

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206110Orig1s000

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

NDA #: 206110 (dated October 31, 2016)

Sponsor: Fresenius Kabi USA, LLC

Name of Drugs: Caspofungin Acetate for Injection

Indication: Treatment of fungal infections.

Biometrics Division: Division of Biometrics IV

Statistical Reviewer: Cheryl Dixon, Ph.D.

Concurring Reviewer: Daphne Lin, Ph.D.

Medical Division: Division of Anti-Infective Products

Medical Reviewer: Hala Shamsuddin, M.D.

Project Manager: Alison Rodgers

Executive Summary:

This contains a resubmission of the NDA for Caspofungin Acetate for Injection submitted by Fresenius Kabi USA, LLC. Tentative approval of this NDA was granted in November, 2015, subject to a period of patent protection such that final approval of the application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] could not be made effective until December 30, 2016.

No new clinical studies were submitted by the Applicant in this NDA. The Applicant is relying on the Agency's findings of safety and efficacy for Cancidas, the reference listed drug. The label is consistent with the most recent version of the Cancidas prescribing information. There is no statistical review for this NDA resubmission.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHERYL A DIXON
12/19/2016

TSAE YUN D LIN
12/19/2016

STATISTICAL REVIEW AND EVALUATION

NDA #: 206110 (dated December 12, 2013)

Sponsor: Fresenius Kabi USA, LLC

Name of Drugs: Caspofungin Acetate for Injection

Indication: Treatment of fungal infections.

Biometrics Division: Division of Biometrics IV

Statistical Reviewer: Cheryl Dixon, Ph.D.

Concurring Reviewer: Karen Higgins, Sc.D.

Medical Division: Division of Anti-Infective Products

Medical Reviewer: Hala Shamsuddin, M.D.

Project Manager: Alison Rodgers

Executive Summary:

This NDA is for Caspofungin Acetate for Injection. Caspofungin is currently marketed in the US as Cancidas (NDA 21-227, Merck & Co., Inc.) and is approved in adults and pediatric patients (3 months or older) for the following indications:

- Empirical therapy for presumed fungal infections in febrile, neutropenic patients
- Treatment of candidemia and the following *Candida* infections: intraabdominal abscesses, peritonitis and pleural space infections
- Treatment of esophageal candidiasis
- Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (e.g., amphotericin B, lipid formulations of amphotericin B, itraconazole).

Fresenius Kabi USA, LLC has submitted this 505(b)(2) NDA for caspofungin acetate for injection. The active pharmaceutical ingredient (API) is the same as the API of the reference listed drug (RLD), Cancidas. The inactive ingredients of the proposed drug product are not the same as that of the RLD. The Fresenius Kabi drug product contains L-arginine and hydrochloric acid/sodium hydroxide required for pH adjustment. Cancidas contains sucrose, mannitol, glacial acetic acid and sodium hydroxide. The route of administration, dosage form and strength of the Fresenius Kabi drug product are the same as those of Cancidas. The differences in the formulation are not expected to affect the pharmacologic activity of caspofungin. Therefore, the 2 formulations are considered therapeutic equivalents. As such, the Applicant is relying on the information presented in the Cancidas approved labeling and the Agency's findings of safety and efficacy for Cancidas, to support approval of this application.

Conclusion and Recommendations

No new clinical studies were submitted by the Applicant in this NDA. Therefore, there are no statistical comments regarding the safety and efficacy of the Fresenius Kabi Caspofungin Acetate for Injection product. Since the Applicant is relying on the approved Cancidas approved labeling for the Adverse Reactions and Clinical Studies sections of the Caspofungin Acetate for Injection labeling, no changes to these sections are recommended.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHERYL A DIXON
09/17/2014

KAREN M HIGGINS
09/17/2014
I concur.