DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21036/S-030

SUPPLEMENT APPROVAL

Glaxo Smith Kline
Attention: Leslie Driver, PharmD
Director, Global Regulatory Affairs
Five Moore Drive
PO Box 13398 Mailstop 5.5B
Research Triangle, NC 27709-3398

Dear Dr. Driver:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 21, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RELENZA (zanamivir inhalation powder).

This Prior Approval supplemental new drug application provides for the following revisions to the US Prescribing Information (PI):

- DRUG INTERACTIONS (Section 7) and Pharmacokinetics (Subsection 12.3) were updated to align with the currently available information
- USE IN SPECIFIC POPULATIONS (Section 8) was revised in accordance with the Pregnancy and Lactation Labeling Rule (PLLR)
- OVERDOSAGE (Section 10) was revised with updated information
- Microbiology (Subsection 12.4) was updated to incorporate FDA Requests regarding addition of associated hemagglutinin (HA) and neuraminidase (NA) substitutions associated with reduced susceptibility
- NONCLINICAL TOXICOLOGY (Subsection 13.1) Impairment of Fertility was updated
- PATIENT COUNSELING INFORMATION section was revised to include addition of a Missed Dose subsection
- Several sections of the PI, Patient Information, and Instructions for Use were revised for consistency with other approved product labeling and to conform to the current best labeling practices

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, Patient Information and Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 CAPT Anitra Johnson, DHSc, MSN, RN, Regulatory Project Manager, at (301) 796-4876.

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(S):
Content of Labeling

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

/s/

DEBRA B BIRNKRANT
06/21/2018