DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-018

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Leo J. Lucisano
Regional Director, CMC Regulatory Affairs

Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated May 4, 2009, received May 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relenza® (zanamivir) Inhalation Powder.

We acknowledge receipt of your submission dated May 8, 2009.

This supplemental new drug application provides for extending the shelf life of Relenza from 5 to 7 years.

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

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 Althea Cuff, Regulatory Project Manager, at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

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

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/s/

Eric Duffy

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