



NDA 22-359

TENTATIVE APPROVAL

Baxter Healthcare Corporation
Attention: Vicki L. Drews
Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Ms. Drews:

Please refer to your New Drug Application (NDA) dated April 18, 2008, received April 21, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Argatroban.

The January 28, 2010, submission constituted a complete response to our January 22, 2010, action letter.

This NDA provides for the use of Argatroban Injection 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).

We have completed our review of this application. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert, and carton and immediate container labels). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you based your application is subject to a period of exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Two or six months prior to the expiration of the exclusivity protection, as appropriate, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. Any changes to in the conditions outlined in this NDA require our review before final approval and the goal date for our review will be set accordingly. Your amendment should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the expiration of the exclusivity protection, you should amend your application accordingly.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

If you have any questions, call Ebla Ali Ibrahim, Regulatory Health Project Manager, at (301) 796-3691.

Sincerely,

{See appended electronic signature page}

Edvardas Kaminskas, M.D.
Acting Deputy Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Carton and Container Labeling

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22359

ORIG-1

BAXTER
HEALTHCARE
CORP

ARGATROBAN INJECTION

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

/s/

EDVARDAS KAMINSKAS

07/28/2010