



NDA 21-036/S-006

GlaxoSmithKline  
Attention: 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 Labeling Supplement-Changes Being Effected, dated March 19, 2003, received March 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELENZA<sup>®</sup> (zanamivir) oral for inhalation.

We acknowledge receipt of your submissions dated April 29, 2003 and June 27, 2003.

This Labeling Supplement-Changes Being Effected includes updating the DESCRIPTION section of the package insert to reflect the presence of milk proteins and the CONTRAINDICATIONS section has also been updated to add a reference to the DESCRIPTION section to alert prescribers to the milk protein component of lactose. In addition, this label supplement added information in the Patient Instruction Leaflet concerning the presence of milk proteins in the lactose vehicle.

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 products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

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

If you have any questions, please contact 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 4  
Center for Drug Evaluation and Research

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/s/

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Debra Birnkrant  
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