DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-152 /S-030

Abbott Laboratories
Attention: Todd Chermak R.Ph.
200 Abbott Park Road, D-491/Bldg., AP30-1E,
Abbott Park, IL 60064-6157

Dear Mr. Chermak:

Please refer to your supplemental new drug applications dated July 25, 2002, received July 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isoptin SR (verapamil hydrochloride) Tablets, 120 mg, 180mg, and 240mg.

This supplemental new drug application provides for changes to the chemistry, manufacturing and controls for Verapamil HCL drug substance, including mo(b)----------
(b)----------

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

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 Denise Hinton, Regulatory Health Project Manager, at (301) 594-5312.

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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