DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036 S-106

GlaxoSmithKline
Attention: Sherman Alfors
Director, Antiviral/Antibacterial Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated February 4, 2008, received February 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA (zanamivir) Inhalation Powder.

We acknowledge receipt of your submissions dated February 13, 2008 and February 14, 2008.

This supplemental new drug application provides for neuropsychiatric labeling revisions to the WARNINGS and PRECAUTIONS section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.
The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

We remind you, as agreed, to prepare a Dear Healthcare Provider letter to be sent out within 2 weeks of the approved labeling.

If you have any questions, call Jaewon Hong, PharmD, Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Debra Birnkrant
2/21/2008 11:46:47 AM
NDA 21-036