DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21036/S-024 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
Attention: Sherman N. Alfors
Director, Antiviral/Antibacterial
US Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated and received April 15, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA (zanamivir) Inhalation Powder.

This "Changes Being Effected" supplemental new drug application provides for the revised Rotadisk printmat label requested during a March 23, 2010 teleconference between FDA and GSK.

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 Elizabeth Thompson, Regulatory Project Manager, at (301) 796-0824.

Sincerely,

{See appended electronic signature page}

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

Enclosure: approved printmat label

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21036	SUPPL-24	GLAXOSMITHKLINE	RELENZA (ZANAMIVIR) INHALATION 5 MG POWD

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/s/

HASMUKH B PATEL
05/04/2010