NDA 21-151

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

Dear Ms. Garrigan:

Please refer to your new drug application dated June 18, 1998, received June 22, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BetapaceAF (sotalol hydrochloride) 80, 120, and 160 mg Tablets.

We acknowledge receipt of your submissions dated January 1 and February 7, 9, 17 and 22, 2000.

This application provides for the new indication of prolongation of time to recurrence of symptomatic AFIB/AFL in patients with symptomatic AFIB/AFL, with or without structural heart disease but in the absence of uncompensated congestive heart failure.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling. The immediate container and carton label must also be identical to those submitted on February 7, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded. Please note that distribution of physician's samples of Betapace AF in an outpatient setting is not consistent with the need for in-hospital initiation.

Please submit 20 copies of the final printed labeling as soon as it is available, in no case more that 30 days after it is printed. Individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-151." Approval of this submission by FDA is not required before the labeling is used.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632) (21 CFR 314.55 (or 601.27)). The Agency has not made a determination if a health benefit would be gained by studying sotalol in pediatric patients for the indication approved in this application. FDA is deferring submission of the pediatric assessments of safety and effectiveness that may be required under these regulations until additional data have been collected and reviewed.

FDA will inform you on or before two years from the date of this letter whether pediatric studies are required under the rule. If FDA determines at that time that pediatric studies are necessary, FDA will also set a specific time at which you must submit the required assessments.

We note that you have agreed to revise the educational program that you had developed so that all facets of the program will include the following key elements:

1. Clear description of the limitations to the indications (i.e., only those patients who are highly symptomatic).

2. Risks associated with Betapace AF (especially emphasizing that Betapace AF can cause serious ventricular arrhythmias).

3. Information on how to minimize this risk (i.e., Betapace AF dosing and treatment initiation information).

Please submit one market package of the drug product when it is available.

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 contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research