



NDA 22-011/S-002

Novartis Pharmaceuticals Corporation
Attention: Michael S. Buska
Director Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Buska:

Please refer to your supplemental new drug application dated April 27, 2009, received April 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TYZEKA® (telbivudine) 600 mg tablet.

This supplemental new drug application updates the TYZEKA® (telbivudine) tablet package insert and Medication Guide to include information approved on April 28, 2009 for the oral solution.

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.

LABELING

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and Medication Guide).

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved product.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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

If you have any questions, call Kenny Shade, Senior Regulatory Health Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: PPI and MedGuide

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

/s/

Kendall Marcus
5/8/2009 02:53:25 PM