DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-012

GlaxoSmithKline
Attn: Sherman N. Alfors, US Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated August 7, 2006, received August 8, 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 October 2, 2006, February 13, 2007, and June 12, 2007.

This supplemental new drug application provides for inclusion of statements regarding the concurrent use of Influenza Virus Vaccine Live, Intranasal in the PRECAUTIONS section and the implementation of a new labeling format, as required by the Physician's Labeling Rule.

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 and with the minor editorial revisions listed below and indicated in the enclosed labeling.

Revisions

- Inclusion of the following text to the proprietary and nonproprietary name, dosage form, and route of administration line in the Highlights section of the label:

  Relenza (zanamivir) inhalation powder, for oral inhalation

- Modification and addition of statements under Mechanism of Action (see Clinical Pharmacology, 12.1 and 12.4)

- Replaced "mutation" with "substitution" under Resistance (see Clinical Pharmacology, 12.4)

- Deletion of the "date of issue" under the Manufacturer Contact Information of the package insert.

- Inclusion of the following text under "Can I take other medications with Relenza?" of the Patient Package Insert:

Before taking Relenza, please let your healthcare provider know if you received live attenuated influenza vaccine (FluMist®) intranasal in the past two weeks.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-036/S-012."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, text for the patient package insert). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-036/S-012**." Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 David Araojo, Pharm.D., Regulatory Project Manager, at (301) 796-0669.

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/

Jeffrey Murray

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