DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020788/S-020, S-021, S-023

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Frank J. Mellina, Pharm.D.
Manager, Regulatory Affairs
126 East Lincoln Avenue
P.O. Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Dr. Mellina:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 8, 19, and May 6, 2011, received April 8, 19, and May 6, 2011, respectively, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Propecia™ (finasteride) Tablet, 1 mg.

We acknowledge receipt of your amendments dated as follows:

S-020
June 1, 23, 30, August 31, September 6, 8, 2011; February 6, March 7, 8, and April 3, 2012

S-021
June 23, 2011; February 6, March 7, 8, and April 3, 2012

S-023
June 23, 2011; February 6, March 7, 8, and April 3, 2012

S-020 is a "Prior Approval" sNDA that proposes the revision of the Propecia™ (finasteride) Tablet, 1 mg full prescribing information to comply with the new labeling content and format requirements for human prescription drug and biological products, according to 21 CFR 201.56(d) and 201.57.

S-021 is a "Changes Being Effected" sNDA that provides for the addition of the adverse reaction "erectile dysfunction that continued after discontinuation of treatment", to the Postmarketing Experience section of the package insert and to the patient labeling.

S-023 is a "Prior Approval" sNDA that proposes the addition of the adverse reactions "male infertility and/or poor seminal quality (normalization or improvement of seminal quality has been reported after discontinuation of finasteride)", to the Postmarketing Experience section of the package insert and to the patient labeling.

We have completed our review of these supplemental 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, 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, text for the patient package insert), 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, call Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

TATIANA OUSSOVA
04/11/2012