DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-005/S-009

Bioglan Pharma. Inc.
Attn.: Vivan Steel-Alberts
Director, Regulatory Affairs
7 Great Valley Parkway, Suite 301
Malvern, PA 19355

Dear Ms. Steel-Alberts:

Please refer to your supplemental new drug application dated March 22, 2004, received March 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solaraze™ (diclofenac sodium) Gel, 3%.

This supplemental new drug application provides for the addition of a 5g package size intended for use as a physician's sample presentation.

We completed our review of this application. This application is 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 immediate container and carton labels submitted March 24, 2004.

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 mount 15 of the copies individually on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-005/S-009." Approval of this submission by FDA is not required before the labeling is used.

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

Sincerely,

{See appended electronic signature page}

Norman R. Schmuff, Ph.D.
Acting Chemistry Team Leader for the
Division of Dermatologic & Dental
Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
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/

Norman Schmuff

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