U.S. FOOD & DRUG ADMINISTRATION

SUPPLEMENT APPROVAL
September 11, 2023

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

Dear Mr. Maloney:

We have approved your requests received May 12, 2023, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to store product up to 4 weeks within the first 24 months of shelf-life at ≤ 25° C (77° F), and after 24 months, product may be stored up to 2 weeks at ≤ 25° C (77° F) until expiry, for the following products:

STN	Name of Biological Products
BL 125590/133	Immune Globulin Intravenous, Human-slra
BL 125389/309	Immune Globulin Intravenous (Human)

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment #3, dated August 29, 2023, and the draft carton and container labels submitted under amendment #3, dated August 29, 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 August 29, 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 29, 2023, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to these BLAs, STN BL 125590 and STN BL 125389 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 these changes.

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

We acknowledge your written commitments as described in your correspondence of August 29, 2023, as outlined below:

1. ADMA commits to placing additional lots of BIVIGAM 100 mL vial size filled at the (b) (4) into a stability monitoring study, specifically evaluating storage at (b) (4) for four weeks just prior to the expiration date of 36 months. ADMA further commits to submitting a PMC Submission – Final Study Report by March 31, 2024.

   Final Report Submission: March 31, 2024

2. ADMA commits to continuing the ongoing stability study for the available ASCENIV lots under stability protocol, SP-DF-3117 V.2 to evaluate storage at (b) (4) for four weeks just prior to the expiration date of 36 months. ADMA further commits to submit a PMC Submission – Final Study Report by June 30, 2024.

   Final Report Submission: June 30, 2024

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLAs, STN BL 125590 and BL 125389. 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 – Correspondence 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 – Correspondence 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**.

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Dorothy Scott, MD
Acting Director
Division of Plasma Derivatives
Office of Plasma Protein Therapeutics
Office of Therapeutic Products
Center for Biologics Evaluation and Research