MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date: March 9, 2015

From: Loan Nguyen, Regulatory Review Officer
OCBQ/DCM/APLB

Through: Lisa Stockbridge, Branch Chief
OCBQ/DCM/APLB

To: Edward Thompson, RPM, OBRR/DBA/RPMB
Chava Kimchi-Sarfaty, Chairperson, Product Reviewer, OBRR/DHRR/LH
Irwin Feuerstein, Clinical Reviewer, OBRR/DHCR/CRB

Subject: Labeling Review - Comments on carton and vial labels

Product: **IXINITY (Coagulation Factor IX [Recombinant])**
BLA STN: **125426/0**
Sponsor: Cangene Corporation

Background

The sponsor submitted:

☒ New Approval
☐ Major Amendment
☐ Prior Approval Supplement
☐ Changes Being Effected Supplement

Submission contains:

☐ Prescribing Information
☐ Patient Package Insert
☒ Carton/Vial labels
☐ Other: Instruction for Use

This labeling review is for the original application (BLA STN 125426) submitted on March 8, 2013 by Cangene Corporation (Cangene) for IXINITY (Coagulation Factor IX [Recombinant]). The action due date for this application is April 29, 2015.

APLB reviewed the carton and vial labels submitted by the sponsor on February 27, 2015.

Comment

- According to the sponsor, IXINITY is available in 500, 1000, and 1500 international units (IU) and will be packaged as kits containing either single vial or multiple vials as follows:

  - Single vial kits

    - ✓ 500 IU
    - ✓ 1000 IU
    - ✓ 1500 IU

  - Multiple vial kits

    - ✓ Two 1000 IU vials
    - ✓ 1000 IU and 1500 IU vials
    - ✓ Two 1500 IU vials

  Because the same volume of diluent (i.e., 5 mL of sterile water for injection) can be used for all the potencies, the final concentration will be different (i.e., approximately 100 IU/mL for the 500 IU vial, 200 IU/mL for the 1000 IU vial, and 300 IU/mL for the 1500 IU). Packaging a 1000 IU vial together with a 1500 IU vial will create a potential for medication error due to confusion in final concentrations. APLB does not recommend this configuration.

- Use the same font size for the presentation of the proprietary name. Tall man lettering (i.e., larger font size for IX than INITY) is used to create a distinction between two proprietary names for the purpose of reducing medication errors. Its use has been at the request and regulatory discretion of the Agency; however, tall man lettering has not been found to be effective or consistent in labeling and is no longer requested.

- The logo containing the number 9 from the carton and vial labels constitutes intervening matter when placed immediately before the proprietary name. It is distracting and can easily make the proprietary name misinterpreted (i.e., it may make the name appear to begin with an "O," a "Q," or a "D"). APLB recommends removing it from the carton and vial labels.

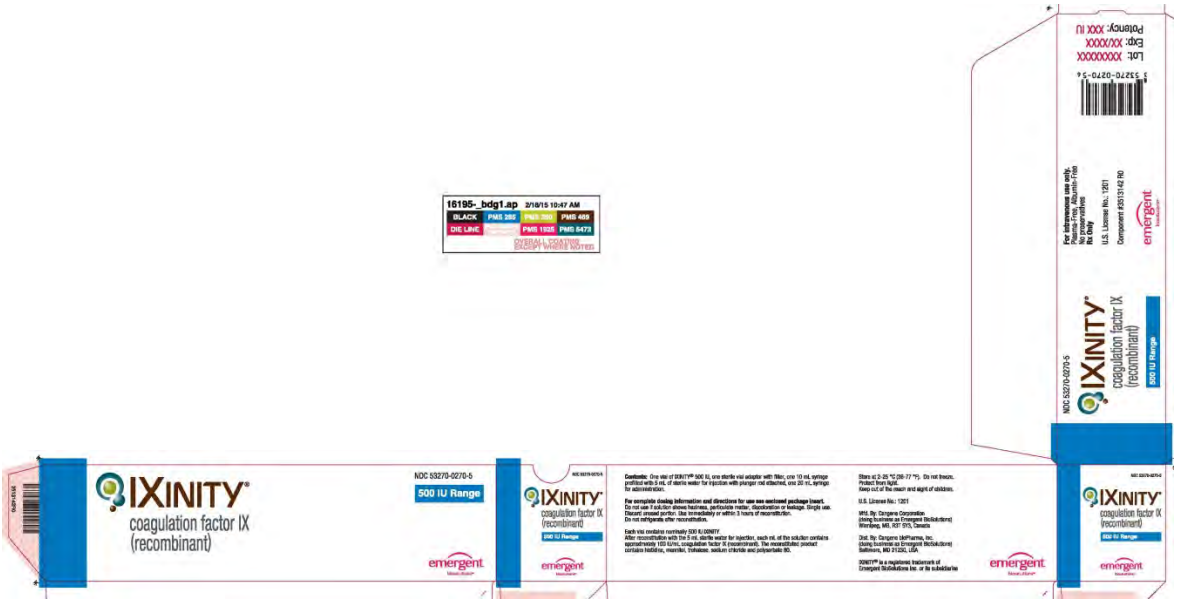
- Add latex information on the labels if available and space permits. Please refer to the final guidance, *"Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is Not Made with Natural Rubber Latex,"* for recommended language.

- The following additional comments are specific to either the carton or the vial labels:

  - Carton Labels

    - ✓ Delete the promotional phrase "Plasma-Free, Albumin-Free" from the labels.

- ✓ Consider giving more emphasis to the route of administration (i.e., For intravenous use only"). For example, move it to the main panel of the carton instead of the back panel.
- ✓ Consider adding the dosage form (i.e., lyophilized powder for solution) if space permits.
- ✓ For clarity, consider grouping relevant information together. For example, present the ingredient paragraph right after the contents and before the storage information.



- Vial Labels:

- ✓ Delete the vial size (i.e., 10 mL) from the description of the vial. Simply use the term "Single-use Vial" instead. There has been a report of medication error due to mistaken of this vial size with the final solution volume.

If you have any questions regarding this review please contact Loan Nguyen, Pharm.D., Regulatory Review Officer at 240-402-9030.

Firm: Cangene Corporation

STN: 125426/0

Document type: Review Memorandum

Bcc: L. Nguyen
APLB Chronologic File
APLB Historical File

History:
Prepared: L. Nguyen 3/3/15, 3/9/15
Concurred w/rev: L. Stockbridge 3/9/15
Finalized: L. Nguyen 3/9/15

File name: LR_IXINITY_CartonVialLabels_125426_9Mar15

Concurrence box:

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