DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-036/S-019 **SUPPLEMENT APPROVAL**

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

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated and received September 24, 2009, submitted under section 505 (b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Relenza (Zanamivir) Inhalation Powder, for oral inhalation.

This "Changes Being Effected" supplemental new drug application was submitted to include serious skin reactions to the Postmarketing Experience section of the package insert and to update the package insert and package labeling to include the August 5, 2009, recommendations from the Division of Antiviral Products and the Division of Medication Error Prevention and Analysis. Specifically, to clearly express the total product strength and the drug contents per blister to avoid medication errors, as described below:

Package Insert

"Blister for oral inhalation: 5 mg" was added to the Dosage Form and Strength section

Carton Labeling

RELENZA
(ZANAMIVIR) INHALATION POWDER
20 mg per Rotadisk
(5 mg per blister)

Container (Tube) Label

RELENZA
(ZANAMIVIR) INHALATION POWDER
20 mg per Rotadisk (5 mg per blister)
5 Rotadisk each containing 4 blisters

Overwrap Labeling

RELENZA
(ZANAMIVIR) INHALATION
20 mg per Rotadisk
(5 mg per blister)

We acknowledge receipt of your submission dated March 8, 2010, which consists of a final version of the package insert and patient package insert and the Rotadisk label. We also refer to the March 23, 2010, telephone conversation between representatives of GlaxoSmithKline and the Division Antiviral Products and the Division of Medication Error Prevention and Analysis during which the Rotadisk label was discussed. During this telephone conversation you agreed to submit a "Changes Being Effected" supplemental new drug application to remove the "5 mg x 4" statement and revise the Rotadisk label to read as follows:

Rotadisk Label

GlaxoSmithKline
Relenza (zanamivir)
20 mg per Rotadisk
(5 mg per blister)

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on September 24, 2009. This approval does not include the Rotadisk label.

CONTENT OF LABELING

We note that your September 24, 2009, submission includes final printed labeling (FPL) for your package insert and patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your September 24, 2009, submission containing final printed carton and container labels.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Victoria Tyson at (301) 796-0827.

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

Enclosures
Content of Labeling
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21036	SUPPL-19	GLAXOSMITHKLINE	RELENZA (ZANAMIVIR) INHALATION 5 MG POWD

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

/s/

VICTORIA L TYSON
03/24/2010

DEBRA B BIRNKRANT
03/24/2010