DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-600/S-003 & S-005

Allergan, Inc.
Attention: Lewis Gryziewicz, R.Ph.
Director, Pharmaceutical Regulatory Affairs
2525 Dupont Drive
P.O Box 19534
Irvine, California 92623-9534

Dear Mr. Gryziewicz:

Please refer to your supplemental drug applications listed below:

- S-003 dated March 13, 2000, received March 14, 2000;
- S-005 dated January 25, 2002, received January 28, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAZORAC® (tazarotene) Gel, 0.05% and 0.1%.

We acknowledge receipt of your submissions S-003 and S-005 dated May 29, 2003.

These supplemental drug applications provide for the revisions to the following label sections: CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, PRECAUTIONS subsections Carcinogenesis, Mutagenesis, Impairment of Fertility, Pregnancy and Geriatric Use, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, HOW SUPPLIED, and the Patient Package Insert.

We completed our reviews of these supplemental applications, as amended. They 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 package insert and patient package insert).

Please submit the PFL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the PFL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 20-600/S003 and S005". Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatologic and Dental Drug products and two copies of both the promotional materials and the package inserts 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 set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Kalyani Bhatt, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K.Wilkin,
Director
Division of Dermatologic and Dental Drug Products Center for Drug Evaluations and Research

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

/s/

Jonathan Wilkin

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