



Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125820/0

From: Alicia Howard, Ph.D.
Lead Reviewer, LBVI/DBSQC/OCBQ

Through: Maryna Eichelberger, Ph.D.
Division Director, DBSQC/OCBQ

Sponsor: Bavarian Nordic A/S

Subject: Suitability of lot-release test methods for Chikungunya Vaccine,
Recombinant (VIMKUNYA) drug substance and drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of VIMKUNYA were reviewed by Karla Garcia (LMIVTS), Alicia Howard (LBVI), and Hsiaoling Wang (LAC). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their validations and/or qualifications reviewed for the VIMKUNYA drug substance and drug product were found to be adequate for their intended use.