DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-126/S-006

Bioglan Pharmaceuticals Company
Attention: James M. Ciciriello
Director, Regulatory Affairs
7 Great Valley Parkway, Suite 301
Malvern, Pennsylvania 19355

Dear Mr. Ciciriello:

Please refer to your supplemental new drug application dated October 23, 2001, received October 24, 2001submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zonalon (doxepin hydrochloride) Cream, 5%.

We acknowledge receipt of your submissions dated November 21(telefacsimile), December 18 (telefacsimile), 19 (telefacsimile), and 20 (one electronic mail and one telefacsimile), 2002.

This supplemental new drug application provides for a Geriatric Use subsection and revisions to the ADVERSE REACTIONS section. In addition, during review of this supplement, all other sections of the label were updated.

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. We note in your December 20, 2002, electronic mail that you commit to making the changes for the labeling components within 3 months. All products manufactured after this date will use the labeling per the approved supplement.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container, and carton labels) and must be formatted in accordance with the requirements of 21 CFR 201.66. 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-126/S-006." Approval of this submission 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 this product. 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 insert 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, HF-2
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 Jacquelyn Smith, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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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