# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 201811Orig1s000

# SUMMARY REVIEW

# Summary Review for Regulatory Action

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|---|---|
| **Date** | (electronic stamp) |
| **From** | Ann. T. Farrell, M.D., Division Director |
| **Subject** | Division Director Summary Review |
| **NDA/BLA #**<br>**Supplement #** | 201811 |
| **Applicant Name** | Fresenius Kabi USA, LLC. |
| **Date of Submission** | January 23, 2015 |
| **PDUFA Goal Date** | March 23, 2015 |
| **Proprietary Name /**<br>**Established (USAN) Name** | Argatroban Injection in Sodium Chloride |
| **Dosage Forms / Strength** | 100 mg/mL concentration |
| **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:** | **Approval** |

| **Material Reviewed/Consulted**<br>OND Action Package, including: | |
|---|---|
| Medical Officer Review | Hyon-Zu Lee, Pharm.D. Virginia Kwitkowski, MS, RN, ACNP-BC |
| Statistical Review | N/A |
| Pharmacology Toxicology Review | Shwu Luan Lee Ph.D./ Haleh Saber, Ph.D. (prior reviews) |
| CMC Review/OBP Review | Anne Marie Russell, Ph.D./Janice Brown, M.S. |
| Microbiology Review | J. Metcalfe, Ph.D./ Bryan S. Riley (prior reviews) |
| Clinical Pharmacology Review | Hua Zhang, Ph.D./ Julie Bullock, Pharm.D. (prior reviews) |
| DDMAC | |
| DSI | N/A |
| CDTL Review | Janice Brown, M.S. |
| OSE/DMEPA | |
| 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

This submission for NDA 201811, a 505 b2 application for argatroban, is a response to a Complete Response Letter sent on February 28, 2014. The February 28, 2014, 2013 Complete Response letter identified a facility inspection deficiency that precluded approval.

The Agency filed the resubmission as a class 1 and granted a PDUFA goal date of March 23, 2015.

## 2. Background

The Reference Listed Drug (RLD) for this submission is Argatroban Injection (NDA 20-883), which is currently marketed by Pfizer.

The following product quality deficiency was conveyed in the February 28, 2014 Complete Response Letter.

During a recent inspection of the Fresenius Kabi USA, LLC, Grand Island, NY manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

## 3. CMC/Device

After the last review cycle, there was a single remaining deficiency reagrding the facility inspection. Ms. Brown stated in her review:

*There is no new CMC information in the resubmission. The facilities listed in this application received an "approve" recommendation from the Office of Process and*

*Facilities, and the product quality reviewer (Nina Ni, Ph.D.), recommended approval pending final acceptance of the container/carton labeling and the PI by the applicant in her review dated March 9, 2015 (signed March 9, 2015).*

I concur that this issue is now resolved and the application can be approved.

## 4. Nonclinical Pharmacology/Toxicology

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 *in vitro* equivalence data to support bridging between this 505 b2 product and the RLD.

## 6. Microbiology

No issues that would preclude approval were identified.

## 7. Clinical/Statistical-Efficacy

No new clinical data was submitted. Previously Dr. Alvandi and Ms. Kwitkowski had 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 not a NME.

## 11. Other Relevant Regulatory Issues

None

## 12. Labeling

All disciplines made recommendations for labeling.

# 13. Decision/Action/Risk Benefit Assessment

- 
- Recommended regulatory action

Approval

- Risk Benefit Assessment

This is a 505 b2.

- Recommendation for Post marketing Risk Management Activities

  None

- Recommendation for other Post marketing Study Requirements/ Commitments

  None

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

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/s/

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ANN T FARRELL
03/16/2015