LATE-CYCLE MEETING MATERIALS

Our STN: BL 125701/0

Sanofi Pasteur, Inc.
Attention: Michael F. Stirr
Discovery Drive
Swiftwater, PA 18370-0187

Dear Mr. Stirr:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for MENQUADFI [Meningococcal (Groups A, C, Y, and W) Polysaccharide Tetanus Toxoid Conjugate Vaccine], a sterile solution for intramuscular injection supplied in 0.5 mL single-dose vials.

Attached are our meeting materials, including our agenda, for the Late-Cycle Meeting (LCM) scheduled for January 7, 2020.

If you have any questions, please contact the Regulatory Project Managers, Mike Smith, PhD, Nikunj Sharma, PhD, and Ramachandra Naik, PhD, at 301-796-2640.

Sincerely,

Loris D. McVittie, PhD
Deputy Directory - Regulatory
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

ENCLOSURE:
Late-Cycle Meeting Materials

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Late-Cycle Meeting Materials

Meeting Date and Time:	January 7, 2019, 1:00 – 2:30 PM
Meeting Location:	Teleconference
Application Number:	STN 125701/0
Product Name:	MENQUADFI [Meningococcal (Groups A, C, Y, and W) Polysaccharide Tetanus Toxoid Conjugate Vaccine]
Indication:	Active primary and booster immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W in individuals 2 years of age and older
Applicant Name:	Sanofi Pasteur, Inc.

INTRODUCTION

The purpose of a Late-Cycle Meeting (LCM) is to share information and to discuss any substantive review issues that we have identified to date, and our objectives for the remainder of the review. The application has not yet been fully reviewed by the signatory authorities, division directors, and application Chair. Therefore, the meeting will not address the final regulatory decision for the application. We are sharing this material to promote a collaborative and successful discussion at the meeting. During the meeting, we may discuss additional information that could be submitted to address any identified issues. We may also discuss whether the submission of such information would be expected to trigger an extension of the PDUFA goal date if the Review Committee should decide, upon receipt of the information, to review it during the current review cycle.

Please note: if you submit any new information in response to the issues identified in this background package prior to this LCM , we may not be prepared to discuss that information at this meeting.

1. Substantive Review Issues to be discussed during the LCM

The following substantive review issues have been identified to date:

Drug Product expiry dating period: As communicated during the Mid-Cycle meeting, the expiry dating period for the Drug Product will depend upon the (b) (4) data, as well as the other stability data, submitted by the Applicant.

For inspections:
CBER will waive the inspections of both of the Swiftwater, PA and (b) (4) manufacturing sites/facilities.

BIMO Inspections are complete. A final recommendation is pending at this time.

Amendments: We acknowledge your amendment listed below. Our review of this amendment is ongoing and a final decision is pending.

Amendment Number	Received date	Information topic
Amendment 19	December 9, 2019	Response to November 19, 2019 tox-related Information Request (IR)
Amendment 20	December 17, 2019	Response to December 11, 2019 IR regarding number of MENQUADFI lots expected to be produced annually

2. Advisory Committee Meeting

An Advisory Committee meeting is not planned.

3. Risk Management Actions (e.g., REMS)

We have not identified any issues related to risk management. We do not believe that a risk management action (e.g., REMS) is needed at this time.

LCM AGENDA

1. Introductory Comments (RPM/Chair)

   Welcome, Introductions, Ground rules, Objectives of the meeting

2. Discussion of Substantive Review Issues

   Drug Product expiry dating period: As communicated during the Mid-Cycle meeting, the expiry dating period for the Drug Product will depend upon the (b) (4) data, as well as the other stability data, to be submitted by the Applicant.

3. Additional Applicant Data

   Drug Product expiry dating period: Stability data, to include information on (b) (4), that will be submitted in January and March 2020.

4. Outstanding Information Requests

Sent date	Information topic
December 6, 2019	Follow-up question regarding Sanofi's November 21, 2019, response to CBER's November 6, 2019 IR on bioburden test results
December 9, 2019	Product-related IR regarding Sanofi's plan for implementation of (b) (4) testing on Menquadfi DP for (b) (4) assessment on stability
December 16, 2019	Follow-up IR to Sanofi's November 14, 2019 responses to CBER's October 29, 2019 IRs regarding DS & DP chemical assays
December 17, 2019	Request for additional reagents for in support testing

5. Risk Management Actions (e.g., REMS)

   We have not identified any issues related to risk management. We do not believe that a risk management action (e.g., REMS) is needed at this time.

6. Postmarketing Requirements/Postmarketing Commitments

   We have not determined which study(ies) will be considered PMCs and/or PMRs at this time. Decisions on PMCs/PMRs will be communicated to you by March 26, 2020.

7. Major labeling issues

   The MENQUADFI package insert (PI), outer carton and container labels are being reviewed. Any issues or comments on these labels will be communicated to you by March 26, 2020.

8. Review Plans

   First Action Due Date: April 25, 2020.

9. Applicant Questions

10. Wrap-up and Action Items