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APPLICATION NUMBER:

205103Orig1s000

OTHER REVIEW(S)

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: August 19, 2016

TO: Donna Griebel, M.D
Director
Division of Gastroenterology and Inborn Errors Products, Office of Drug Evaluation III,
Office of New Drugs

FROM: Hasan A. Irier, Ph.D.
Division of Generic Drug Bioequivalence Evaluation
Office of Study Integrity and Surveillance
Office of Translational Sciences

THROUGH: Young Moon Choi, Ph.D.
Deputy Director (Acting)
Division of Generic Drug Bioequivalence Evaluation
Office of Study Integrity and Surveillance
Office of Translational Sciences

SUBJECT: (b) (4) (b) (4) (b) (4) for NDA 205103

Summary:
The Office of Study Integrity and Surveillance (OSIS) conducted an inspection of the bioanalytical portions of the PA8140-104 and PA32540-119 studies(under NDA 205103) (b) (4) (b) (4) Based on the inspection findings, OSIS recommends accepting the analytical data from the PA8140-104 and PA32540-119 studies for further Agency review.

Studies Audited during this Inspection:

Study number: PA8140-104 (NDA 205103)
Study title: "A Single-Dose Randomized Crossover Study to Assess the Intrasubject Variability of Acetylsalicylic Acid from Administration of Three Tablets (Dosed Concurrently) of PA8140 and to Evaluate the Relative Bioavailability of Three Tablets (Dosed Concurrently) of Two Formulations of PA8140 with the Partial Reference-Replicated 3-Way Design and the Reference-Scaled Average Bioequivalence

Approach."

Sample Analysis: Analysis of human plasma samples began on 07 January 2016 and was completed on 17 January 2016.

Study number: PA32540-119 (NDA 205103)
Study title: "A Single-Dose Randomized Crossover Study to Assess the Intrasubject Variability of Acetylsalicylic Acid from Administration of PA32540 and to Evaluate the Relative Bioavailability of Two Formulations of PA32540 with the Partial Reference-Replicated 3-Way Design and the Reference-Scaled Average Bioequivalence Approach."

Sample Analysis: Analysis of human plasma samples began on 22 February 2016 and was completed on 07 March 2016

OSIS scientist Hasan Irier, Ph.D. conducted an inspection of the bioanalytical portions of the studies specified above [redacted] The audit covered the bioanalytical method validation and the PA8140-104 and PA32540-119 sample analyses for acetylsalicylic acid. The audit also included a thorough review of facilities, equipment, study records and correspondences, and interviews and discussions with [redacted] management and staff. At the conclusion of the inspection, no Form FDA 483 observations were issued.

Conclusion:

Based on the inspectional fi
bioanalytical study conduct [redacted] this OSIS reviewer concluded that the data from the PA8140-104 and PA32540-119 studies are reliable. Therefore, OSIS recommends accepting the analytical portions of the PA8140-104 and PA32540-119 studies for further (FDA) Agency review.

Hasan A. Irier, Ph.D.
OSIS, DGDBE

Final Site Classification:

NAI – FEI: [redacted]

Page 3. Review of EIR [redacted] (b) (4)

DARRTS CC:
OTS/OSIS/Kassim/Taylor/Haidar/Turner-Rinehardt/Nkah/Fenty-Stewart
OTS/OSIS/DGDBE/Cho/Skelly/Choi/Au/Irier
OTS/OSIS/DNDBE/Bonapace/Dasgupta/Ayala/Biswas

Draft: HAI 08/15/16,
Edits: SA 08/15/16, YMC 08/17/16, HAI 8/19/16

ECMS: Cabinets/CDER_OC/OSI/Division of Bioequivalence & Good
Labora [redacted] gram/ANALYTICAL
SITES/ [redacted] (b) (4)

OSI fil 38
FACTS: [redacted] (b) (4)

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/s/

HASAN A IRIER
08/19/2016

YOUNG M CHOI
08/19/2016

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