

021205\_S002

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package**

***APPLICATION NUMBER:***

**21-205/S-002**

***Trade Name:*** Trizivir

***Generic Name:*** (Abacavir, Sulfate, Lamivudine, and Zidovudine)

***Sponsor:*** GlaxoWellcome, Inc.

***Approval Date:*** February 2, 2002

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*APPLICATION NUMBER:*

**21-205/S-002**

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### **Reviews / Information Included in this NDA Review.**

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter</b>	
<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	
<b>EA/FONSI</b>	
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	
<b>Microbiology Review(s)</b>	<b>X</b>
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*APPLICATION NUMBER:*

**21-205/S-002**

**APPROVAL LETTER**



NDA 21-205/S-002

GlaxoSmithKline  
Attention: Martha Anne A. Moore, R.Ph.  
Product Director – Antiviral/Anti-Infective Regulatory Affairs  
Five Moore Drive  
P.O. Box 13398  
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug application dated April 6, 2001 (S-002), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trizivir® (abacavir sulfate, lamivudine, and zidovudine) Tablets.

We acknowledge receipt of your submission dated May 3, 2001.

The purpose of this submission is to incorporate appropriate changes into the Trizivir Tablets labeling that have recently been made for Ziagen and Retrovir products. This includes the following:

- Results from studies CNAAB3005 and CNA1012 incorporated into the product labeling for Ziagen Tablets and Oral Solution that was approved by the Division of Antiviral Drug Products on December 15, 2001.
- General updates to the Retrovir products' labeling which include incorporation of statements from **PRECAUTIONS**, Patient Information, Drug Interactions regarding the concomitant use of doxorubicin, ribavirin and stavudine that was approved by the Division of Antiviral Drug Products on March 30, 2001.

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 submitted final printed labeling (package insert and patient package insert submitted May 3, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

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Food and Drug Administration  
Rockville MD 20857

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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, call Karen A. Young, RN, Regulatory Project Manager, at (301) 827-2335.

Sincerely yours,

*{See appended electronic signature page}*

Debra B. Birnkrant  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Attachment: Final Printed Labeling dated May 3, 2001

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

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Debra Birnkrant  
2/5/02 04:40:38 PM  
NDA 21-205 SE8 002

**APPEARS THIS WAY  
ON ORIGINAL**