DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-005/S-007

Bioglan Pharmaceuticals, Inc.
Attn.: James M. Ciciriello
Director, Regulatory Affairs
7 Great Valley Parkway, Suite 301
Malvern, PA 19355

Dear Mr. Ciciriello:

Please refer to your supplemental new drug application dated February 13, 2003, received February 14, 2003, amended May 19, 2003 and November 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SOLARAZE® (diclofenac sodium) Gel, 3%.

We acknowledge receipt of your submission dated November 14, 2003.

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 labeling text.

The changes proposed in your amendment for the carton, container and package insert labeling of the 100 gram package size, dated May 19, 2003, are acceptable. The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels submitted May 19, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-005/S-007." Approval of this submission by FDA is not required before the labeling is used.

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, call Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp II, Ph.D.
Chemistry Team Leader
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V

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/

Wilson H. DeCamp
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approved