DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-011\S-001
Novartis Pharmaceuticals Corporation
Attention: Michael Buska
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Buska:

Please refer to your supplemental new drug application(s) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TYZEKA (telbivudine) 600 mg tablet.

We also refer to the approval letter issued January 23, 2009 for NDA 22-011/S-001. The final draft of the REMS you submitted January 21, 2009 was not attached to the approval letter. Please find the REMS attached to this coorespondence.

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

Sincerely,

{See appended electronic signature page}

Kenny Shade, JD, BSN
Regulatory Health Project Manager
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Tyzeka® (telbivudine)

NDA 22-011

Risk Evaluation and Mitigation Strategy (REMS)

Author(s):	Ortega H, Mayer H, Avila C, Zeldin G, Buska M
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I. Goals

The goals of the Tyzeka REMS are:

1. To increase patient awareness of the potential for peripheral neuropathy to occur with Tyzeka treatment.
2. To raise patient awareness of the increased risk of developing peripheral neuropathy when Tyzeka is used in combination with pegylated interferon alfa-2a or other interferons.

II. REMS Elements

A. Medication Guide

Novartis has developed a medication guide to be distributed to patients taking Tyzeka.

Novartis will include a medication guide with each Tyzeka finished package. Medication guides will be included in each carton containing a bottle of Tyzeka; there will be instructions on the carton and container label to the pharmacist instructing that the medication guide be distributed with the dispensed product.

Novartis will conduct patient surveys to confirm distribution and understanding of the medication guide.

The Medication Guide is appended to the REMS.

B. Communication Plan

The REMS for Tyzeka does not include a specific Communication Plan.

C. Elements Regarding Safe Use

The REMS for Tyzeka does not include elements to assure safe use.

D. Implementation System

Because the REMS for Tyzeka (telbivudine) does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The Tyzeka REMS will be evaluated periodically with formal assessments as described in Table 1.

Table 1 Timetable for REMS Assessments

1st Assessment	July 2010	18 months post-approval
2nd Assessment	January 2012	3 years post-approval
3rd Assessment	January 2016	7 years post-approval