

**MEMORANDUM**

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

Date: July 10, 2007

From: Maryann R. Gallagher, Consumer Safety Officer *mg*  
Advertising and Promotional Labeling Branch (HFM-602)  
Division of Case Management

Through: Ele Ibarra-Pratt, Branch Chief, APLB (HFM-602) *for the Division Chief*  
Robert A. Sausville, Director, DCM (HFM-610)

To: Nisha Jain, MD, OBRR/DH/CRB, (HFM-392)  
Mark Shields, RPM, DBA/OBRR, (HFM-380)

Subject: Review of Proposed Proprietary Name WILATE/WILNATIV (Human Von Willebrand factor and Human coagulation factor VIII)  
BLA 125251

Recommendation: WILATE - ACCEPTABLE  
WILNATIV - UNACCEPTABLE

**Executive Summary:**

APLB recommends that the proposed proprietary name WILATE (Human Von Willebrand factor and Human coagulation factor VIII) is found Acceptable and WILNATIV (Human Von Willebrand factor and Human coagulation factor VIII) is found Unacceptable.

**Background:**

On May 7, 2007, Octapharma submitted a request to the FDA Center for Biologics Evaluation and Research (CBER) Advertising and Promotional Labeling Branch (APLB) to review the two proposed proprietary names WILATE/WILNATIV (Human Von Willebrand factor and Human coagulation factor VIII). This request was submitted as an amendment to the WILATE (Human Von Willebrand factor and Human Coagulation Factor VIII) BLA.

The sponsor performed a trademark search and filed the trademark on September 9, 2006. No objections were filed and the proprietary names were registered on November 28, 2006.

**Rationale for use of the proprietary names:**

The sponsor's rationale for choosing WILATE

- "WIL" stems from Willebrand factor
- "ATE" refers to coagulation factor VIII

The sponsor's rationale for choosing WILNATIV

- "WIL" stems from Willebrand factor
- "NATIV" refers to the fact that during the manufacturing, the native VWF/FVIII complex has been purified to a 1:1 ratio.

**Overview of the Proposed Indication, Dose, Dosage Form, Administration, and Storage Information:**

WILATE/WILNATIV is a human plasma-derived, stable, high purity, double virus inactivated concentrate of freeze-dried FVIII and VWF. It is prepared using cryoprecipitate harvested plasma collected in the U. S. and is supplied as a powder for reconstitution and intravenous injection. WILATE/WILNATIV is indicated in adult and pediatric patients for the treatment of spontaneous and trauma-induced bleeding episodes in severe Von Willebrand disease (VWD), and in mild and moderate VWD where use of DDAVP (1-deamino-8-D-arginine vasopressin/desmopressin) treatment is ineffective or contraindicated.

(b)(4)  
(b)(4) The recommended dosage of WILATE/WILNATIV is based on the bleeding severity and varies between 20-60 IU/kg body weight (BW) and a maintenance dose of 20 b(4) IU/kg every 12-24 hours by intravenous infusion in a hospital setting, doctor's office, or self-administered. The product may be stored for 24 months at +2°C to +8°C (36°F to 46°F) and protected from light. Within this period WILATE/WILNATIV may be stored at any time 6 months at room temperature (max. temperature not to exceed +25° C /77° F); however, the shelf-life expires after storage at room temp +25° C /77° F.

**Proposed Proprietary Name Evaluation**

**1) False or Misleading [21 CFR 201.6 (a)]:**

The proposed proprietary name WILATE is not regarded to be false or misleading, however the proposed proprietary name WILNATIV is regarded to be false or misleading because it includes the inappropriate use of a roman numeral "IV" and the suffix also represents the route of administration.

**2) Fanciful [21CFR 201.10 (c)(3)]:**

A proprietary name would be found unacceptable if it were fanciful and implied that the product had some unique effectiveness. This product is a combination of Human Von Willebrand factor and Human coagulation factor VIII. The proposed proprietary names WILATE and WILNATIV are not regarded to be fanciful and do not imply a unique composition, advanced formulation, or superiority over existing products beyond that supported by the data.

**3) Similarity in Spelling or Pronunciation [21 CFR 201.10 (c) (5)]:**

APLB has not identified any proprietary names with similarity in spelling and pronunciation with the proposed proprietary name WILATE and WILNATIV.

**Recommendations:**

APLB recommends that the proposed proprietary names WILATE be found acceptable and WILNATIV be found unacceptable.

If OBRR accepts our recommendation that the proposed proprietary names WILATE be found acceptable and WILNATIV be found unacceptable, please include the following text in your letter to the manufacturer:

We have considered your proposed proprietary names WILATE and WILNATIV in consultation with CBER's Advertising and Promotional Labeling Branch (APLB) and conclude that under 21 CFR Part 201 the proposed proprietary names WILATE be found acceptable and WILNATIV be found unacceptable.

If you have any questions regarding this review, please contact Maryann Gallagher at 301-827-6330.

The following references were used:

1. <http://www.thomsonhc.com/pdref/librarian> (Electronic Physicians' Desk Reference 2007)
2. <http://www.fda.gov/cder/ob> (Electronic Orange Book) through January 2007.
3. <http://www.rxlist.com> (RxList)
4. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (CDER approved drug products through February 5, 2007)
5. <http://www.factsandcomparisons.com/cfacts.asp> (Drug Facts and Comparisons)
6. <http://www.ama-assn.org/ama/pub> American Medical Association Website-Newly Approved USAN stems through January 26, 2007.
7. <http://www.fda.gov/cber/products/nm> (CBER New BLA, 510(k) Devices, NDA and PMA approvals lists through February 5, 2007.
8. APhA Handbook of Nonprescription Drugs, 13th Edition, ©2002
9. 2002 American Drug Index.