DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-036 / S-007

GlaxoSmithKline
Attn: Brenda E. Shafiei
Senior Project Manager
CMC Regulatory Affairs
Five Moore Drive
Research Triangle Park
North Carolina, 27709-3398

Dear Ms. Shafiei:

Please refer to your supplemental new drug application dated September 26, 2003, received September 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA® (zanamivir) Powder for Inhalation, 5 mg/blister.

This "Changes Being Effected" supplemental new drug application provides for addition of bacterial endotoxin testing to the specification of an excipient.

We completed our review of this supplemental new drug application. This supplement is approved.

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

If you have any questions, call Donald Reese, PharmD, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Paul Miller
3/25/04 04:47:01 PM
NDA 21-036 / S-007 is approved