*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 19, 2016

From: Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer
OCBQ/DCM/APLB

Through: Lisa Stockbridge, Ph.D., Branch Chief
OCBQ/DCM/APLB

Robert A. Sausville, Division Director
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To: Lorraine Wood, RPM, OMPT/CBER/OBRR/RPMS
Victor Baum, Medical Officer, OMPT/CBER/OBRR/DHCR/HPRB

Subject: Review of Proposed Proprietary Name "**FIBRYNA**" (fibrinogen concentrate (Human))
BLA: 125612

Sponsor: Octapharma USA Inc.

Recommendation: **FIBRYNA – Acceptable**

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**Executive Summary**

APLB has completed the review of the proposed proprietary name, **FIBRYNA**, a human fibrinogen concentrate indicated for the treatment of acute bleeding episodes (b) (4) in adult and pediatric patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. We recommend that the name **FIBRYNA** be found **Acceptable.**

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 a proposed proprietary name. To meet the PDUFA performance goal, OBRR must communicate this decision to the sponsor within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is September 7, 2016.

If OBRR accepts our recommendation that the proposed proprietary name, **FIBRYNA**, be found unacceptable, we offer the following communication-ready language:

> *In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, **FIBRYNA**, is **Acceptable**.*

OBRR is responsible for communicating CBER's decision to the sponsor and should enter the communication issuance date into RMSBLA before September 7, 2016, in order to meet the deadline and stop the performance clock. In this case of an unacceptable name, it is desirable to inform the sponsor as soon as possible following review. Please notify APLB when this action has been completed.

## Background

On June 9, 2016, Octopharma USA, Inc. (Octopharma) submitted a PNR request for its proposed human fibrinogen agent (BLA 125612). A Drug Safety Institute (DSI) Proprietary Name Safety Evaluation was conducted on December 28, 2015. The proposed proprietary name, **FIBRYNA**, is pronounced fye bri' nah. According to the sponsor, **FIBRYNA** is derived from the nonproprietary name.

**FIBRYNA**'s proposed indication is the treatment of acute bleeding episodes (b) (4) in adult and pediatric patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. It will be available as a 1 g/vial reconstitutable powder for injection. The initial dose, 70 mg/kg body weight, will be a single intravenous infusion. Following the initial dose, subsequent doses should be given to maintain a target level of 1.5g/l. Dose and frequency of administration will vary with the patient, dependent on management of bleeding and functional fibrinogen levels.

**FIBRYNA** can be stored for up to 24 months from the date of manufacture at 2°C to 25°C (36°F to 77°F). It must be protected from light. The product will be dispensed from a hospital pharmacy and administered in a hospital or clinic under the supervision of a physician.

## Method

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

1. CBER list of Licensed Products ending June 30, 2016, at http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149970.pdf
2. DailyMed at http://dailymed.nlm.nih.gov/dailymed/about.cfm
3. Drugs@FDA current through June 30, 2016, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda
4. Electronic Orange Book current through June 30, 2016, 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-application-process/search-trademark-database
8. USAN Stem List accessed on June 30, 2016.

## Results

### 1. Prescreening for Objectionable Naming Practices

The proposed proprietary name, **FIBRYNA**, was 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 proposed proprietary name, **FIBRYNA**, is not regarded as fanciful or misleading.

### 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 searches using POCA, with Drugs@FDA, RxNorm, Orange Book, and names entered by evaluators as data sources, to identify names with potential similarity to the proposed name, **FIBRYNA**. Any name with a combined match percentage score greater than 70% is considered to be "highly similar," and names between 50% and 69% is considered to be "moderately similar."

The search yielded one name, FYBRANTA, was considered highly similar, with a POCA score of 70, while131 names were considered moderately similar. FYBRANTA (bran and calcium phosphate), supplied as an oral tablet, is used as a stool softener for the treatment of constipation. It is highly unlikely that this would be used in the same setting as FIBRYNA.

The moderately similar names are not a cause for concern because they do not share a similar dose, dosage form, or strength with FIBRYNA.

**Recommendation**

APLB recommends that the proposed proprietary name, **FIBRYNA**, be found **Acceptable.**

If you have any questions regarding this review please contact Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer, at 240-402-8930.