DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-005/S-010

Bradley Pharmaceuticals, Inc.
Attention: Donna Heren
Director, Regulatory Compliance
383 Route 46 West
Fairfield, NJ 07004

Dear Ms. Heren:

Please refer to your supplemental new drug application dated January 31, 2007, received February 1, 207, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solaraze® (diclofenac sodium) Gel, 3%.

This new drug application provides for the use of Solaraze® (diclofenac sodium) Gel for the treatment of actinic keratoses.

We have completed our review of this/these application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 31, 2007.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. 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 21-005/S-010**." 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.

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Jim Vidra

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