DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020788/S-015 **SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp.
Attention: Siyoung Ahn
Manager, Regulatory Affairs
126 East Lincoln Avenue
P.O. Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Ms. Ahn:

Please refer to your supplemental new drug application dated August 14, 2009, received August 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Propecia™ (finasteride) Tablet, 1mg.

We acknowledge receipt of your submission dated March 4, 2010.

This Prior Approval supplemental new drug application provides for revisions to the PRECAUTIONS, General section of the labeling.

We have completed our review of this 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, 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 (text for the package insert and the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 020788/S-015.

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 Jeannine M. Helm, at (301) 796-0637.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, M.D.
Deputy Safety Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures
Content of Labeling- Package Insert and Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20788	SUPPL-15	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	PROPECIA

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
03/24/2010