



NDA 201811/S-003

**SUPPLEMENT APPROVAL**

Fresenius Kabi USA, LLC  
Attention: Kurt Pearl, MChE  
Regulatory Affairs Specialist  
Three Corporate Drive  
Lake Zurich, IL 60047

Dear Mr. Pearl:

Please refer to your Supplemental New Drug Application (sNDA) dated March 21, 2016, received March 21, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Argatroban, Injection, 100 mg/mL in 5 cc vial.

We also refer to our letter dated March 11, 2016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Argatroban products. This information pertains to the risk of medication errors.

This supplemental new drug application provides for revisions to the labeling for Argatroban. The agreed upon changes to the language included in our March 11, 2016, Safety Labeling Change Notification Letter, and agreed upon revisions included in our electronic correspondence dated April 19, 2016, are as follows (additions are noted by underline and deletion are noted by ~~strikethrough~~).

In the **HIGHLIGHTS** section, addition of **RECENT MAJOR CHANGES** section that reads:

“-----**RECENT MAJOR CHANGES**-----  
Dosing and Administration, Dosing in Patients Undergoing Percutaneous Coronary Intervention  
(2.3) 5/2016”

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **PROPRIETARY NAME**

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, “Contents of a Complete Submission for the Evaluation of Proprietary Names”, at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

*{See appended electronic signature page}*

Barry W. Miller  
Acting Deputy Director for Safety  
Division of Hematology Products  
Office of Hematology Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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

/s/  
-----

BARRY W MILLER  
05/25/2016