



Our STN: BL 125590/190

SUPPLEMENT APPROVAL
PMR FULFILLED
April 30, 2026

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

Dear James Malony:

We have approved your request received June 30, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Intravenous, Human-sra, (ASCENIV) to fulfill the required pediatric assessment for ASCENIV per STN BL 125590/0, and to expand the label to include pediatric patients 2 to 11 years of age for the treatment of primary humoral immunodeficiency, based on the data from the pediatric study ADMA-004.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT05070455

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 11, dated April 29, 2026.

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 April 29, 2026. 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 125590 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR#1 identified in the April 1, 2019, approval letter for BLA STN BL 125590/0 for Immune Globulin Intravenous, Human-slr. The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA for the treatment of primary immunodeficiency in pediatric patients ages 2 to 12 years.

Final Protocol Submission: December 31, 2019

Study Completion Date: December 31, 2022

Final Report Submission: June 30, 2023

New Final Report Submission: June 30, 2026

This completes all of your PMR(s) and PMC(s). As such, your **Annual Status Report of Postmarketing Requirements/Commitments** is no longer required until such time a new Requirement or Commitment subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act is issued.

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 ages 2 to 12 years for this application.

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

Sincerely,

Patroula Smpokou MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research