SUPPLEMENT APPROVAL
March 1, 2024

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

Dear James Maloney:

We have approved your request received February 2, 2024, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act, to extend the approved 4-week room temperature (≤ 25 ºC) storage conditions during the first 24 months of shelf life, to allow a 4-week room temperature (≤ 25 ºC) storage at any time during the 36-month approved shelf life, for the following products:

STN	Name of Biological Products
BL 125590/155	Immune Globulin Intravenous, Human-slra
BL 125389/324	Immune Globulin Intravenous (Human)

LABELING

We hereby approve the draft content of labeling Package Insert submitted on February 2, 2024, for BIVIGAM, and Package Insert submitted under amendment #1 dated February 27, 2024, for ASCENIV, and the draft carton and container labels submitted on February 2, 2024.

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 February 2, 2024 for BIVIGAM and February 27, 2024 for ASCENIV. 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.

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

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on February 2, 2024, 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 this BLA, STN BL 125590 and 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)).

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

Sincerely,

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