Our STN: BL 103931/5265 **SUPPLEMENT APPROVAL**

Sanofi Pasteur SA
Attention: Michael F. Stirr October 25, 2019
Discovery Drive
Swiftwater, PA 18370-0187

Dear Mr. Stirr:

We have approved your request submitted June 28, 2019, received June 28, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Rabies Vaccine (IMOVAX®) (b) (4) manufacturing and batch control operations to a contract manufacturer site, (b) (4) with the following changes:

- (b) (4)
- Revision of the *Dosage and Administration* section of the package insert and revised NDCs.

LABELING

We hereby approve the draft package insert and carton labeling submitted under amendment 5003, dated October 23, 2019 and the draft container labeling submitted under amendment 5001, dated October 15, 2019.

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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on June 28, 2019, 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 103931 at the time of use (prior to marketing) 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.

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

We acknowledge your written commitment as described in your correspondence of October 23, 2019 as outlined below:

1. Sanofi commits to performing a validation study using the (b) (4) method with (b) (4) for the container closure integrity test (CCIT) for the stability program of the Rabies Vaccine (IMOVAX®) Sterile Water (diluent for reconstitution) container closure system. The study will include using positive controls with defect sizes that approach a critical leak defect size and providing sensitivity data demonstrating that the method can achieve this level of detection.

   Final Report Submission: October 31, 2020

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your BLA STN BL 103931. Please refer to the sequential number for each commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to this postmarketing study commitment 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;
- a description of what has been accomplished to fulfill the non-section 506B PMC; and,
- a summary of 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,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccine
Research and Review
Center for Biologics
Evaluation and Research