CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202123Orig1s000

CROSS DISCIPLINE TEAM LEADER REVIEW

CROSS DISCIPLINE TEAM LEADER ADDENDUM

Date	August 8, 2011
From	Sarah Robertson, Pharm.D.
Subject	Cross Discipline Team Leader – Addendum to Review
NDA #	202-123
Applicant	Gilead Sciences Inc.
Date of Submission	February 10, 2011
PDUFA Goal Date	August 10, 2011
Proprietary Name / Established (USAN) names	Complera (Emtricitabine/Rilpivirine/Tenofovir DF Fixed-Dose Combination)
Dosage forms / Strength	200 mg / 25 mg / 300 mg (FTC/RPV/TDF)
Proposed Indication(s)	A complete regimen for the treatment of HIV-1 infection in treatment-naïve adult patients
Recommended:	Approval

1. Introduction

At the time of finalization of the CDTL review for this NDA, the final PMC language proposed by the biopharmaceutics reviewer had not been agreed to by the Applicant. In addition, a recommendation from the Office of Compliance regarding the acceptability of a remaining manufacturing site (b) (4) manufacturing site for emtricitabine drug substance) was pending. FDA Form 483 was issued to the site by the Office of Compliance outlining significant issues; the site was unable to provide an adequate response to the issues outlined. Thus, on 8/2/11 the Office of Compliance provided an Overall Recommendation of "Withhold" for the facilities for this NDA.

This CDTL addendum serves to document the following:

1. Gilead withdrew (b) (4) as one of the emtricitabine drug substance manufacturers in their August 4, 2011 correspondence. Upon withdrawal of the (b) (4) site, the Office of Compliance issued an Overall Recommendation of Acceptable (8/5/11). For further details, please refer to the revised review by CMC reviewer Dr. Rao Kambhampati (8/8/11).

2. The Applicant has agreed to the final PMC language, as proposed by the biopharmaceutics reviewer, as follows:

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

2. Recommended Regulatory Action

I concur with the assessments made by the review team and recommend that the NDA be approved.

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/s/

SARAH M ROBERTSON
08/09/2011