DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 9-330/S-021

SmithKline Beccham Corporation d/b/a GlaxoSmithKline
Attention: Kim M. Tyndall
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Tyndall:

Please refer to your supplemental new drug application dated April 19, 2002, received April 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lanoxin (digoxin) Injection 0.25 mg/mL.

We acknowledge receipt of your submissions dated May 16, May 30, and June 13, 2002.

This supplemental new drug application provides for: 1) an alternate manufacturing, packaging and testing site (Draxis Pharma Inc., Kirkland, Quebec, Canada) with related process changes, 2) an alternate HPLC testing method for digoxin identification and content, and 3) an alternate kinetic bacterial endotoxin test method.

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

We remind you that a 24 month expiration date will apply to your drug product manufactured at your new facility and that final printed labeling (FPL) incorporating appropriate revisions relating to this site change should be submitted 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 Edward Fromm, Regulatory 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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