DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-716/S-023

Prometheus Laboratories Inc.
Attention: Marilyn R. Carlson, D.M.D, M.D.
5739 Pacific Center Blvd.
San Diego, CA, 92121

Dear Dr. Carlson:

Please refer to your supplemental new drug application dated December 23, 2002, received December 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trandate (labetalol hydrochloride) Tablets, 100 mg, 200 mg and 300 mg.

We acknowledge receipt of your submission dated January 31, 2003.

This supplemental new drug application provides for the manufacturing, packaging and testing of Trandate tablets at the (b)(4)----------

We have completed the review of this supplemental application, and it is approved.

Please provide final printed labeling for Trandate identical to the submitted draft labeling in your next annual report.

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

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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