

**MEMORANDUM**

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

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**Date:** July 20, 2015

**From:** Michael Brony, Pharm.D.  
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Division of Case Management

**Through:** Lisa L. Stockbridge, Ph.D.  
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**Through:** Robert A. Sausville  
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**To:** Victor Baum, M.D. OMPT/CBER/OBRR/DHCR/CRB  
Thomas J. Maruna, RPM, OMPT/CBER/OBRR/DBCD

**Subject:** Review of Proposed Proprietary Name “(b) (4)” and “AFSTYLA”  
((Antihemophilic Factor (Recombinant), Single Chain))  
BLA - 125591

**Recommendation:** (b) (4) – Unacceptable  
AFSTYLA- Acceptable at this time

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**Executive Summary**

APLB has completed the proprietary name review (PNR) for the proposed proprietary names, (b) (4) (primary) and AFSTYLA (alternative), for recombinant single-chain coagulation factor VIII (rVIII-Single Chain). We recommend that the proposed proprietary name, (b) (4), be found **Unacceptable** and the proposed alternative name, AFSTYLA, be found **Acceptable at this time**.

According to SOPP 8001.4 (Review of CBER Regulated Product Proprietary Names), the product office, Office of Blood Research and Review (OBRR), makes the final decision on the acceptability of the proposed proprietary name. To meet the PDUFA IV performance goal, the product office must communicate this decision to the sponsor, CSL Behring, within 90 days of the receipt of the complete PNR submission. The PDUFA goal date for this PNR is August 27, 2015.

If the OBRR accepts our recommendation that the proposed proprietary name, **AFSTYLA**, is acceptable, we offer the following communication-ready language:

*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 alternative proposed proprietary name, **AFSTYLA**, is acceptable at this time.*

*The primary proposed proprietary name, (b) (4), is unacceptable because it implies that the product has a unique composition and effectiveness beyond that supported by the data.*

### **Background**

On May 29, 2015, CSL Behring, Inc. (CSL Behring) submitted a proprietary name review request for their recombinant single-chain coagulation factor VIII (rVIII-Single Chain) product. The proposed indication is the control and prevention of bleeding episodes in adult and adolescent patients with hemophilia A (congenital Factor VIII deficiency), routine prophylaxis to prevent or reduce the frequency of bleeding episodes, and perioperative management.

The primary proposed proprietary name is (b) (4), and its intended pronunciation is (b) (4). The alternative proposed proprietary name is **AFSTYLA**, and its intended pronunciation is af- styeh- lah. CSL Behring contracted with the (b) (4) to conduct nomenclature research on the proposed proprietary names, (b) (4) and **AFSTYLA**.

The product will be available as a 250 IU, 500 IU, 1000 IU, 2000 IU, and 3000 IU lyophilized reconstitutable powder for injection and will be administered intravenously twice per week as prophylaxis. Prior to reconstitution, it may be stored at 2°C to 8°C (36°F to 46°F). The reconstituted product may be stored at 2°C to 8°C (36°F to 46°F) or at room temperature, not to exceed 25°C (77°F), for up to 4 hours. It will be dispensed in hospital pharmacies and specialty pharmacies for use in clinics and homes.

### **Method**

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) and the following databases:

1. CBER list of Licensed Biological Products at <http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm>
2. DailyMed at <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
3. Drugs@FDA current through July 07, 2015 at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
4. Electronic Orange Book current through July 07, 2015 at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>
5. Google Internet search at <http://www.google.com>
6. Micromedex at <http://www.micromedexsolutions.com/micromedex2/librarian>
7. United States Patent and Trademark Office (USPTO) at <http://www.uspto.gov/trademarks/index.jsp>

APLB also consulted the review team for input. No issues/concerns were raised.

## **Results**

### **1. Prescreening for Objectionable Naming Practices**

The proposed names, (b) (4) and AFSTYLA, were screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
  - Use of numerals as modifiers
  - Device-related modifiers
  - Descriptive modifiers
- Brand name extensions (Umbrella branding)
- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the sponsor's name

### **2. Evaluating for Promotional and Safety Concerns**

#### **a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]**

The two syllables in the proposed proprietary name are (b) (4). Thus, (b) (4) may be regarded as misleading or fanciful because it can imply that it is the only product with a single chain structure, when that is not the case. There are many recombinant products with single chain structure, and there are other single chain recombinant blood factors (e.g., ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein]).

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

**b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]**

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or established names sound or look alike. APLB conducted a search using POCA, with DPRF, Drugs at FDA, and RxNorm as data sources, to identify names with potential similarity to **AFSTYLA**.

The combined orthographic and phonetic moderately similar matches are listed below:

**Results**

Proposed name: <b>AFSTYLA</b> – kit containing a single-dose vial (250IU, 500IU, 1000IU, 2000IU, 3000IU)			
Name of Concern	Match Percentage Score	Dosage Form and Strength	Notes
AFTERA	61	1.5 mg Tablet	
SKYLA	60	Intrauterine device	
AFEMTRA	58	Oral contraceptives	Abandoned name
ALUSTRA	58	Topical cream 4%	
KADCYLA	57	Lyophilized powder in single-use vials containing 100 mg per vial or 160 mg per vial	
ASCLERA	51	0.5% and 1% solution in 2 mL glass ampules	
AMPYRA	50	10 mg Tablet	
ANTARA	50	30 mg or 90 mg Capsule	

Data Source: DPRF, Drugs at FDA, and/or RxNorm

Because the differences in dose and strength may decrease the risk of confusion among two or more moderately similar products, APLB reviewed the above names for similarity in dose and strength to **AFSTYLA** and found that the above products, while similar, do not share a common dose or strength.

**Recommendation**

APLB recommends that the proposed proprietary name, **AFSTYLA**, be found acceptable at this time.

If you have any questions regarding this review please contact Michael Brony, Pharm.D, Regulatory Review Officer, at 240-402-8898.

Firm name: (b) (4)

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