Our STN: BL 103788/5341

SUPPLEMENT APPROVAL
May 8, 2017

BTG International Inc.
Attention: Ms. Andreia Collier, MSc
Five Tower Bridge Suite 800
300 Barr Harbor Drive
West Conshohocken, PA 19428

Dear Ms. Collier:

We have approved your request dated July 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 Crotalidae Polyvalent Immune Fab (Ovine) to modify the package insert with new information from pediatric and geriatric subgroup analyses from a retrospective medical chart review (Protocol MC03/03/05).

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT00363116, and NCT00927381.

LABELING

We hereby approve the draft package insert labeling submitted on May 5, 2017.

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 your BLA, STN BL 103788 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.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

We will include information contained in the above-referenced supplement in your Biologics License Application file.

Sincerely,

Tejashri Purohit-Sheth, M.D., FACAAI
Director
Division of Clinical Evaluation and
Phamacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research