CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202123Orig1s000

Trade Name: COMPLERA™

Generic Name: emtricitabine/rilpivirine/tenofovir disoproxil fumarate

Sponsor: Gilead Sciences, Inc.

Approval Date: 08/10/2011

Indications:

COMPLERA, a combination of 2 nucleoside analog HIV-1 reverse transcriptase inhibitors (emtricitabine and tenofovir disoproxil fumarate) and 1 non-nucleoside reverse transcriptase inhibitor (rilpivirine), is indicated for use as a complete regimen for the treatment of HIV-1 infection in treatment-naive adults.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202123

NDA APPROVAL

Gilead Sciences, Inc
Attention: Shalini Gidwani, M.Sc. RAC
Associate Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Gidwani

Please refer to your New Drug Application (NDA) dated and received February 10, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COMPLERA™ (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) 200 mg/25 mg /300 mg fixed dose combination tablets.

We acknowledge receipt of your amendments dated:

September 3, 2010
October 19, 2010
November 5, 2010
November 23, 2010
November 30, 2010
December 3, 2010
December 10, 2010
December 20, 2010
December 22, 2010
February 10, 2011
February 14, 2011
March 9, 2011
May 2, 2011
May 13, 2011
May 18, 2011
May 19, 2011
May 20, 2011
May 27, 2011
May 31, 2011
June 2, 2011
June 3, 2011
June 10, 2011
June 21, 2011
June 23, 2011
June 24, 2011
July 7, 2011,
July 8, 2011
July 13, 2011
July 15, 2011
July 18, 2011
July 25, 2011
July 29, 2011
August 3, 2011
August 4, 2011.

We also acknowledge receipt of your information related to emtricitabine/rilpivirine/tenofovir disoproxil fumarate, 200 mg/25 mg/300 mg fixed dose combination tablets for your Gilead Access Program that was included in this application.

This new drug application provides for the use of COMPLERA™ (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) fixed dose combination tablets as a complete regimen for the treatment of HIV-1 infection in treatment-naïve adult patients.

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.

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 package insert and text for the patient package insert). 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/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 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 titled "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 202123**." 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.

If sending via USPS, please send to:

Linda C. Onaga, MPH
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6321
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Linda C. Onaga, MPH
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6321
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

1809-1 Collect dissolution profile data from all full-scale batches manufactured during the first year after approval date. The collection of the dissolution data will target the dissolution specifications recommended by the FDA and will include dissolution testing at Stage 1, 2, or 3 as appropriate. Submit the final dissolution report with complete dissolution information/data, a proposal for final dissolution specifications, and data analysis with the number/percentage of batches tested at Stage 1, 2, or 3 or which failed the dissolution specifications recommended by FDA.

The timetable you submitted on July 29, 2011 states that you will conduct this study according to the following schedule:

Study/Trial Completion: August 2012
Final Report Submission: November 2012

Submit clinical protocols to your IND 106,252 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

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
Division of Drug Marketing, Advertising, and Communications
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. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), 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 Linda C. Onaga, MPH, Regulatory Project Manager, at (301) 796-0759.

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
Container Label

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

08/10/2011

I am in agreement with the conclusions of the reviewers of this application.