CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
19-865/S-010

Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-865/S-010

OCT - 1 2001

Berlex
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 October 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betapace (sotalol hydrochloride) 80, 120, 160 and 240 mg Tablets.

We acknowledge receipt of your submissions dated February 16 and June 27, 2001. Your submission of June 27, 2001 constituted a complete response to our January 30, 2001 action letter.

This supplemental new drug application provides for revised labeling to include information from pediatric studies in the Clinical Pharmacology, Precautions, Adverse Reactions and Dosage and Administration sections.
In addition, we note the following changes:

1. In the Black Box, the sentence, "Calculations of creatinine clearance should be calculated prior to dosing." has been changed to, "Creatinine clearance should be calculated prior to dosing."

2. Under the CLINICAL PHARMACOLOGY/Mechanism of Action, the phrase, "slows AV nodal conduction," in the second sentence, has been changed to, "decreases AV nodal conduction."

3. Under the HOW SUPPLIED section, the sentence, "Store at 25°C with excursions permitted between 15°-30°C" has been changed to "Store at 25°C (77°F) with excursion permitted between 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

We have completed the review of this supplemental 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 submitted final printed package insert included in your June 27, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to

use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely, /S/ 10/1/01

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
19-865/S-010

Approvable Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDAs 19-865/S-010
21-151

Berlex
Attention: Ms. Maria C. Garrigan
340 Changebridge Road
P.O. Box 1000
Montville, NJ 0745-1000

Dear Ms. Garrigan:

Please refer to your supplemental new drug application dated October 19, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betapace (sotalol hydrochloride) 80, 120, 160 and 240 mg Tablets.

We acknowledge receipt of your submissions dated May 22 and August 9, 2000 and January 5, 2001.

This supplemental new drug application provides for revised draft labeling to include information from pediatric studies in the Clinical Pharmacology, Precautions, Adverse Reactions and Dosage and Administration sections.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed labeling (text for the package insert).

Please submit a supplement with final printed labeling with the same changes as in this supplement to the Betapace AF application (NDA 21-151).

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

Please submit 20 paper copies of the final printed labeling ten of which are individually mounted on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999).

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes prior to approval of this supplemental application.

If you have any questions, call

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

Sincerely,

/S/

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

20 pages redacted from this section of the approval package consisted of draft labeling