Our STN: BL 125748/0

MID-CYCLE COMMUNICATION SUMMARY
December 9, 2021

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

Dear Dr. Schwartz:

Attached is a copy of the summary of your December 2, 2021 Mid-Cycle Communication Teleconference with CBER. This memorandum constitutes the official record of the Teleconference. If your understanding of the Teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to STN 125748/0 in your future submissions related to Measles, Mumps and Rubella Virus Vaccine, Live.

If you have any questions, please contact Regulatory Project Managers, Nikunj Sharma, Ph.D. (Nikunj.Sharma@fda.hhs.gov) and Julianne Clifford, Ph.D. (Julianne.Clifford@fda.hhs.gov).

Sincerely,

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

Mid-Cycle Communication Teleconference Summary

Application type and number:	BLA STN 125748/0
Product name:	Measles, Mumps and Rubella Virus Vaccine, Live
Proposed Indication:	For active immunization for the prevention of Measles, Mumps, and Rubella in individuals 12 months of age and older
Applicant:	GlaxoSmithKline Biologicals
Meeting date & time:	December 2, 2021
Committee Chair:	Luba Vujcic, M.S.
RPMs:	Nikunj Sharma, Ph.D. and Julianne Clifford, Ph.D.

Attendees:

CBER
Julianne Clifford
Kirk Prutzman
Nikunj Sharma
Elizabeth Sutkowski
Meghan Maguire Thon
Luba Vujcic

Applicant (GSK)

Remon Abu-Elyazeed	Medical
Corine Lecomte	Global Regulatory Affairs
Michael Povey	Statistics
Didier Relin	Global Regulatory Affairs
Michael Schwartz	Global Regulatory Affairs
Christine Van Hoof	Global Regulatory Affairs
Eric Van Quaquebeke	Global Regulatory Affairs

Discussion Summary:

Agenda items:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.
   a. Clinical: None identified to date;
   b. CMC: None identified to date;
   c. Toxicology: None identified to date;
   d. Statistical: None identified to date;
   e. BIMO: None identified to date; and
   f. Facilities: None identified to date.

There was no additional discussion of this item during the telecon.

2. Information regarding major safety concerns.
   There are no major safety concerns identified at this time.

   There was no additional discussion of this item during the telecon.

3. Preliminary Review Committee thinking regarding risk management.
   The review of the Risk Management Plan is ongoing.

   There was no additional discussion of this item during the telecon.

4. Any information requests sent and responses not received.
   IR responses have been submitted on schedule to date.

   There was no additional discussion of this item during the telecon.

5. Any new information requests to be communicated.
   No new information requests are planned at this time.

   GSK stated that responses to several information requests, which have requested due dates of December 6, 7 or 8, 2021, are currently in preparation for submission. GSK inquired whether the responses for all these pending information requests, except for a few items from one request, could be provided as a single submission on December 10, 2021. The remaining response items would be submitted the following week on December 17. We replied that GSK's planned dates for submitting the responses to the information requests are acceptable.

6. Proposed date(s) for the Late-Cycle meeting (LCM).
   i. The LCM between you and the Review Committee will be scheduled for no later than Thursday, February 17, 2022;
   ii. We intend to send the LCM materials to you approximately 5 days in advance of the LCM date; and
   iii. If these timelines change, we will communicate updates to you during the course of the review.

   The Applicant asked if the LCM is mandatory or if it only occurs if there are significant review issues to discuss. The Applicant was advised that they would have the option to cancel the meeting after they receive the LCM agenda if no significant issues were identified.

7. This BLA will not be brought to the Vaccines and Related Biological Products Advisory Committee.

   There was no additional discussion of this item during the telecon.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.
   i. Initial labeling comments will be communicated no later than May 5, 2022;
   ii. Any postmarketing requirement/commitment requests will be communicated no later than May 5, 2022; and
   iii. First Action Due Date: June 4, 2022.

There was no additional discussion of this item during the telecon.

Additional discussions:

1. GSK referred to the November 24, 2021, information request for a Use-Related Risk Analysis (URRA) noting that they are discussing internally their approach to responding to this request and they may either submit a response based on experience with another product (b) (4) or provide new data for PRIORIX. The URRA for (b) (4) could be submitted as early as next week, but the latter would be available for submission in January or February 2022. GSK will advise CBER of their decision in the coming weeks.

2. GSK informed CBER that they are considering a proprietary name change from PRIORIX to (b) (4) . Dr. Schwartz had notified Dr. Clifford of this potential change in advance of the meeting and Dr. Clifford was able to consult with the lead labeling reviewer who provided the following points for GSK to consider:

   a. It is generally not advisable that a proprietary name be hyphenated because the parts after the hyphen are often dropped in practice;

   b. (b) (4) is currently included in the proper name of this product;

   c. Adding (b) (4) to the proprietary name may take up valuable space on the small vial and carton labels that could be used for important information;

   d. If the change is based upon a concern for potential medication errors, then changing the first portion of the name may provide a better way of addressing that concern than changing the latter portion of the proprietary name as mediations are listed alphabetically in directories and confusion or medication errors are more likely to occur due to similarities in the first part of the name;

   e. CBER would be very interested in knowing the rationale or justification for a name change; and

   f. If GSK decides to submit a request for a new Proprietary Name Review (PNR), it would be reasonable to expect the review to be complete within 90 days of submission.

In addition to the comments for consideration from the labeling reviewer, Dr. Prutzman added that including a hyphenated portion to a new proprietary name may raise questions or result in confusion since there is an FDA labeling guidance requirement to add a 4-letter suffix to non-proprietary product names but vaccines are currently exempt from this requirement. GSK stated that they will take into consideration all of these suggestions before they make their final decision whether to request another PNR or not.

3. GSK inquired about the scheduling of Prior Approval Inspections of manufacturing facilities and noted that while PRIORIX is not currently scheduled for production at the (b) (4) site within the review cycle of this BLA, there is another similar product scheduled for production at that site if CBER is open to viewing a similar product instead of MMR. We stated that this information will be shared with the inspection team and we will advise them that GSK is open to coordinating with them.