DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203093 S-2

**SUPPLEMENT APPROVAL**

Gilead Sciences, Inc.
Attention: Christophe Beraud, Ph.D.
Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Beraud:

Please refer to your Supplemental New Drug Application (sNDA) dated January 28, 2015, received January 28, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VITEKTA® (elvitegravir), tablet, 85 mg and 150 mg.

We acknowledge receipt of your amendments dated June 22, 2015 and July 15, 2015.

This "Prior Approval" supplemental new drug application proposes to update the labeling with the following information:

- To update the DRUG INTERACTIONS section with information related to buprenorphine/norbuprenorphine, naloxone, and methadone.
- To update the CLINICAL PHARMACOLOGY, Drug Interaction Studies subsection, with information on cobicistat.
- To update the CLINICAL PHARMACOLOGY, Pharmacokinetics subsection, with information on carbamazepine, buprenorphine, norbuphrenorphine, and naloxone.
- To update the PATIENT INFORMATION section titled "What should I tell my healthcare provider before taking VITEKTA?" with information regarding use with buprenorphine/naloxone.
- To delete telaprevir information from the labeling because it is no longer marketed or distributed in the United States.

## APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 and text for the patient package insert 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 includes 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).

## PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

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

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/s/

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POONAM MISHRA
07/27/2015