DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125329/112

**BLS APPROVAL LETTER**

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

Dear Ms. Deloux:

We have approved your request to supplement your biologics license application for Immune Globulin Intravenous (Human), 5% Liquid (Gammaplex), for the indication of "the treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years of age and older" and to include the revision of the package insert to reflect the pediatric age groups two years and older studied in the postmarketing study (GMX04).

Please refer to your September 29, 2014 submission addressing post marketing requirement #1 identified in the September 17, 2009 approval letter for STN 125329/0. The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA for the treatment of primary humoral immunodeficiency in pediatric patients >2 to 16 years of age : A Phase 3, Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Gammaplex® in Primary Immunodeficiency Diseases in Children and Adolescents.

   Besides safety and efficacy endpoints, the study design should include pharmacokinetic evaluation in both the children (>2 to <12 years of age) and adolescent (>12 to 16 years of age) age groups.

   Protocol Submission: November 2009
   Study Initiation: January 2010
   Study Completion: September 2012
   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