



Our STN: BL 103334/5402

SUPPLEMENT APPROVAL

Bavarian Nordic A/S
Attention: Arden Tesmer
Bavarian Nordic Inc.
1005 Slater Rd, Suite 101
Durham, NC 27703

October 3, 2023

Dear Ms. Tesmer,

We have approved your request received April 3, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Rabies Vaccine (RabAvert) manufactured at (b) (4) (b) (4) to revise the carton label, freeze-dried vaccine vial label and sterile diluent pre-filled syringe label to incorporate a new design, and to update the manufacturer and US license number in the Package Insert.

LABELING

We hereby approve the draft content of labeling for the Package Insert submitted under amendment 6, dated October 3, 2023; the draft carton label submitted under amendment 2, dated September 26, 2023; and the draft container labels submitted under amendment 5, dated October 2, 2023.

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 October 3, 2023. 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 label submitted on September 26, 2023, and container labels submitted on October 2, 2023, 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 103334 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 the information contained in the above-referenced supplement in your BLA file.

Sincerely,

For David C. Kaslow, MD
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research