DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125351/172

BLS APPROVAL LETTER

August 5, 2015

Takeda Pharma A/S
Attention: Ms. Valerie Tews
Takeda Development Center Americas, Inc.
One Takeda Parkway
Deerfield, IL 60015

Dear Ms. Tews:

This letter supersedes the approval letter issued on July 15, 2015 which did not state the fulfillment of your Pediatric Research Equity Act (PREA) Post Marketing Requirement.

We have approved your request to supplement your biologics license application for Fibrin Sealant Patch [TachoSil], to include changes to the Full Prescribing Information (FPI) to expand the indication to include results from Study TC-2402-040-SP, entitled, "A Randomized, Open-Label, Parallel Group, Multi-Center Trial to Compare the Efficacy and Safety of TachoSil® versus Surgicel® Original for the Secondary Treatment of Local Bleeding in Adult and Pediatric Patients Undergoing Hepatic Resection Surgery" throughout the relevant sections of the FPI.

The review of this product was associated with the following National Clinical Trial (NCT) number: NCT01192022.

Please refer to your June 20, 2014 submission addressing post marking requirement #1 identified in the April 5, 2010 approval letter of STN BL 125351/0. The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA for use of TachoSil as an adjunct to hemostasis in pediatric patients 0-16 years undergoing hepatic resection surgery.

   Final Report Submission: December 2012

We have completed the review of your submission and find that this requirement has been fulfilled.

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.

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,

Paul D. Mintz, MD
Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research