



Our STN: BL 125039/1078

**SUPPLEMENT APPROVAL**

December 20, 2022

Baxalta US Inc.  
Attention: Dani Sweeney  
650 East Kendall Street  
Cambridge, MA 02142

Dear Ms. Sweeney:

We have approved your request received June 22, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Alpha-1-Proteinase Inhibitor (Human) [ARALAST NP] to update the Reconstitution and Administration sections of the United States Prescribing Information (USPI) to include clear handling and pooling instructions.

## **LABELING**

We hereby approve the draft content of labeling Package Insert submitted under amendment 3, dated December 16, 2022, and the draft carton submitted under amendment 2, dated December 14, 2022.

## **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 16, 2022. 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.

## **CARTON**

Please electronically submit final printed carton identical to the carton submitted on December 14, 2022, 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 125039/0 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.

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

Sincerely,

Basil Golding, MD  
Director  
Division of Plasma Protein Therapeutics  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research