M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: Oct. 21, 2014

FROM: Jeff Murray, M.D.
Division of Antiviral Products

SUBJECT: Deputy Director Memorandum for NDA 204311
Abacavir and Lamivudine Scored Tablets for Oral Suspension (60mg/30mg)

TO: Division files

I. Introduction

The availability of a wide range of safe and effective antiretroviral drug products is hoped to facilitate a wider distribution of anti-HIV drugs to better meet the demands of the global HIV/AIDS pandemic. On Oct. 17, 2006 FDA published a guidance entitled "Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV.`` The guidance encourages sponsors to develop various drug product versions of previously approved antiretroviral drugs and encourages sponsors to submit drug applications for these products to FDA for review. Although many antiretroviral drug product versions of previously approved antiretrovirals cannot be currently marketed in the US because of patent and exclusivity restrictions, FDA is able to review these products for quality, safety and efficacy and potentially grant a tentative approval. The President's Emergency Plan for AIDS Relief will consider procurement of products reviewed by FDA that have been granted approval or tentative approval. Such products may be distributed outside the US, depending on legal requirements in other countries.

II. Background

Mylan submitted this 505(b)(2) NDA for this scored fixed dose combination (FDC) tablet of abacavir and lamivudine intended for pediatric use. These tablets contain two commonly used nucleoside reverse transcriptase inhibitors that can be combined with a non-nucleoside reverse transcriptase inhibitor, integrase inhibitor, or a protease inhibitor to form a complete HIV treatment regimen. This scored tablet is a smaller dosage strength (60 mg of abacavir and 30 mg of lamivudine) version [redacted (b) (4)] The dose strengths of abacavir and lamivudine submitted in this application are intended for use in pediatric patients. Abacavir and Lamivudine Tablets can be suspended in water for pediatric patients unable to swallow tablets. FDA previously granted tentative approval of

NDA 202381 for Mylan's unscored FDC tablet containing Abacavir Sulfate and Lamivudine (60 mg/30 mg) intended for pediatric use.

III. Reviewers findings

Please refer to the labeling review prepared by Monica Zeballos PharmD for a description of dosing recommendations and other pertinent edits to the label. She recommends this product for tentative approval.

I concur with the CMC review prepared by Dr.Ragiv Agarwal, who recommends tentative approval of Abacavir Sulfate and Lamivudine Tablets for Oral Suspension. Dr. Agarwal states that the NDA has provided sufficient information to assure identity, strength, purity, and quality of the drug product. An 'Acceptable' site recommendation from the Office of Compliance has been made. The Product Quality Microbiology review also recommends tentative approval.

I concur with the Biopharmaceutics (ONDQA) review prepared by Dr. Minerva Hughes. Dr. Hughes recommends tentative approval of Abacavir and Lamivudine Scored Tablets for Oral Suspension. The Applicant conducted two bioequivalence studies, fed and fasted, comparing Abacavir Sulfate and Lamivudine Tablets for Oral Suspension (60 mg/ 30 mg) to the Reference Listed Drugs (RLD), ZIAGEN (Abacavir Sulfate) Oral Solution 20 mg/mL (NDA #020978) and EPIVIR (Lamivudine) Oral Solution, 10 mg/mL (NDA # 020596). Both studies met criteria for bioequivalence. The Office of Scientific Investigations found the data for the bioequivalence studies acceptable for review.

IV. Recommendations

Mylan's version of Abacavir and Lamivudine Scored Tablets for Oral Suspension (60mg/30 mg) intended for use in pediatric patients should receive tentative approval.

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Jeffrey S. Murray M.D., M.P.H.

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/s/

JEFFREY S MURRAY
10/23/2014