DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-789/S-001

Paul M. Clark
Vice President, Regulatory Affairs
Galderma Laboratories, L.P.
14501 N. Freeway
Fortworth, Texas 76177

Dear Mr. Clark:

Please refer to your supplemental new drug application dated September 13, 2005, received September 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for METROGEL (metronidazole gel), 1%.

We acknowledge receipt of your submission dated October 31, 2005.

This submission provides for a revision to the carton and container to use the 1 % logo adjacent to the product's proprietary name, Metrogel.

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 agreed upon text for the immediate carton and container label.

The final printed labeling (FPL) must be identical to the labeling (text for the immediate container and carton label).

Please submit an electronic version of the FPL according to the guidance for industry titled Providing *Regulatory Submissions in Electron Format-NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon 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 this submission "FPL for approved supplement NDA 21-789/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, as required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of this product. Submit all proposed materials in draft or mock up form, not final print. Send one copy to the Division of Dermatology & Dental Products and two copies of both the promotional materials and the proposed 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Kalyani Bhatt, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, MD
Acting Division Director,
Division of Dermatology & 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
11/14/2005 04:13:05 PM