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APPLICATION NUMBER:

209463Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA	**209463**
Submission Date (s)	**June 7, 2016**
PDUFA Date:	**July 7, 2017**
Brand Name	**Pantoprazole Sodium for Injection for intravenous use**
Generic Name	**Pantoprazole**
Submission Type	**505(b)(2)**
Dosage Form, Strength	**Pantoprazole sodium for Injection, 40 mg/mL**
Proposed Indication	• **Short-term treatment (7 to 10 days) of GERD associated with a history of erosive esophagitis (EE)** • **Pathological hypersecretion conditions, including Zollinger-Ellison (ZE) syndrome.**
Proposed Dosage:	**40 mg pantoprazole given once daily by intravenous infusion for 7 to 10 days**
Applicant	**Exela Pharma Sciences, LLC**
OND Division	**Division of Gastroenterology and Inborn Errors Products**
OCP Division	**Division of Clinical Pharmacology 3**
OCP Reviewer	**Dilara Jappar, Ph.D.**
OCP Secondary Reviewer	**Insook Kim, Ph.D.**

Executive Summary

The applicant (Exela Pharma) submitted a NDA for pantoprazole under the 505(b)(2) regulatory pathway. PROTONIX IV (pantoprazole sodium) for Injection for intravenous use has been identified as the reference listed drug (RLD) which was approved on Mar 22, 2001. The formulation for Exela's Pantoprazole Sodium for Injection has the same active ingredient, dosage form, route of administration, and indications as the reference listed drug ("RLD") PROTONIX I.V. (intravenous pantoprazole sodium) for Injection.

Exela's Pantoprazole Sodium for Injection formulation differs from the RLD with respect to the inactive ingredients that it doesn't contain any buffering agents, antioxidants, preservatives, chelating agents, or stabilizers compared to the RLD.

The proposed indication is the same as the RLD, short-term treatment (7 to 10 days) of adult patients with gastroesophageal reflux disease (GERD) with a history of erosive esophagitis and the treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome in adults. The clinical pharmacology information in the proposed label is the same as in the labeling for PROTONIX.

In support of this new product, no new clinical study and no new clinical pharmacology study has been conducted. The applicant has requested a waiver of BA/BE requirements per 21 CFR 320.22(a) for this product.

Recommendation

There was no new clinical pharmacology study/information submitted in this NDA. As such, there is no outstanding clinical pharmacology issue that would preclude the approval of this NDA.

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/s/

DILARA JAPPAR
06/16/2017

INSOOK KIM
06/16/2017