CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-896

MICROBIOLOGY REVIEW

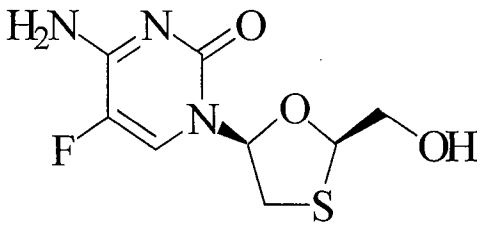
Microbiology Review
Division of Antiviral Drug Products (HFD-530)

NDA: 21-896	**Serial #:** 000	**Reviewer:**	N. Battula
Date submitted:	March 29, 2005	**Date received:**	March 30, 2005
Date assigned:	April 10, 2005	**Date reviewed:**	August 10, 2005

Sponsor: Gilead Sciences.
333 Lakeside Drive
Foster City, CA 94404

Product name(s):
Non-proprietary: Emtricitabine, FTC
Proprietary: Emtriva®
Chemical: 5-fluoro-1-(2R,5S)-[2-(hydroxymethyl)-[1,3]-oxathiolan-5-yl] cytosine

Structural formula:



Molecular formula: $C_8H_{10}FN_3O_3S$

Molecular weight: 247.24

Dosage form/route of administration: Solution (10mg/ml) or hard gelatin capsules (200 mg) / Oral

Indication: Treatment of HIV-1 infected children in combination with other antiretroviral agents

Related documents: IND 53,971 and NDA 21-500

Background and Summary: Emtricitabine (Emtriva®) is a nucleoside analog reverse transcriptase inhibitor of HIV-1. On July 2, 2003, Gilead Sciences, Inc. of Foster City, California received approval for the 200 mg hard gelatin capsule formulation (NDA 21-500) of emtricitabine for the treatment of HIV-1 infection in adults.

In the current New Drug Application (NDA 21-896), Gilead Sciences, Inc. is seeking approval for the 10 mg/ml oral solution of emtricitabine in combination with other antiretroviral agents for the treatment of HIV-1 infected pediatric patients. In support of the pediatric indication the applicant submitted data from three clinical studies conducted in infected children of greater than three months of age using 10 mg/ml oral solution of emtricitabine. The three clinical studies, FTC-202, FTC-203 and FTC-211, include data of multiple dose pharmacokinetic efficacy and safety studies in pediatric patients (for details of evaluation of the studies see the clinical pharmacology review by Jen DiGiacinto and the clinical reviews by Russ Fleischer).

The applicant has not conducted any additional microbiology studies as a part of this NDA. Therefore, there are no reports for review or changes to the microbiology section of the emtricitabine (Emtriva®) package insert.

Conclusions and Recommendations: There are no changes to the current microbiology section of the emtricitabine (Emtriva®) package insert. With regard to microbiology the pediatric formulation of emtricitabine (Emtriva®) is recommended for approval.

Narayana Battula, Ph.D.
Microbiologist

Concurrence:

HFD 530/ Assoc Dir. _____ Date _____

HFD 530/TLMicro. _____ Date _____

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/s/

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