DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020560/S-051, S-055, S-057
NDA 021575/S-012, S-016, S-018

SUPPLEMENT APPROVAL

Merck & Co., Inc.
Attention: James Adams
Associate Director, Worldwide Regulatory
126 E. Lincoln Avenue
P.O. Box 2000
Mail Drop: RY33-200
Rahway, NJ 07065-0900

Dear Mr. Adams:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FOSAMAX (alendronate sodium) Tablets and Oral Solution:

NDA 020560 FOSAMAX (alendronate sodium) tablets		
Supplement Number	**Letter Date**	**Date Received**
S-051	July 9, 2007	July 9, 2007
S-055	June 10, 2009	June 10, 2009
S-057	July 2, 2009	July 2, 2009

NDA 021575 FOSAMAX (alendronate sodium) oral solution		
Supplement Number	**Letter Date**	**Date Received**
S-012	July 9, 2007	July 9, 2007
S-016	June 10, 2009	June 10, 2009
S-018	July 2, 2009	July 2, 2009

We also acknowledge receipt of the following submissions:

NDA 020560 FOSAMAX (alendronate sodium) tablets		
Supplement Number	**Letter Date**	**Date Received**
S-051	June 25, 2009	June 25, 2009
S-051	January 13, 2010	January 13, 2010
S-055	June 23, 2009	June 23, 2009
S-055	January 13, 2010	January 13, 2010
S-057	July 30, 2009	July 30, 2009
S-057	January 13, 2010	January 13, 2010

NDA 021575 FOSAMAX (alendronate sodium) oral solution		
Supplement Number	**Letter Date**	**Date Received**
S-012	June 25, 2009	June 25, 2009
S-012	January 13, 2010	January 13, 2010
S-016	June 23, 2009	June 23, 2009
S-016	January 13, 2010	January 13, 2010
S-018	July 30, 2009	July 30, 2009
S-018	January 13, 2010	January 13, 2010

Your submissions of June 25, 2009, constituted complete responses to our April 3, 2008, action letter.

These supplemental new drug applications provide for the following labeling changes:

NDA 020560/S-051 and NDA 021575/S-012

- Revision of the *Dental* subsection of PRECAUTIONS and the *Post-Marketing Experience* subsection of ADVERSE REACTIONS of Physician Labeling that relate to osteonecrosis of the jaw.
- Revision of Patient Labeling (section entitled "What should I tell my doctor before using FOSAMAX?") to include dental conditions.

NDA 020560/S-055 and NDA 021575/S-016

- Minor revision of the WARNINGS Section of Physician Labeling regarding the use of bisphosphonates in patients with active upper gastrointestinal problems and the upper gastrointestinal adverse events associated with the use of bisphosphonates.

NDA 020560/S-057 and NDA 021575/S-018

- A change to the *Post-Marketing Experience* subsection of ADVERSE REACTIONS of Physician Labeling. The change added "low-energy femoral shaft and subtrochanteric fractures" to the *Musculoskeletal* subsection.
- Revision of Patient Labeling (section entitled "What are the possible side effects of FOSAMAX?") to inform patients about femoral fractures.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "SPL for approved NDAs 020560/S-051, 020560/S-055, 020560/S-057, 021575/S-012, 021575/S-016, and 021575/S-018."

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21575	SUPPL-18	MERCK AND CO INC	FOSAMAX 70 MG ORAL BUFFERED SOLUTION
NDA-21575	SUPPL-16	MERCK AND CO INC	FOSAMAX 70 MG ORAL BUFFERED SOLUTION
NDA-21575	SUPPL-12	MERCK AND CO INC	FOSAMAX 70 MG ORAL BUFFERED SOLUTION
NDA-20560	SUPPL-57	MERCK AND CO INC	FOSAMAX
NDA-20560	SUPPL-55	MERCK AND CO INC	FOSAMAX
NDA-20560	SUPPL-51	MERCK AND CO INC	FOSAMAX

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

/s/

SCOTT E MONROE
03/01/2010