DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203093

NDA APPROVAL

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

Dear Dr. Beraud:

Please refer to your New Drug Application (NDA) dated and received June 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VITEKTA® (elvitegravir), 85 and 150 mg Tablets.

We acknowledge receipt of your amendments dated:

July 3, 2012	December 6, 2012	March 11, 2013	March 4, 2014
August 6, 2012	December 20, 2012	March 26, 2013	April 4, 2014
August 27, 2012	January 8, 2013	March 29, 2013	April 9, 2014
September 13, 2012	January 10, 2013	April 2, 2013	April 25, 2014
September 27, 2012	January 15, 2013	April 10, 2013	May 12, 2014 (x2)
October 4, 2012	January 23, 2013	April 18, 2013	May 13, 2014
October 16, 2012	January 29, 2013	April 22, 2013	August 27, 2014
October 18, 2012	February 1, 2013	April 24, 2014	September 12, 2014
October 25, 2012	February 18, 2013	August 13, 2013	September 16, 2014
November 5, 2012	March 1, 2013	September 30, 2013	September 22, 2014
November 9, 2012	March 4, 2013	December 13, 2013	
November 13, 2012	March 8, 2013	January 29, 2014	

The April 4, 2014, submission constituted a complete response to our April 26, 2013, action letter.

We also acknowledge receipt of information related to VITEKTA® (elvitegravir), 85 and 150 mg tablets for your Gilead Access Program that was reviewed as part of this application.

This new drug application provides for the use of VITEKTA® (elvitegravir), in combination with an HIV protease inhibitor coadministered with ritonavir and other antiretroviral drugs, for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults.

We have completed our review of this 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). 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*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate-container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 203093**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Myung-Joo Patricia Hong
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6235
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 4 weeks because necessary studies are impossible or highly impracticable as few patients in this age group will have need of a regimen intended for treatment-experienced patients and the co-administered protease inhibitors are not approved in this age group.

We are deferring submission of your pediatric study for ages 4 weeks to less than 18 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. This required study is listed below.

2030-1 Evaluate the pediatric pharmacokinetics (PK), safety, and antiviral activity of once daily elvitegravir combined with a background regimen including a protease inhibitor coadministered with ritonavir in HIV-1 treatment-experienced pediatric subjects from 4 weeks to less than 18 years of age. Initial evaluation of elvitegravir exposure (when combined with a protease inhibitor and ritonavir) must be performed to allow dose selection to be agreed upon with the FDA. Evaluation of longer term treatment with elvitegravir, plus background regimen including protease inhibitor and ritonavir, must assess treatment response on the basis of HIV-1 RNA virologic response and conduct safety monitoring over at least 24 weeks of dosing.

Protocol Submission:	05/16/2013
Trial Completion:	04/30/2017
Final Report Submission:	01/15/2018

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

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

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Myung-Joo Patricia Hong, Regulatory Project Manager, at (301) 796-0807.

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

Enclosures:
Content of Labeling
Container Labels

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

/s/

DEBRA B BIRNKRANT
09/24/2014