DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-015

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Brenda E. Shafiei
Assistant Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Ms. Shafiei:

Please refer to your supplemental new drug application dated August 14, 2007, received August 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relenza® (zanamivir for inhalation).

We acknowledge your submission dated December 11, 2007 withdrawing the (b) (4) Protocol.

This supplemental application proposes registration of (b) (4) site for lactose (b) (4). We completed our review of this supplemental new drug application. This supplement, as amended, 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

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/s/

Hasmukh Patel

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