CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201743Orig1s000

SUMMARY REVIEW

Summary Review for Regulatory Action

Date	(electronic stamp)
From	Ann. T. Farrell, M.D., Acting Division Director
Subject	Division Director Summary Review
NDA/BLA # **Supplement #**	201743
Applicant Name	Sandoz Canada, Inc.
Date of Submission	April 26, 2011
PDUFA Goal Date	June 26, 2011
Proprietary Name / **Established (USAN) Name**	Argatroban Injection in Dextrose
Dosage Forms / Strength	1 mg/mL
Proposed Indication(s)	Indicated for 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).
Action/Recommended Action for NME:	**Full Approval**

Material Reviewed/Consulted OND Action Package, including:	
Medical Officer Review	Firoozeh Alvandi, M.D./ Virginia Kwitkowski, RNP
Statistical Review	
Pharmacology Toxicology Review	Shwu Luan Lee Ph.D./ Haleh Saber, Ph.D.
CMC Review/OBP Review	Ravindra Kasliwal, Ph.D./Janice Brown, Ph.D./ Sarah Pope Miksinski, Ph.D.
Microbiology Review	Stephen Langille, Ph.D.
Clinical Pharmacology Review	Hua Zhang, Ph.D./ Julie Bullock, Pharm.D. Angelica Dorantes, Ph.D./Patrick J. Marroum, Ph.D.
DDMAC	
DSI	N/A
CDTL Review	Same as this memo
OSE/DMEPA	Yelena Maslov, Pharm. D./ Carol Holquist, R. Ph.
OSE/DDRE	
OSE/DSRCS	
Other	

OND=Office of New Drugs
DDMAC=Division of Drug Marketing, Advertising and Communication
OSE= Office of Surveillance and Epidemiology
DMETS=Division of Medication Errors and Technical Support
DSI=Division of Scientific Investigations
DDRE= Division of Drug Risk Evaluation
DSRCS=Division of Surveillance, Research, and Communication Support
CDTL=Cross-Discipline Team Leader

Signatory Authority Review Template

1. Introduction

NDA 201743 is a 505 b2 application for argatroban which was initially submitted to the Agency on April 14, 2010. The Agency filed the application and granted a standard review and due to Waxman-Hatch exclusivity granted a tentative approval on January 13, 2011. On April 26, 2011, Sandoz submitted their complete response to the tentative approval. In their complete response letter, they informed the Agency that there had been no changes to their application since the original submission which received a tentative approval.

2. Background

The Reference Listed Drug (RLD) for this submission is Argatroban Injection (NDA 20-883), which is currently marketed by Pfizer. This NDA was approved on June 30, 2000. The RLD has Waxman-Hatch Exclusivity which does not expire until May 5, 2011.

3. CMC/Device

Based on the stability data provided, a 12-month expiration dating period is granted for room temperature storage conditions and a Do not freeze statement is to be included in labeling.

4. Nonclinical Pharmacology/Toxicology

There were no new nonclinical pharmacology/toxicology studies provided in this submission. The pharmacology/toxicology review team reviewed the submission and participated in labeling review. No issues that would preclude approval were identified.

5. Clinical Pharmacology/Biopharmaceutics

No issues that would preclude approval were identified. The only information submitted for review was data to support bridging between this 505 b2 product and the RLD.

6. Clinical Microbiology

This argatroban product is (b) (4). There are no outstanding microbiology issues related to the manufacturing process and/or overall sterility assurance. No issues that would preclude approval were identified.

7. Clinical/Statistical-Efficacy

No new clinical data was submitted. Dr. Alvandi and Ms. Kwitkowski reviewed the labeling.

8. Safety

No new safety issues have been identified.

9. Advisory Committee Meeting

This product is not a NME.

10. Pediatrics

This product is a 505 b2.

11. Other Relevant Regulatory Issues

12. Labeling

All disciplines made recommendations for labeling which were incorporated.

13. Decision/Action/Risk Benefit Assessment

-
- Recommended regulatory action

Full Approval

- Risk Benefit Assessment

N/A

- Recommendation for Post marketing Risk Management Activities
  None

- Recommendation for other Post marketing Study Requirements/ Commitments

  None

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/s/

ANN T FARRELL
05/09/2011