DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020560/S-062

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Elinor Chen, Ph.D.
Director, Worldwide Regulatory Affairs
126 E. Lincoln Ave., P.O. Box 2000, RY33-212
Rahway, NJ 07065

Dear Dr. Chen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fosamax™ (alendronate sodium) Tablets.

We acknowledge receipt of your amendments dated February 17 and June 12, 2012.

This "Prior Approval" supplemental new drug application proposes changes to the Dosage and Administration (Full Prescribing Information) section of the package insert indicating that alendronate tablets 5 mg, 10 mg, 35 mg, and 40 mg are available in the marketplace, but that Fosamax is no longer marketed in these strengths. This supplemental application also proposes deletion of references to the discontinued Fosamax strengths from the Dosage Forms and Strengths (Full Prescribing Information and Highlights of Prescribing Information), Description, and How Supplied/Storage and Handling sections of the package insert. In addition, this supplemental application proposes changing a reference to taking Fosamax daily in the Medication Guide, to taking alendronate daily.

We have completed our review of this supplemental application, as amended. It is 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication

Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, contact Martin Kaufman, D.P.M., M.B.A., Senior Regulatory Project Manager, at (301) 796-0928.

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, M.D., M.M.Sc.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Medication Guide

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

/s/

HYLTON V JOFFE
06/27/2012