DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-611/S-007
NDA 20-554/S-007
NDA 20-273/S-009

Warner Chilcott (US), Inc.
Attention: Deepa B. Desai, M.S.
Senior Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug applications dated March 27, 2007, received March 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dovonex Scalp Solution 0.005%, Dovonex Cream 0.005%, and Dovonex Ointment 0.005%.

These supplemental new drug applications provide for changes to the Carcinogenesis, Mutagenesis, Impairment of Fertility Section of the package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-611/S-007, NDA 20-554/S-007, NDA 20-273/S-009**." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Margo Owens, Regulatory Project Manager, at (301) 796-0966.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, MD
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Stanka Kukich

9/26/2007 05:24:51 PM