DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-010

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Kevin A. Miller, R.Ph., RAC
Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Miller:

Please refer to your supplemental new drug application dated May 19, 2006, received May 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relenza® (zanamivir for inhalation).

This "Changes Being Effected in 30 days" supplemental new drug application provides for GlaxoSmithKline's site in Jurong, Singapore as an alternate manufacturing and quality control testing site for the (b) (4) zanamivir drug substance.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Valerie Jimenez, MS, Senior Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

11/22/2006 09:02:46 AM