



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-036/S-013

GlaxoSmithKline
Attention: Sherman Alfors
Director, Antiviral/Antibacterial Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated September 15, 2006, received September 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA® (zanamivir for inhalation).

We acknowledge receipt of your submission dated February 8, 2007.

This supplemental new drug application provides for US Department of Health and Human Services and US Department of Defense stockpile drug product package labeling distinct from that of regular use package labeling.

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.

The final printed labeling (FPL) must be identical to the immediate container and carton labels submitted February 8, 2007.

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).

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If you have any questions, call David Araujo, 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

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

/s/

Debra Birnkrant
3/9/2007 08:49:25 AM
NDA 21-036