this supplement. Also attached to this submission is a hard copy print out of the training documentation for the programs and datasets.

Any questions relating to these files should be addressed to Larry P. Bell, M.D. (610/397-2905) or, in my absence, Marie Dray (301/881-9000).

Sincerely,

Larry P. Bell

Larry P. Bell, M.D.
Senior Director, Regulatory Affairs

q:carnal\mk0217\035_037\sascov.doc

Attachment
Enclosure: Compact Disk (CD) - Serial # 8086 2047 1070 (CD1/1)

Federal Express #1

cc (cover letter with attachment):
K. Edmunds, Div. of Technology Support Services Staff, HFD-73, Rm 8B-45, Fed Exp #1
G. Brolund, Div. of Applications Development Services, HFD-70, Rm 12A-43, Fed Exp #2
M. Buster, Div. of Infrastructure Management Services, HFD-88, Rm 15A-55, Fed Exp #3
S. Sobel, M.D., HFD-510, Room 14B-04, Federal Express #4
R. Hedin, R. Ph., HFD-510, Room 14B-04, Federal Express #4
J.T. Sahlroot, Ph.D., HFD-715, Room 14B-45, Federal Express #5

Michelle W. Kloss, Ph.D.
Director
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486-0004
Tel 610 397 2905
Fax 610 397 2516

DUPLICATE

April 14, 1999

MERCK

Mr. Randy Hedin, Senior Regulatory Manager
Division of Metabolism and Endocrine Drug Products
HFD-510, Room 14B-04
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-560/S-013: FOSAMAX™
(Alendronate Sodium Tablets)

Response to FDA Request for Information

Dear Mr. Hedin:

Reference is made to the supplemental new drug application cited above for FOSAMAX™ that was submitted on June 5, 1998. Further reference is made to our April 12, 1999 telephone conversation during which you requested an additional desk copy of volumes 1, 3 and 4 of the supplemental application cited above.

With the attachments to this submission, we are providing the requested desk copies.

Please direct any questions to Michelle Kloss, Ph.D. (610-397-2905) or, in my absence, Larry P. Bell, M.D. (610-397-2310).

Sincerely yours,

Michelle W. Kloss

Michelle W. Kloss, Ph.D.
Director
Regulatory Affairs

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Federal Express

Desk Copy (Letter Only):
NDA 20-560, HFD-510, Room 14B-04 Federal Express #1

Merck & Co., Inc.
West Point, PA 19486

May 26, 1999

DESK COPY

Solomon Sobel, MD, Director
Division of Metabolism and Endocrine Drug Products
HFD-510, Room 14B-04
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

MERCK
Research Laboratories

NDA 20-560/S-013: FOSAMAX™
(Alendronate Sodium Tablets)

AMENDMENT TO PENDING SUPPLEMENTAL APPLICATION

Dear Dr. Sobel:

Reference is made to the Supplemental New Drug Application cited above, submitted on June 5, 1998, which provided longer-term clinical efficacy and safety documentation from 2-year extensions (Years 4 and 5) of Protocols 035 and 037. Reference is also made to a May 3, 1999 facsimile communication from Mr. Randy Hedin (FDA) to Dr. Michelle Kloss (MRL, a Division of Merck & Co., Inc.) providing labeling comments for the above referenced supplemental application.

With this submission, we are providing a revised mockup package circular showing revisions from, in three columns: the original June 5, 1998 submission; the Agency's May 3, 1999 facsimile; and MRL's comments/proposals regarding the Agency's facsimile. All Agency comments have been addressed in the attached mockup package circular.

Questions concerning this submission should be addressed to Michele R. Flicker, MD, PhD (610/397-3193) or, in my absence, Larry P. Bell, MD (610/397-2310).

Sincerely,

Michele R. Flicker

Michele R. Flicker, MD, PhD
Director
Regulatory Affairs

q/carnal/mk0217/amends/s013amnd

Attachment

Fax / Federal Express #1
Desk copy: Mr. Randy Hedin, CSO, HFD-510, Room 14B-19 - Fed. Ex. #1
Dr. Gloria Troendle, HFD-510, Room 14B-04 - Fed. Ex. #1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-013

JUN 17 1998

Merck Research Laboratories
Sumneytown Pike P.O. Box 4
West Point, PA 19486

Attention: Michelle W. Kloss, Ph.D.

Dear Dr. Kloss:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Fosamax™ (Alendronate Sodium Tablets)
NDA Number:	20-560
Supplement Number:	S-013
Date of Supplement:	June 05, 1998
Date of Receipt:	June 08, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on August 07, 1998, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/ [redacted]

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research