DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-831/S-047

Valeant Pharmaceuticals International
Attention: Edward F. Smith III, Ph.D.
Director, Corporate Regulatory Affairs
3300 Hyland Avenue
Costa Mesa, CA 92626

Dear Dr. Smith:

Please refer to your supplemental new drug application dated December 23, 2003, received December 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efudex® (fluorouracil) Topical Cream, 5%.

We acknowledge receipt of your correspondence dated June 22, 2004.

This "Changes Being Effected" supplemental new drug application provides for revisions to the CONTRAINDICATIONS and WARNINGS sections, and strengthening the statement of dosage.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the revised enclosed agreed-upon labeling text.

Please implement these labeling revisions with your next printing or within six months.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jacquelyn Smith, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
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
6/24/04 03:29:01 PM
Signing off for Dr. Wilkin, Division Director