DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-014

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Leo J. Lucisano, R.Ph.
Regional Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Mr. Lucsiano:

Please refer to your supplemental new drug application dated December 21, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relenza® (zanamivir for inhalation).

We acknowledge receipt of your submissions dated February 28 and May 4, 2007.

This supplemental application proposes GlaxoSmithKline, Zebulon, NC, as a US-based manufacturing, packaging, and testing site for Relenza®.

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

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/s/

Hasmukh Patel
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