



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 22, 2015

BLS APPROVAL LETTER

Our STN: BL 101130/5723

Grifols Therapeutics, Inc.
Attention: Ms. Joan Robertson
8368 US 70 Business Highway West
Clayton, NC 27520

Dear Ms. Robertson:

We have approved your request to supplement your biologics license application for Antihemophilic Factor (Human) [KOATE-DVI] to support the use of Mix2Vial™ as an alternative to filter and transfer needles to aid in the reconstitution of Antihemophilic Factor (Human) along with assignment of new National Drug Code numbers and revisions to the product labeling.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h and Form FDA 2567 as appropriate.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled, "SPL Standard for Content of Labeling Technical Qs and As at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely,

/s/

for

Basil Golding, MD

Director

Division of Hematology Research and Review

Office of Blood Research and Review

Center for Biologics Evaluation and Research