CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209552Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

Date: April 13, 2017

To: File for ND 209552

From: Ramadevi Gudi, PhD
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Through: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Subject: NDA 209552 SDN 1
NDA: 209552
NDA type: 505(b)(2)
Applicant: Aurobindo Pharma Limited
Drug: Argatroban Injection in 0.9% Sodium Chloride, 50 mg/50 mL.
Indication: Prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) and as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).

Aurobindo Pharma Limited is relying on the FDA's previous findings of safety and effectiveness for the listed drug (NDA 022485), of Sandoz Inc. Argatroban Injection in 0.9% Sodium Chloride, 125 mg/125 mL (1 mg/mL).

No nonclinical study reports are provided with this application. Argatroban is a direct thrombin inhibitor that reversibly binds to the thrombin active site. Argatroban inhibits thrombin with an inhibition constant (Ki) of 0.04 μM. Argatroban is capable of inhibiting the action of both free and clot-associated thrombin.

1.3 Recommendations

1.3.1 Approvability

Aurobindo Pharma Limited's Argatroban for injection 505(b)(2) NDA 209552 is approvable from the perspective of pharmacology/toxicology.

1.3.3 Labeling

The label was updated to comply with the Pregnancy and Lactation Labeling Rule (PLLR) content and format requirements.

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

/s/

RAMADEVI GUDI
04/13/2017

CHRISTOPHER M SHETH
04/13/2017