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APPLICATION NUMBER:

50-720/S-001

APPROVAL LETTER

50-720/S-001

MAY 15 1996

Peter J. Kitz
Director, U.S. Regulatory Affairs
Smithkline Beecham Pharmaceuticals
1250 S. Collegeville Road
Collegeville, Pennsylvania 19426-0989

Dear Mr. Kitz:

Reference is made to your supplemental New Drug Application (NDA) dated March 27, 1996, submitted pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act for Augmentin (amoxicillin/clavulanate potassium) 875/125mg Tablets.

The supplemental application provides for re-instating [redacted] facility for the [redacted]

We have completed our review and the supplemental application is approved effective as the date of this letter.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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

Sincerely yours,

/S/ 5/15/96

Suva B. Roy, Ph.D.
Team Leader, DNDC III
Division of Anti-infective Drug Products (HFD-520)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research