DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022011/S-021
NDA 022154/S-018

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Bijal Pandhi, Pharm.D.
Senior Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936

Dear Dr. Pandhi:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on March 22, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TYZEKA® (telbivudine) tablets, 600 mg (NDA 022011) and TYZEKA® (telbivudine) oral solution, 100 mg/5 mL (NDA 022154).

These Prior Approval supplemental new drug applications provide for updates to the existing information related to the lactic acidosis and rhabdomyolysis in the Warnings and Precautions section, and removal of information related to lactic acidosis/severe hepatomegaly with steatosis from the Boxed Warning of the US Prescribing Information (USPI), based on the available post-marketing data as well as to be consistent with current information for this drug class. The Medication Guide was updated to reflect changes made to the USPI. The formatting for the Instructions for Use was updated without any changes to content.

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.

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 package insert, text for the Medication Guide, text for the Instructions for Use), 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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

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

/s/

POONAM MISHRA
03/28/2018
on behalf of Debra Birnkrant, MD