CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022577Orig1s000

Trade Name: Viread Oral Powder

Generic Name: Tenofovir Disoproxil Fumarate

Sponsor: Gilead Sciences, Inc.

Approval Date: 01/18/2012

Indications: For the Treatment of HIV-1 Infection in Adults and Pediatric Patients 2 Years of Age and Older.

For the Treatment of Chronic Hepatitis B in Adults.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22577

NDA APPROVAL

Gilead Sciences, Incorporated
Attention: Dara Wambach, M.A.
Associate Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Wambach:

Please refer to your New Drug Application (NDA) dated June 16, 2011, received July 18, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viread® (tenofovir disoproxil fumarate) oral powder, 40 mg/gram.

We acknowledge receipt of your amendments dated:

June 16, 2011	September 29, 2011	December 8, 2011
June 29, 2011	September 30, 2011	December 12, 2011
July 18, 2011	October 10, 2011	December 22, 2011
August 19, 2011	October 11, 2011	December 23, 2011
August 26, 2011	October 12, 2011	January 6, 2012
September 13, 2011	November 3, 2011	January 11, 2012
September 27, 2011	November 23, 2011	January 13, 2012

The NDA provides for the use of Viread® (tenofovir disoproxil fumarate) oral powder in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients 2 years of age and older.

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 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 22577**." Approval of this submission by FDA is not required before the labeling is used.

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

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric study for ages 0 to 2 years for NDA 22577 because the studies in older pediatric patients have now been completed and are ready for approval. Studies of tenofovir DF in this age group were previously deferred until after the review of safety was completed in patients 2 years of age and older.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act 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 Federal Food, Drug, and Cosmetic Act. This required study is listed below.

We reference the partial deferral granted in the March 8, 2006 approval letter for NDA 21356 S-016:

212-2 Deferred pediatric study under PREA for the use of Viread® treatment, in combination with other antiretroviral agents, of HIV-1 in pediatric patients ages birth to 2 years of age. Due to safety concerns for this age group, we are waiting for completion and review of studies in the 2 to 18 years age group before determining whether it is appropriate to study tenofovir in the birth to 2 years age

group. Should further pediatric studies in this age group be required, the timeline for completion is as follows:

Final Report Submission: 01/2010

Submit the protocol to your IND 52,849, with a cross-reference letter to this NDA.

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.

This product is appropriately labeled for use in ages 12 to less than 18 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 2 to less than 18 years for this application.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

1865-1 During the filling of one commercial full-scale Viread oral powder lot, execute a stratified sampling plan to determine the potency of the powder blend and verify that potency variation does not occur due to segregation. Include individual measurements of strength from at least one single scoop sample per container for containers spanning the full packaging run. Include both individual values and statistical analysis of the data in the study report.

The timetable you submitted on January 17, 2012, states that you will conduct this study according to the following schedule:

Study Completion: 12/2012
Final Report Submission: 01/2013

1865-2 Submit data from a simulated in-use study of strength per scoop where a bottle is exhaustively sampled one scoop at a time. Use a bottle subjected to appropriate simulated shipping conditions so that it is representative of a bottle obtained by a patient. Include data from each scoop sampled and appropriate statistical analysis in the study report.

The timetable you submitted on January 17, 2012, states that you will conduct this study according to the following schedule:

Study Completion:	12/2012
Final Report Submission:	01/2013

Submit nonclinical and chemistry, manufacturing, and controls protocols and all 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
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. For instruction on completing the Form FDA 2253, see page 2 of the Form. 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 Katherine Schumann, Regulatory Project Manager, at (301) 796-1182.

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
Carton and Container Labeling

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

/s/

JEFFREY S MURRAY
01/18/2012