



OUR STN: BL 125329/151

**SUPPLEMENT APPROVAL**

February 6, 2017

Bio Products Laboratory  
Attention: Ms. Benedicte Deloux  
Dagger Lane  
Elstree, Hertfordshire, Hertford WD6 3BX  
United Kingdom

Dear Ms. Deloux:

We have approved your request dated April 8, 2016, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Immune Globulin Intravenous (Human), 5% Liquid to include a 10% formulation to treat Primary Humoral Immunodeficiency and Chronic Immune Thrombocytopenic Purpura.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 01963143.

## **LABELING**

We hereby approve the draft package insert labeling submitted under amendment 15, dated January 25, 2017, and the draft carton and container labeling submitted on April 8, 2016.

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 BLA 125329/0 at the time of use (prior to marketing) and include implementation information on Form FDA 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 *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 Form FDA 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 advertising 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.

### **PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B**

We acknowledge your written commitment as described in your correspondence of January 25, 2017, as outlined below:

BPL commits to re-validate the (b) (4) assay to further (b) (4) and re-evaluate both test specifications after (b) (4) new lots or (b) (4). BPL will submit the (b) (4) assay validation and re-evaluation of the (b) (4) specifications as a PMC submission- Final Study Report by September 1, 2019.

Final Report Submission: September 1, 2019.

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLA 125329/0. Please refer to the sequential number for each commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a **Postmarketing Study Commitment – Status Update**. The status report for each commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- describe what has been accomplished to fulfill the non-section 506B PMC; and,
- summarize any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment – Final Study Report**.

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

Sincerely,

Wilson W. Bryan, MD  
Director  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research