DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21470/S-012

APPROVAL LETTER

Bayer HealthCare Pharmaceuticals Inc.
Attention: Paulina D. Estrada, PharmD, Global Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981-0915

Dear Dr. Estrada:

Please refer to your supplemental new drug application dated June 30, 2015, received June 30, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Finacea® (azelaic acid) Gel, 15%.

This "Prior Approval" supplemental new drug application provides for revisions to the carton and container labels for the 50 gram tube Finacea® (azelaic acid) Gel.

We have completed our review of this supplemental new drug application and it is approved.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21470**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Business Process Manager, at (301) 796-1649.

Sincerely,

Ramesh Raghavachari, Ph.D., Branch Chief, on behalf of:

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling