Our STN: BL 125389/300

SUPPLEMENT APPROVAL/
PMR FULFILLED
December 8, 2023

ADMA Biologics, Inc.
Attention: James Maloney
Senior Director, Regulatory Affairs
5800 Park of Commerce Boulevard, N.W.
Boca Raton, FL 33487

Dear Mr. Maloney:

We have approved your request received February 9, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Intravenous (Human), 10% Liquid [BIVIGAM] to:

1. Submit the Final Study Report for the Required Pediatric Assessment as required in Postmarketing Requirement #1 in your December 19, 2012 BLA approval letter (STN BL 125389/0) and

2. Revise the prescribing information to expand the primary humoral immunodeficiency (PI) indication to pediatric patients 2 years of age and older, update relevant sections with pediatric data from the pediatric studies, and ensure compliance with the Pregnancy and Lactation Labeling Rule (PLLR).

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT03164967.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 14, dated December 6, 2023.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on December 6, 2023. 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.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125389/300 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

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 [this][these] change(s).

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement (PMR) #1 identified in the December 19, 2012 approval letter for STN BL 125389/0 for Immune Globulin Intravenous (Human), 10% Liquid. The requirement addressed in this submission is as follows:

1. A Phase IV, Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of BIVIGAM in Primary Immune Deficiency Disorders in Children and Adolescents ages 2 to 16.

Final Protocol Submission: July 2013

Study Completion Date: July 2017

Final Report Submission: October 2017

Revised Final Report Submission: December 31, 2022

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.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research