Our STN: BL 125488/107

SUPPLEMENT APPROVAL
PMC FULFILLED
April 1, 2021

Rare Disease Therapeutics, Inc.
Attention: Michelle Taylor
12975 Brookprinter Place, Suite 170
Poway, CA 92064

Dear Ms. Taylor:

We have approved your request submitted and received September 30, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Crotalidae Immune F(ab')2 (Equine) [Anavip®] to fullfill postmarketing commitment (PMC) #6 (potency release specifications for the 3 additional North American snake species) listed in the approval letter for BLA STN BL 125488, and to provide a new label to reflect the expanded indication of Anavip® to include all North American Pit Vipers.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 12, dated March 26, 2021, and the draft carton and container labels submitted under amendment 6, dated March 12, 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. Content of labeling must be identical to the Package Insert submitted on March 26, 2021. 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 AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on March 12, 2021, 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 125488 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.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your PMC #6 identified in the May 6, 2015, approval letter for STN BLA 125488/0 for Crotalidae Immune F(ab')2 (Equine). The commitment addressed in this submission is as follows:

STN BL 125488/0

PMC #6: Bioclon commits to provide the proposed potency release specifications for the three additional North American snake species. The revised lot release specifications and the final study report will be submitted as a BLA supplement by May 31, 2018.

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.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

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

We acknowledge your written commitment as described in your correspondence of March 24, 2021 as outlined below:

1. Rare Disease Therapeutics, Inc. (RDT) and Instituto Bioclon/Silanes commit to reevaluate the potency specifications for *B. asper*, *C. simus* (formerly *C. durissus*), *C. adamanteus*, *C. atrox*, *C. scutulatus*, *A. contortrix* and *A. piscivorus* after (b) (4) additional Anavip lots are manufactured. The Reevaluation Report will be submitted as a Postmarketing Commitment-Final Study Report, by December 31, 2026. If you decide to change the potency specifications, a PAS will be submitted containing the change request and the final study report, by December 31, 2026. If a PAS is submitted, this PMC should be referenced in the cover letter.

   Final Report Submission: December 31, 2026

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLA, STN BL 125488/0. 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,

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