DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-151/S-005

Berlex Laboratories, Inc.
Attention: Ms. Maria C. Garrigan
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Garrigan:

Please refer to your supplemental new drug application dated May 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betapace AF (sotalol hydrochloride) 40, 60, 80, 100, 120, and 160 mg Tablets.

We acknowledge receipt of your submissions dated September 29 and December 4, 2002 and March 18 and 20, 2003.

Your submission of December 4, 2002 constituted a complete response to our October 4, 2002 action letter.

This supplemental new drug application provides for new 40 mg and 60 mg strength tablets.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 4, 2002 (container labeling) and March 18, 2003 (package insert).

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 Cardio-Renal 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Melissa Robb
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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 Stockbridge
4/2/03 01:54:09 PM
On behalf of Douglas Throckmorton