CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208562Orig1s000

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

NDA #:	208562 SDN 14 (dated January 9, 2017)
Sponsor:	Xellia
Name of Drugs:	Voriconazole 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:	Caroline Jjingo, M.D.
Project Manager:	Naseya Minor, MPH

Executive Summary:
This is a NDA class 1 resubmission for Voriconazole for Injection. Xellia received Tentative Approval for the NDA on May 24, 2016 due to patent protection of one of the drugs that the application was relying upon. Issues regarding the patent protection have been resolved; therefore Xellia is now requesting Final Approval.

Minor changes have been made to the package insert that was included in Tentative Approval letter. However, no further changes have been made to the Adverse Reactions or Clinical Studies sections. As such, there are no further recommendations from a statistical perspective.

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/s/

CHERYL A DIXON
02/03/2017

KAREN M HIGGINS
02/03/2017

STATISTICAL REVIEW AND EVALUATION

NDA #:	208562 (dated July 24, 2015)
Sponsor:	Xellia
Name of Drugs:	Voriconazole 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:	Caroline Jjingo, M.D.
Project Manager:	Naseya Minor, MPH

Executive Summary:
This NDA is for Voriconazole for Injection. Voriconazole is currently marketed in the United States as Vfend (NDA 21-267, Pfizer, Inc.) and is approved for the following indications:

- Treatment of invasive aspergillosis
- Treatment of candidemia (nonneutropenic) and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds
- Treatment of esophageal candidiasis
- Treatment of serious infections caused by *Scedosporium apiospermum* and *Fusarium* species including *Fusarium solani,* in patients intolerant of, or refractory to, other therapy.

The treatment of esophageal candidiasis indication was evaluated only with the oral formulation of Vfend.

Xellia has submitted this 505(b)(2) NDA for voriconazole for injection. The active pharmaceutical ingredient (API) is the same as the API of the reference listed drug (RLD), Vfend for injection. This intravenous formulation differs from the RLD by the replacement of sulfobutyl ether β-cyclodextrin (SBECD) with hydroxypropyl β-cyclodextrin (HPβCD) (b) (4). The route of administration, dosage form and strength of the proposed drug product are the same as those of the RLD. Due to the changes in the inactive ingredient, the proposed product does not qualify for submission via the 505(j) regulatory pathway. Instead, the Sponsor is submitting this NDA via the 505(b)(2) pathway and intends to rely on the information presented in the Vfend approved labelling and the Agency's findings of safety and efficacy for Vfend, 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 Xellia Voriconazole for Injection product. Since the Applicant is relying on the approved Vfend approved labeling for the Adverse Reactions and Clinical Studies sections of the Voriconazole for Injection labeling, no changes with respect to the data presented in these sections are recommended other than removal of reference to the [redacted] (b) (4) in the Clinical Studies section, as this was [redacted] (b) (4) study.

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/s/

CHERYL A DIXON
05/10/2016

KAREN M HIGGINS
05/10/2016
I concur.