DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-011/S-011
NDA 22-154/S-008

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Novartis Pharmaceuticals Corporation
Attention: Ilham Benassou
Manager, Regulatory Affairs
One Health Plaza
East Hanover, NJ 07856-1080

Dear Ms. Benassou:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tyzeka® (telbivudine) 600 mg Tablets and 100 mg/5mL Oral Solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 29, 2010.

These supplemental new drug applications provide for proposed elimination of the requirement for the approved REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Tyzeka® (telbivudine) Tablets and for Tyzeka® (telbivudine) Oral Solution were originally approved on January 23, 2009 and April 28, 2009 respectively, and the most recent REMS modification was approved on September 10, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Tyzeka® (telbivudine) Tablets and Oral Solution.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefit of Tyzeka® (telbivudine) Tablets and Oral Solution outweigh their risks. Therefore, we agree with your proposal, and a REMS for Tyzeka® (telbivudine) Tablets and Oral Solution is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Stacey Min, Pharm.D., Regulatory Project Manager, at (301) 796-4253.

Sincerely,

{See appended electronic signature page}

/Kendall Marcus, M.D/
for 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/

KENDALL A MARCUS
05/05/2011