



Our STN: BLA 125820/0

MID-CYCLE COMMUNICATION
OCTOBER 9, 2024

Bavarian Nordic A/S
Attention: Todd Phillips
Bavarian Nordic Inc.
1005 Slater Road, Suite 101
Durham, NC 27703

Dear Dr. Phillips:

Based on the progress of the review, we do not have any substantive review issues to discuss at this time. If you do not have any questions, additional data, or analyses to discuss for this application, the Mid-Cycle meeting may be cancelled upon your request. Please inform us in writing within two business days if you would like to cancel this meeting. If not, please identify your topics for discussion at the Mid-Cycle meeting.

Please include a reference to STN 125820/0 in your future submissions related to Chikungunya Vaccine, Recombinant.

If you have any questions, please contact the Regulatory Project Managers, Georgeta Crivat, Ph.D. (Georgeta.Crivat@fda.hhs.gov), Vera Stupina, Ph.D. (Vera.Stupina@fda.hhs.gov), and Ms. Katherine Berkhausen (Katherine.Berkhausen@fda.hhs.gov), by email.

Sincerely,

Loris D. McVittie, Ph.D.
Director
Division of Review Management and
Regulatory Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research