CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20180/S11

ADMINISTRATIVE DOCUMENTS

M.O. Labeling Review

NDA 20-180
Drug: Proscar/finasteride
Sponsor: Merck Research Laboratories
Submission February 16, 1996
Date: June 25, 1996/Revised July 2, 1996

This is a review of requested label changes submitted by Merck Research Laboratories for Proscar (finasteride). The changes are supported by studies regarding the amounts of secreted finasteride in the semen in both human and monkey studies. The sponsor believes these studies reduce the previous estimate of potential exposure of a pregnant woman to finasteride from the semen of men on finasteride. The calculated dose of finasteride from semen to a pregnant woman would be approximately 1 or 2 ng/kg/day based on semen concentrations of ng/mL or ng/mL. The no-effect dose in the rhesus teratology study was ng/day, with intravenous administration, or ng/kg/day which provides a safety ratio of at least 60 to 120 times the expected exposure to finasteride from semen in humans.

The sponsors have made the following changes to the label:

These changes (page 5 of the attached label) are satisfactory and supported by the sponsor's data.

The sponsor has made minor and editorial changes under the sections regarding Warnings, Exposure of Women, and Precautions . These are found on page 12 - 13 of the attached label. These changes are all satisfactory.

The sponsor has added a paragraph regarding the *in utero* effects of finasteride based on pharmacology/toxicology studies. They are found on page 17 of the attached label. The statements added are all documented and satisfactory.

The sponsor has included minor editorial changes in the patient package insert which are all satisfactory.

In summary all of the label changes the sponsor has submitted are satisfactory.

/S/

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Medical Officer

7-1-96 /S/

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