CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19002/S002

APPROVABLE LETTER

20-1

NDA 19-002/S-002

MAY 12 1994

The R.W. Johnson Pharmaceutical
Research Institute
Attention: Gary P. Horowitz, Ph.D
Walsh and McKean Roads
Spring House, PA 19477-0776

Dear Dr. Horowitz:

Please refer to your March 18, 1992 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for VASCOR (bepridil hydrochloride) Tablets.

We also acknowledge receipt of your amendment dated March 14, 1994.

The supplemental application provides for the revised protocol to monitor the stability of marketed VASCOR (bepridil hydrochloride) Tablets according to FDA's "Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics" issued February 1987, and 21 CFR 314.80 and 314.81.

We have completed the review of this supplemental application, and it is approved with storage conditions of 25°C ± 2°C at a relative humidity, RH, of 50% ± 10% with the intent of increasing the RH to 60% ± 5% by 1995.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

y Wem

/S/ 5/12/94

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-002/S-002

SEP 8 1992

The R.W. Johnson Pharmaceutical
Research Institute
Division of McNeil Lab., Inc.
Attention: Gary P. Horowitz, Ph.D.
Walsh & McKean Roads
Spring House, PA 19477-0776

Dear Dr. Horowitz:

Please refer to your March 18, 1992 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for VASCOR (bepridil hydrochloride) Tablets.

The supplemental application provides for a revised protocol to monitor the stability of marketed VASCOR (bepridil hydrochloride) Tablets according to FDA's "Guildeline for Submitted Documentation for the Stability of Human Drugs and Biologics" issued February 1987.

We have completed the review of this supplemental application and it is approvable if the storage conditions are changed from [ ] at the ambient relative humidity to 25°C ± 2°C at a specific relative humidity to be stated (We are considering a value of NLT 60% ± 5% RH).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research