Our STN: BL 125587/70

SUPPLEMENT APPROVAL
February 11, 2021

Octapharma Pharmazeutika Produktionsges.m.b.H
Attention: Stanley Ammons
Octapharma USA.
117 West Century Rd.
Paramus, NJ 07652

Dear Mr. Ammons:

We have approved your request submitted and received April 21, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Immune Globulin Intravenous (Human)-ifas 10% [Panzyga®] to include the following:

1. a new indication for the treatment of adults 18 years of age and older with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment, and

2. to remove the distinction between new and experienced patients in section 2.1 in the prescribing information label.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 02638207.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert labeling submitted under amendment 8 January 28, 2021.

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. 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.

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.

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 are waiving the pediatric study requirement for children birth to less than 2 years of age years because the necessary studies are impossible or highly impracticable due to low prevalence.

We are deferring submission of your pediatric study for children 2 to less than 17 years of age years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Study Requirement (PMR)** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125587/0 until all requirements and commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. In your PREA PMR study, please include assessment of the percentage of subjects with excellent response, defined by modified Rankin scale of 0 or 1 in each arm as a key secondary endpoint. This required study is listed below:

1. Deferred pediatric study studies under PREA for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in pediatric patients ages 2 to 17 years of age.

   Final Protocol Submission: June 30, 2021

   Study Completion Date: June 30, 2025

   Final Report Submission: December 31, 2025

Submit the protocol to your IND 14096, with a cross-reference letter to BLA STN BL 125587/0 explaining that this protocol was submitted to the IND.

Submit final study reports to this BLA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as:

- **Required Pediatric Assessment**

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

We acknowledge your written commitments as described in your correspondence of February 5, 2021, as outlined below:

2. Octapharma commits to develop and validate an (b) (4) assay as a lot release test, such as (b) (4) , and to propose a release specification.

Octapharma will submit a Prior Approval Supplement (PAS) with the validated test method and a proposed release specification based on (b) (4) lots of Panzyga tested latest by April 30, 2022.

Final Report Submission: April 30, 2022

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLA, STN BL 125587/0. 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 – 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 – 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 supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation
and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research