

Memo - Proprietary Name Review, November 9, 2010 - Corifact

Date: November 09, 2010

From: Michael Brony, Pharm.D.
Regulatory Review Officer
Advertising and Promotional Labeling Branch (APLB) (HFM-602)
Division of Case Management

Through: Lisa L. Stockbridge, Ph.D.
Acting Branch Chief
Advertising and Promotional Labeling Branch (APLB) (HFM-602)
Division of Case Management

Through: Robert A. Sausville
Director, DCM

To: Nannette Cagungun, OBRR/DBA
Daniela Vanco, MD, Medical Officer, OBRR/DH/CRB

Subject: Review of proposed proprietary name **CORIFACT (Factor XIII Concentrate (Human))**
BLA -125385

Recommendation: **CORIFACT** proprietary name found **Acceptable**

Executive Summary:

APLB has completed the review of the proprietary name **Corifact** and found it **Acceptable** at this time.

According to SOPP 8001.4 (Review of CBER Regulated Product Proprietary Names), OBRR makes the final decision on the acceptability of **Corifact** and, to meet the PDUFA IV performance goal, communicates this decision to CSL Behring within 90 days of the receipt of the complete PNR submission. The PDUFA goal date for this PNR is November 16, 2010.

If OBRR accepts our recommendation that the proposed proprietary name **Corifact** be found Acceptable, please include the following text in your letter to the sponsor:

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, CORIFACT, is acceptable at this time.

OBRR is responsible for communicating CBER's decision to CSL Behring and should enter the communication issuance date into RMS BLA before November 16, 2010, in order to stop the performance clock. Please notify APLB when this action has been completed.

Background:

CSL Behring submitted a request, on August 18, 2010, for the review of the proposed name, Corifact.

Corifact would be pronounced kore' i fakt. There is no intended meaning in the name, Corifact.

Analysis Summary for Corifact:

Corifact's proposed indication is the routine prophylactic treatment of congenital FXIII deficiency.

Corifact will be available as a lyophilized concentrate for reconstitution with 20 mL of sterile water for injection. The dosing for Corifact should be individualized with an initial dose of 40 IU/kg body weight of FXIII every 28 days (4 weeks) to maintain a FXIII activity trough level of approximately 5-20%. Dosing adjustments will be based on FXIII activity trough levels and the patients' clinical condition.

The lyophilized concentrate product will be stored up to 24 months at 2 to 8° C (36 to 46° F) in the original carton. Within the expiration date, the product may be stored at room temperature (up to 25°C), not to exceed a cumulative storage period of 6 months. It should not be frozen and should be protected from light.

The primary environment in which the product will be administered is in an inpatient/hospital setting, a long-term care facility, physician's office/clinic or in a home setting. This product will primarily be dispensed from a retail clinical pharmacy setting; however, this product could also be dispensed from a hospital pharmacy setting.

Discussion

CSL Behring submitted an independent proprietary name analysis (-----b(4)-----) for orthographically and phonetically similar names to Corifact.

The independent analysis yielded seventeen sound-alike and look-alike names. The analysis concluded that the “proposed proprietary name has minimal, if any, risk of name confusion with the identified products that could result in a medication error.”

APLB conducts its own independent review of existing proprietary and established/proper names.

1. False, Misleading, or Fanciful

The proposed proprietary name Corifact is not regarded to be false, misleading, or fanciful.

2. Similarity in Spelling or Pronunciation:

There appears to be a low potential for medication errors due to similarity in spelling with proprietary names for other marketed products (see the table below). Particular concern exists when similar letters occur in the first part of a proprietary or established name because the prescriber’s handwriting may become less legible at the end of the name, making these names indistinguishable with look-alike names for products that already exist in the U.S. marketplace.

- o Carafate and Cortifoam may look similar to Corifact when scripted.

There appears to be a minimal risk for medications errors products when taking into account spelling, phonetics/orthographics, therapeutic class, indication, storage, dosage form, route of administration, and likely care environment for dispensing and use. Thus, APLB believes that the overall potential for confusion for all of these products is expected to be minimal.

3. Similarity in Product Characteristics:

APLB’s independent review did not identify any products with similar product characteristics.

Name	Dosage Form	Rx or OTC	Dosage & Administration	Indication	Storage	Potential for Medication Error
Corifact (Factor XIII Concentrate (Human))	Lyophilized concentrate for reconstitution	Rx	Initial dose of 40 IU/kg body weight of FXIII every 28	Routine prophylactic treatment of congenital	Up to 24 months at 2 to 8° C (36 to 46° F) in the	N/A

	with 20 mL of sterile water for injection		days (4 weeks) to maintain a FXIII activity trough level of approximately 5-20%.	FXIII deficiency.	original carton. Within the expiration date, the product may be stored at room temperature (up to 25°C), not to exceed a cumulative storage period of 6 months.	
Corvite (Vitamin B Complex/Vitamin C/Folic Acid/Iron/Zinc)	Tablet	Rx	Once a day	Prevention of vitamin deficiency.	Store at room temperature, between 59 and 86 degrees F (15 and 30 degrees C). Store away from heat, moisture, and light. Do not store in the bathroom.	Low
Cortifoam (hydrocortisone acetate)	Rectal foam	Rx	1-2 applications /day	Treatment of ulcerative prostatic.	Store below 68-77 degrees F (20-25 degrees C) away from light and moisture.	Low
Crofab [Crotalidae Polyvalent Immune Fab) (Ovine)]	Injection	Rx	2-6 vials/daily	Treatment of minimal and moderate North American Crotalidae Envenomation.	The product should be stored at 2° to 8°C (36° to 46°F). Do not freeze. The product must be used	Low

					within 4 hours after reconstitution.	
Carafate (sucralfate)	Oral Tablets and oral suspension	Rx	2-4g/day	For the treatment of duodenal ulcers and GERD.	Store it at room temperature and away from excess heat and moisture.	Low

Recommendation:

APLB recommends that the proposed proprietary name **Corifact** be found **Acceptable**. There appears to be a minimal risk for medications errors with the proprietary names for other marketed products taking into account similarity in spelling, therapeutic class, indication, pronunciation, handwriting, storage, dosage form, route of administration, and setting of use (see comparison table above).

If OBRR accepts our recommendations that the proposed proprietary name Corifact be found Acceptable, please include the following text in your letter to the manufacturer:

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, CORIFACT, is acceptable at this time.

If you have any questions with regards to this review please contact Michael Brony, Consumer Safety Officer at 301-827-6342.