

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

212035Orig1s000

Trade Name: Argatroban in sodium chloride Injection, 50 mg/50 mL

Generic or Proper Name: Argatroban in sodium chloride Injection, 50 mg/50 mL

Sponsor: Accord Healthcare Inc.

Approval Date: June 7, 2021

Indication: For prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT)

As an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI)

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CONTENTS

| |
|---|
| Reviews / Information Included in this NDA Review. |
|---|

| | |
|--|----------|
| Approval Letter | X |
| Other Action Letters | X |
| Labeling | X |
| REMS | |
| Summary Review | X |
| Officer/Employee List | X |
| Office Director Memo | |
| Cross Discipline Team Leader Review | |
| Clinical Review(s) | X |
| Product Quality Review(s) | X |
| Non-Clinical Review(s) | X |
| Statistical Review(s) | |
| Clinical Microbiology / Virology Review(s) | |
| Clinical Pharmacology Review(s) | |
| Other Reviews | X |
| Risk Assessment and Risk Mitigation Review(s) | |
| Proprietary Name Review(s) | |
| Administrative/Correspondence Document(s) | X |

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APPROVAL LETTER



NDA 212035

NDA APPROVAL

Accord Healthcare Inc.
Attention: Sabita Nair, RAC, ASQ-CPGP
Senior Director, Regulatory Affairs
1009 Slater Road, Suite 210-B
Durham, NC 27703

Dear Ms. Nair:

Please refer to your new drug application (NDA) dated April 30, 2018, received April 30, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for argatroban in sodium chloride Injection, 50 mg/50 mL.

We acknowledge receipt of your amendment dated April 8, 2021, which constituted a complete response to our February 28, 2019, action letter.

This NDA provides for the use of Argatroban in Sodium Chloride Injection, 50mg/50mL:

- For prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT)
- As an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI)

APPROVAL & LABELING

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

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information) as well as annual reportable changes not included in the

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 212035.**” Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for argatroban in sodium chloride Injection shall be 24 months from the date of manufacture when stored at 20 to 25°C.

ADVISORY COMMITTEE

Your application for argatroban was not referred to an FDA advisory committee because this drug is not the first in its class.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling 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 *Contents of a Complete Submission for the Evaluation of Proprietary Names*. and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

the claimed indication 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

REPORTING REQUIREMENTS

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

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

If you have any questions, contact Courtney Hamilton, Regulatory Project Manager at 301-796-6849 or at Courtney.Hamilton@fda.hhs.gov.

Albert Deisseroth, MD, PhD
Deputy Division Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALBERT B DEISSEROTH
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