LATE-CYCLE MEETING MATERIALS
February 25, 2022

Our STN: BL 125748

GlaxoSmithKline Biologicals
Attention: Michael P. Schwartz, Ph.D.
1250 South Collegeville Road
Collegeville, PA 19426

Dear Dr. Schwartz:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Priorix (Measles, Mumps and Rubella Virus Vaccine, Live), a suspension for subcutaneous injection (0.5 ml per dose) supplied as a single-dose vial of lyophilized vaccine to be reconstituted with the accompanying prefilled syringe of sterile water diluent.

Attached are our meeting materials, including our agenda, for the Late-Cycle Meeting (LCM) scheduled for March 3, 2022, 10:30 AM to 11:30 AM.

If you have any questions, please contact the Regulatory Project Managers, Julianne Clifford, Ph.D. (Julianne.Clifford@fda.hhs.gov) and Nikunj Sharma, Ph.D. (Nikunj.Sharma@fda.hhs.gov), via email or at (301) 796-2640.

Sincerely,

Loris D. Mcvittie -S

Digitally signed by Loris D. Mcvittie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000647881, cn=Loris D. Mcvittie -S
Date: 2022.02.25 17:01:07 -05'00'

Loris D. McVittie, Ph.D.
Deputy Director – 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

Late-Cycle Meeting Materials

Meeting Date and Time:	March 3, 2022, 10:30 – 11:30 AM
Meeting Location:	Teleconference
Application Number:	BLA STN 125748/0
Product Name:	PRIORIX (Measles, Mumps and Rubella Virus Vaccine, Live)
Indication:	For active immunization for the prevention of Measles, Mumps and Rubella in individuals 12 months of age and older
Sponsor/Applicant Name:	GlaxoSmithKline Biologicals

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

At this time, we do not have any substantive review issues.

For inspections: BIMO inspections are complete but facility inspections are ongoing. A final recommendation is pending at this time. However, if we learn of any issues from the ongoing facility inspections, the agenda will be modified accordingly.

Amendment: We acknowledge your amendment 20 submitted/received February 11, 2022. A review of this amendment is ongoing.

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. Information Requests

   Outstanding IRs:

   November 10, 2021 validation data for uKF method. Expected response in March 2022.

   December 21, 2021 regarding URRA. Expected in March 2022.

   February 15, 2022 regarding solicited adverse reactions. Submission targeted for March 11, 2022.

   February 16, 2022 regarding CMC serology (bacterial assays). Response submitted February 24, 2022. Under review.

   Feb 17, 2022 for statistical clarification. Status update will be provided by March 4, 2022.

   February 25, 2022, regarding CCIT, stability testing. Response requested by March 7, 2022.

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

   There is no anticipation of a REMS at this time.

4. Postmarketing Requirements/Postmarketing Commitments

   No indication of PMR/PMC at this time.

5. Major labeling issues

   The Priorix package insert (PI), outer carton and container labels are currently under review. Any comments or requests for revisions will be communicated no later than May 5, 2022.

6. Review Plans

   We are preparing an IR regarding DP/virological assays in early March. Additional IRs might be provided pending review of additional information expected to be submitted in the coming weeks.

If there are any PMC/PMR's they will be communicated to you by no later than May 5, 2022.

Action Due Date: June 3, 2022

7. Applicant Questions
8. Wrap-up and Action Items