DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020180/S-033 **SUPPLEMENT APPROVAL**

Merck & Co., Inc.
Attention: Siyoung Ahn
Manager, Regulatory Affairs
126 East Lincoln Avenue
PO BOX 2000, RY33-200
Rahway, NJ 07065-0900

Dear Ms. Ahn:

Please refer to your supplemental new drug application dated and received August 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Proscar® (finasteride) tablets 5mg.

We acknowledge receipt of your submissions dated December 16 and December 23, 2009, and January 7, 2010.

This supplemental new drug application provides changes in the labeling regarding the effect of finasteride on prostate-specific antigen (PSA). Revisions have been made to the following sections of the labeling to furnish adequate information for the safe and effective use of PROSCAR®.

- **PRECAUTIONS** section of the package insert, subsection "*Effects on PSA and Prostate Cancer Detection"*
- A new **Patient Package Insert** (PPI)

Edits were also made to the **HOW SUPPLIED** section.

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 text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 020180/S-033."

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 REQUIREMENT

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 Olga Salis, Regulatory Project Manager, at (301) 796-0837.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III

Enclosure: Package Insert and Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20180	SUPPL-33	MERCK AND CO INC	PROSCAR

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

/s/

GEORGE S BENSON
03/23/2010