CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-560/S036

Trade Name: Fosamax Tablets

Generic Name: alendronate sodium

Sponsor: Merck & Co., Inc.

Approval Date: August 5, 2002
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APPLICATION NUMBER:
20-560/S036

APPROVAL LETTER
NDA 20-560/S-036

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:


We acknowledge receipt of your submission dated March 8, 2002.

This supplemental application, submitted as a "Supplement - Changes Being Effectuated" supplement, proposes alternative ("push-through" design) packaging to the currently approved 35 and 70 mg once weekly tablet 4-count trade bifold packaging ("peel-push" design). The "push-through" design blister is identical to the design of the approved 1-count sample package approved with supplements -021 and -022.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (text for the 35, and 70 mg strength 4-count trade bifold blister packages submitted February 15, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857
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}

Sheldon Markofsky, Ph.D.
Acting Chemistry Team Leader II, DNDC II for the Division of Metabolic and Endocrine Drug Products
Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure
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/s/

Sheldon Markofsky
8/5/02 02:11:31 PM
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-560/S036

LABELING
FOSAMAX®
ONCE WEEKLY

Protect your bones. Once you take FOSAMAX® to help you take once weekly. That's why it is important to break bones. It causes bone loss in postmenopausal women. For the prevention of osteoporosis. Osteoporosis is a disease. It becomes thin, weak, and easy to break. 

Important Information:

Please read the enclosed Patient Information.
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-560/S036

CHEMISTRY REVIEW(S)
CHEMIST'S REVIEW

1. ORGANIZATION
DMEDP, HFD-510
20-560

3. NAME AND ADDRESS OF APPLICANT
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065

4. SUPPLEMENT NUMBER, DATE
SCP-036, (CBE-30)
2/15/02
User Fee date:
8/16/02 (6 months)

5. NAME OF THE DRUG
Fosamax™

6. NONPROPRIETARY NAME
Alendronate sodium tablets

7. SUPPLEMENT PROVIDES FOR:
The addition of an alternative "push-through"
bifold packaging to the currently approved 4-count
trade "peel-push" bifold packaging for the 35 and
70 mg tablets.

8. AMENDMENTS/REPORT, DATE
3/8/02

9. PHARMACOLOGICAL CATEGORY
Treatment and prevention of
osteoporosis. Treatment of
Paget's disease of bone.

10. HOW DISPENSED
Rx

11. RELATED IND/NDA/DMF

12. DOSAGE FORM
Tablet
5 mg, 10 mg, 35 mg,
40 mg, and 70 mg

13. POTENCY

14. CHEMICAL NAME AND STRUCTURE
(4-amino-1-hydroxybutylidene) bisphosphonic acid monosodium salt
trihydrate, C₄H₁₂NNaO₇P₂·3H₂O

15. COMMENTS
This supplement is submitted, in electronic format, to HFD-510 as a CBE-30. The sponsor is requesting the addition of an alternative 4-count bifold packaging (child-resistant package ("push through") blister) to the currently approved 4-count trade bifold packaging (child-resistant ("peel push") blister package) for the 35 and 70 mg tablets. The amendment dated 3/8/02 provides samples of the currently approved and the proposed packaging materials.

16. CONCLUSION AND RECOMMENDATION
From a chemistry standpoint, adequate information has been provided. Issue an approval letter.

17. NAME
Elisabeth G. Chikhale, Ph.D.

REVIEWER SIGNATURE
DATE COMPLETED
7/18/02

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Init. by:
CC: HFD-510, NDA 20-560/S-036
HFD-510/S Markofsky /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
Environmental Assessment:

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

Elsbeth Chikhaie
7/18/02 01:50:24 PM
CHEMIST

Sheldon Markofsky
7/18/02 02:26:01 PM
CHEMIST
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-560/S036

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
Division of Metabolic and Endocrine Drug Products

PROJECT MANAGER LABELING REVIEW

Application Number: 20-560/S-036

Name of Drug: Fosamax (alendronate sodium) 35, and 70 mg Tablets

Sponsor: Merck Research Laboratories

Material Reviewed

Submission Dates:

- February 15, 2002, containing text for the 35, and 70 mg strength 4-count trade bifold blister package.

Background and Summary Description:

This Changes-Being-Effectuated (CBE) supplemental new drug application was submitted on April 9, 2001, and proposes an alternative to the currently approved 35 and 70 mg Once Weekly Tablet 4-count trade bifold packaging. The "peel-push" design will be replaced with a "push-through" blister identical to that approved for the 1-count sample package approved with supplements -021 and -022.

Review

- The submitted final printed labeling (FPL) for the text for the 35, and 70 mg strength 4-count trade bifold blister package (Identifier Number 9508400 (35 mg) and 9508000 (75 mg), Issued No Date) was compared to the currently approved FPL for the text for the 35, and 70 mg strength 4-count trade bifold blister package (Identifier Number 9362000 (35 mg), Revised No Date, Approved with S-021 on May 17, 2000, Acknowledged and Retained April 17, 2001 and Identifier Number 9361900 (70 mg), Revised No Date, Approved with S-022 on May 17, 2000, Acknowledged and Retained April 17, 2001).
The following changes have been made:

The "How to remove tablets:" section is changed from:

1. 
2. 

To:

1. Tear away tab along perforations or use scissors.
2. Turn card over, peel backing off at corner notch. Push tablet through foil.

These revisions are acceptable.

Conclusions

The label is acceptable, and an approval letter should be issued.

Reviewed by: Randy Hedin, R.Ph., Senior Regulatory Management Officer
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/s/

Randy Hedin.
8/5/02 01:22:58 PM
CSO
CBE-30 SUPPLEMENT

Merck & Co., Inc.
Attention: Michele R. Flicker, M.D., Ph.D., FACP
Director, Regulatory Affairs
P.O. Box 2000
Mail Drop: Ry 33-720
Rahway, NJ 07065-0900

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: S-036
Date of Supplement: February 15, 2002
Date of Receipt: February 19, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes an alternative to the currently approved 35 and 70 mg Once Weekly Tablet 4-count trade bifold packaging. The “peel-push” design will be replaced with a “push-through” blister identical to that approved for the 1-count sample package approved with supplements -021 and -022.

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 April 20, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be August 19, 2002.
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, 14B-19
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
This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.

/s/

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Randy Hedin
3/18/02 10:27:58 AM