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APPLICATION NUMBER:

20-154/S-040, S-041
20-155/S-030, S-031
20-156/S-031, S-032

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS
TEAM LEADER NOTE

NDA: 20-154/SLR-041 (Videx® Chewable/dispersible Tablets)
20-155/SLR-031 (Videx® Buffered Powder for Oral Solution)
20-156/SLR-032 (Videx® Pediatric Powder for Oral Solution)
21-183/SLR-006 (Videx® Enteric Coated Tablets)

Generic name: Didanosine
Sponsor: Bristol-Myers Squibb
Submission Date: July 11, 2002
Team Leader: Kellie Schoolar Reynolds, Pharm.D.

The purpose of this labeling supplement is to update the Videx labels to reflect the pharmacokinetic interaction that occurs when Videx or Videx EC are administered with tenofovir. The changes to the label are based on a study conducted by Gilead Sciences, GS-01-932. Dr. Jooran Kim reviewed the study under NDA 21-356/SLR-001 (put into DFS by Kellie Reynolds). Dr. Kim concluded that there is an interaction between tenofovir and didanosine that leads to increased plasma concentrations of didanosine. However, adequate data were not available at the time of this supplement to allow a dose adjustment recommendation.

See Russ Fleischer's and Destry Sillivan's reviews of these supplements for a discussion of specific labeling changes.

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/s/

Kellie Reynolds
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BIOPHARMACEUTICS

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