CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-560/S032

Trade Name: Fosamax Tablets

Generic Name: alendronate sodium

Sponsor: Merck & Co., Inc.

Approval Date: November 27, 2001

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APPLICATION NUMBER:

20-560/S032

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APPLICATION NUMBER:

20-560/S032

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-032

Merck & Co., Inc.
Attention: Michele Flicker, M.D., Ph.D.
Director, Regulatory Affairs
P.O. Box 2000
Mail Drop: Ry 33-720
Rahway, NJ 07065

Dear Dr. Flicker:

Please refer to your supplemental new drug application dated May 23, 2001, received May 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application proposes to add the Merck Manufacturing Division (MMD) facility (4633 Merck Road, Wilson, NC 27893) as an alternate drug substance stability testing site.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Duu-Gong Wu, Ph.D.
Chemistry Team Leader II, DNDC II for the
Division of Metabolic and Endocrine Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Duu-gong Wu
11/27/01 09:28:43 AM

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APPLICATION NUMBER:

20-560/S032

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1.ORGANIZATION DMEDP, HFD-510	2. NDA ~~NUMBER~~ 20-560
3. NAME AND ADDRESS OF APPLICANT		4.SUPPLEMENT NUMBER,DATE
Merck & Co., Inc. Sumneytown Pike P.O. Box 4 BLA-20 West Point, PA 19486		SCS-032, 5/23/01 (CBE) User Fee date: 11/24/01 (6 months)
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	
Fosamax™ tablets	Alendronate sodium	
		8.AMENDMENTS/REPORT,DATE
7. SUPPLEMENT PROVIDES FOR:		None
Addition of the Merck, Wilson, North Carolina site as an alternative stability testing site for Alendronate Sodium.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11.RELATED IND/NDA/DMF
Treatment and prevention of osteoporosis. Treatment of Paget's disease of bone.	R_x	
12. DOSAGE FORM	13. POTENCY	
Tablet	5;10;35;40;70 mg	

14. CHEMICAL NAME AND STRUCTURE.

(4-amino-1-hydroxybutylidene) bisphosphonic acid monosodium salt trihydrate, $C_4H_{12}NNaO_7P_2.3H_2O$

15. COMMENTS

The supplement provides for the addition of the Merck Wilson, NC facility (CFN# 1036761) as an alternate stability testing site for the bulk drug substance, Alendronate Sodium. In accordance with the two guidances for Industry: Changes to an Approved NDA or ANDA (Nov. 1999) (section VI. C. 1d.) and PAC-ATLS: Postapproval Changes - Analytical Testing Laboratory Sites (Apr. 1998), this kind of change is considered to be a moderate change and can be reported in a supplement - Change Being Effective (CBE-30). An EER was filled with the office of compliance and the Merck Wilson facility was found acceptable on 6-14-01 (see attached report).

16. CONCLUSION AND RECOMMENDATION

From a chemistry standpoint, adequate information has been provided. Issue an approval letter.

17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Elsbeth G. Chikhale, Ph.D.		11/6/01

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Init. by:
CC: HFD-510, NDA 20-560/S-032
HFD-510/ DG Wu / R Hedin / EG Chikhale / Division file / NDA 20-560

1 Page(s) Withheld

√ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-560

S032

B: Enviromental Impact Analysis Report:

The sponsor is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR §25.31(a). This categorical exclusion is **acceptable**, because this supplement will not increase the use of the active drug moiety.

05-NOV-2001 FDA CDER EES Page 1 of 1

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 20560/032
Stamp: 24-MAY-2001 Regulatory Due: 24-NOV-2001
Applicant: MERCK
SUMNEYTOWN PIKE BLA20
WEST POINT, PA 19486

Priority: 1P Org Code: 510
Action Goal: District Goal: 20-OCT-2001
Brand Name: FOSAMAX
Established Name:
Generic Name: ALENDRONATE SODIUM
Dosage Form: TAB (TABLET)
Strength: 10, 35, 40 AND 70 MG

FDA Contacts:			
	D. HEDIN	(HFD-510)	301-827-6392 , Project Manager
	E. CHIKHALE	(HFD-820)	301-827-6420 , Review Chemist
	D. WU	(HFD-510)	301-827-6375 , Team Leader

Overall Recommendation:

ACCEPTABLE on 14-JUN-2001 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: 1036761
MERCK AND CO INC
4633 MERCK RD
WILSON, NC 27893

DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 14-JUN-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: DRUG SUBSTANCE STABILITY TESTER

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/s/

Elsbeth Chikhale
11/6/01 02:37:31 PM
CHEMIST

Duu-gong Wu
11/6/01 04:59:52 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-560/S032

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-032

CBE-30 SUPPLEMENT

Merck & Co., Inc.
Attention: Michele R. Flicker, M.D., Ph.D, F.A.C.P.
Director, Regulatory Affairs
P.O. Box 2000
Rahway, NJ 07065

Dear Dr. Flicker:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Fosamax (alendronate sodium) Tablets

NDA Number: 20-560

Supplement Number: 032

Date of Supplement: May 23, 2001

Date of Receipt: May 24, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days", proposes to add the Merck Manufacturing Division (MMD) facility (4633 Merck Road, Wilson, NC 27893) as an alternate drug substance stability testing site.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 23, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 24, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application.

All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Randy Hedin, R.Ph.
Senior Regulatory Management Officer
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Randy Hedin
6/27/01 09:17:59 AM