

NDA 205834/S-031
NDA 212477/S-001

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Hilary White
Associate II, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. White:

Please refer to your supplemental new drug applications (sNDAs), dated and received on March 19, 2019 for HARVONI® (ledipasvir and sofosbuvir) tablets, 90 mg/400 mg and 45 mg/200 mg and September 5, 2019, for HARVONI® (ledipasvir and sofosbuvir) oral pellets, 33.75 mg/150 mg and 45 mg/200 mg, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

These Prior Approval supplemental new drug applications provide for an update to the DRUG INTERACTIONS section, 7.2 subsection with information regarding the risk of dysglycemia in patients with diabetes who received direct-acting antiviral drugs for the treatment of chronic hepatitis C virus infection.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert), with the addition of any labeling

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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 *SPL Standard for Content of Labeling Technical Qs and As*.²

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(I)(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 Kyong Hyon, Safety Regulatory Project Manager, at 301-796-0734.

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(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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
09/19/2019 11:55:28 AM
on behalf of Debra Birnkrant