



NDA 21-036/S-005

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

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated December 18, 2002, received December 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA® (zanamivir) for oral inhalation.

We acknowledge receipt of your submissions dated April 11, 2003 and May 9, 2003.

This supplemental new drug application provides a revision in the INDICATIONS AND USAGE section of the package insert to recommend that RELENZA® (zanamivir) not be used in patients with underlying airways disease.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
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  
8/5/03 10:17:40 AM  
NDA 21-036