

## Document Information Page

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**Application #(s):** NDA 20-560/S-036

**Document Type:** Supplement Letter  
**Document Group:** Approval Letters  
**Document Name:** Approval letter based on enclosed/submitted labeling text  
**Letter Code:** SNDA-II

**COMIS Decision:** AP: APPROVAL

**Drafted by:** RHedin/July 23, 2002  
**Revised by:**  
**Initialed by:**  
**Finalized:**  
**Filename:** N20560AP\_Lt25

**DFS Key Words:**

**Notes:**

**Linking Instructions:** If this is the first action on the application, link the outgoing letter to the initial submission, RS, AR, or FO coded incoming document for the supplement being acted on, as appropriate. Otherwise, the outgoing letter must be linked to the major amendment submitted in response to the previous action letter.  
In addition, the outgoing document should also be linked to all associated amendments and correspondences included in the action.

**END OF DOCUMENT INFORMATION PAGE**

The letter begins on the next page.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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:

Please refer to your supplemental new drug application dated February 15, 2002, received February 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets.

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

This supplemental application, submitted as a "Supplement - Changes Being Effected" 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

NDA 20-560/S-036

Page 2

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

<p><b>WEEK 1</b></p> <p>Peel back strip</p> <p><b>Important information:</b>                  Please read the enclosed Patient Information leaflet before taking Once Weekly FOSAMAX<sup>®</sup> (Alendronate Sodium Tablets). Keep this and all drugs out of the reach of children. Store at room temperature, 15–30°C (59–86°F).</p> <p><b>ONCE WEEKLY FOSAMAX<sup>®</sup></b>                  (Alendronate Sodium Tablets)</p>	<p>For the prevention of osteoporosis in postmenopausal women</p> <p><b>ONCE WEEKLY FOSAMAX<sup>®</sup></b>                  (Alendronate Sodium Tablets)</p> <p><b>35 mg</b></p> <p>Each tablet contains 45.68 mg alendronate sodium (35 mg free acid equivalent)</p> <p>4 Tablets                  No. 3813                  Rx only</p> <p>USUAL ADULT                  DOSAGE:                  ONE 35 mg TABLET                  ONCE WEEKLY</p> <p>See accompanying circular for complete dosage information.</p>
<p><b>WEEK 2</b></p> <p>Peel back strip</p> <p>5 0006-0077-449</p>	<p>Osteoporosis is a disease that causes bones to become thin, weak, and easy to break</p>
<p><b>WEEK 3</b></p> <p>Peel back strip</p> <p>Apply Prescription Label Here</p>	<p>That's why it is important you take <i>Once Weekly FOSAMAX</i> to help protect your bones.</p>
<p><b>WEEK 4</b></p> <p>Peel back strip</p> <p>9508400</p>	<p><b>Once Weekly FOSAMAX<sup>®</sup> (Alendronate Sodium Tablets) 35 mg – No. 3813</b></p> <p><b>MERCK &amp; CO., INC.</b>                  Whitehouse Station, NJ 08889, USA</p>

### How to take

#### Once Weekly FOSAMAX® 35 mg

*(Alendronate Sodium Tablets)*

**Choose the day of the week that best fits your schedule.**  
 Every week, take one FOSAMAX tablet on your chosen day.

**After getting up for the day on your chosen day of the week,** swallow (do not chew or suck) one FOSAMAX tablet with a full glass (6–8 oz.) of plain water on an empty stomach. Do not take FOSAMAX at bedtime or before arising for the day.

**Begin your morning activities...** but don't lie down, eat, drink, or take other medication for at least 30 minutes. If you want to lie down after 30 minutes, you must eat breakfast first.

**Remember to take one FOSAMAX tablet once each week on that same day** for as long as your doctor prescribes it.

**If you miss a dose,** take only one FOSAMAX tablet on the morning after you remember. Do not take two tablets on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day.

There is important additional information about how to take Once Weekly FOSAMAX in the enclosed Patient Information leaflet. Please read it carefully.

**FOSAMAX®**  
ONCE WEEKLY  
 (alendronate sodium tablets)

9508300

### Choose your day for taking

#### Once Weekly FOSAMAX® 35 mg

*(Alendronate Sodium Tablets)*

Write in the best date for you to start FOSAMAX.

SUNDAY		WEEK 1
MONDAY		WEEK 2
TUESDAY		WEEK 3
WEDNESDAY		WEEK 4
THURSDAY		
FRIDAY		
SATURDAY		

(Time to refill)



○

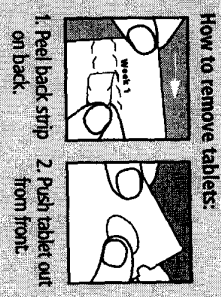
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NDA 20-560/S-036  
Page 5

**WEEK 1**  
Peel back strip

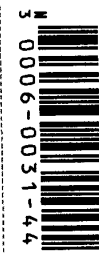
**WEEK 2**  
Peel back strip

**WEEK 3**  
Peel back strip

**WEEK 4**  
Peel back strip


**Important information:**  
Please read the enclosed Patient Information leaflet before taking **Once Weekly FOSAMAX<sup>®</sup>** (Alendronate Sodium Tablets). Keep this and all drugs out of the reach of children. Store at room temperature, 15–30°C (59–86°F).

**ONCE WEEKLY FOSAMAX<sup>®</sup>**  
(alendronate sodium tablets)



3 0006-0031-44 1

Apply Prescription Label Here



9508000

**Once Weekly FOSAMAX<sup>®</sup> (Alendronate Sodium Tablets) 70 mg – No. 3814**

For the treatment of osteoporosis in postmenopausal women

**ONCE WEEKLY FOSAMAX<sup>®</sup> 70 mg**  
(Alendronate Sodium Tablets)

Osteoporosis is a disease that causes bones to become thin, weak, and easy to break.

That's why it is important you take **Once Weekly FOSAMAX** to help protect your bones.

Each tablet contains 91.37 mg alendronate sodium (70 mg free acid equivalent)

4 Tablets  
No. 3814  
Rx only

USUAL ADULT  
DOSAGE:  
ONE 70 mg TABLET  
ONCE WEEKLY

See accompanying circular for complete dosage information.

**MERCK & CO., INC.**  
Whitehouse Station, NJ 08889, USA

NDA 20-560/S-036

Page 6

**How to take**  
**Once Weekly FOSAMAX® 70 mg**  
(Alemdronate Sodium Tablets)

**Choose the day of the week that best fits your schedule.**  
 Every week, take one FOSAMAX tablet on your chosen day.  
**After getting up for the day on your chosen day of the week,** swallow (do not chew or suck) one FOSAMAX tablet with a full glass (6-8 oz.) of plain water, on an empty stomach. Do not take FOSAMAX at bedtime or before arising for the day.  
**Begin your morning activities..** but don't lie down, eat, drink, or take other medication for at least 30 minutes. If you want to lie down after 30 minutes, you must eat breakfast first.  
**Remember to take one FOSAMAX tablet once each week on that same day** for as long as your doctor prescribes it.  
**If you miss a dose,** take only one FOSAMAX tablet on the morning after you remember. **Do not take two tablets on the same day.** Return to taking one tablet once a week, as originally scheduled on your chosen day.  
 There is important additional information about how to take Once Weekly FOSAMAX in the enclosed Patient Information leaflet. Please read it carefully.

**FOSAMAX®**  
(Alemdronate sodium tablets)


9507900

**Choose your day for taking**  
**Once Weekly FOSAMAX® 70 mg**  
(Alemdronate Sodium Tablets)


Write in the best date for you to start FOSAMAX.

SUNDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
MONDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
TUESDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
WEDNESDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
THURSDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
FRIDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
SATURDAY	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**How to remove tablets:**




1. Peel back strip on back.



2. Push tablet out from front.

	<input type="text"/>	<input type="text"/>	<input type="text"/>
	WEEK 1	WEEK 2	WEEK 3
(Time to refill)	<input type="text"/>	<input type="text"/>	<input type="text"/>
	WEEK 4		



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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Sheldon Markofsky  
8/5/02 02:11:31 PM