



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125612/0

PROPRIETARY NAME ACCEPTABLE

Octapharma Pharmazeutika Produktionsges.m.b.H
Attention: Mr. Stanley Ammons
Octapharma USA Inc.
121 River Street Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

We have reviewed your June 9, 2016, submission to your Biologics License Application (BLA) for Human Fibrinogen, requesting a proprietary name review for FIBRYNA.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, FIBRYNA is Acceptable.

If you have any questions, please contact Lorraine Wood at (240) 402-8439 or lorraine.wood@fda.hhs.gov.

Sincerely yours,

Howard Chazin, MD, MBA
Acting Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research