



NDA 022011/S-022
NDA 022154/S-019

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Dakshina Reddy
Global Program Regulatory Director
One Health Plaza
East Hanover, NJ 07936

Dear Ms. Reddy:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on June 29, 2018, and to your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TYZEKA[®] (telbivudine) 600 mg tablets (NDA 022011) and TYZEKA[®] (telbivudine) 100 mg/5 mL, oral solution (NDA 022154).

These Prior Approval supplemental new drug applications provide for the following updates to the US Prescribing Information:

- **USE IN SPECIFIC POPULATIONS, *Pregnancy and the Lactation subsections*:** Updated to conform to the Pregnancy and Lactation Labeling Rule (PLLR)
- **DRUG ABUSE AND DEPENDENCE:** Section was removed, per current labeling practices. This section is reserved for drugs controlled by DEA that have potential for abuse or dependence
- **NONCLINICAL TOXICOLOGY:** Information was added to clarify that both male and female rats were included in a nonclinical fertility study
- **PATIENT COUNSELING INFORMATION:** Information was revised per current best labeling practices and the Guidance for Industry on Patient Counseling Information
- **MEDICATION GUIDE:** Updated for consistency with the information updates made to the prescribing information.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Suzanne Strayhorn, Regulatory Project Manager, at (240) 402-4247.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

Content of Labeling
Prescribing Information
Medication Guide
Instructions for Use

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
12/27/2018 04:20:33 PM
on behalf of Debra Birnkrant