DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

FILING MEETING SUMMARY

To:	The file
Date and Time:	December 6, 2016, 11:00 AM - 12:00 PM
STN #:	125614/0
Submission Type:	BLA
Applicant:	GlaxoSmithKline Biologicals
Product:	Shingrix (Zoster Vaccine Recombinant, Adjuvanted)
Proposed indication:	Prevention of herpes zoster (shingles) in adults aged 50 years and older
Meeting Chair:	Carmen Collazo-Custodio, Ph.D.
Meeting recorders:	Ramachandra Naik, Ph.D. and Michael Smith, Ph.D.

1.0 PURPOSE AND BACKGROUND

BLA STN 125614/0 was submitted by GlaxoSmithKline Biologicals (GSK) on October 21, 2016, and received by CBER on October 21, 2016. The purpose of this meeting was to discuss the completeness of the BLA submission and ensure it is acceptable to file.

2.0 Review Committee and Discipline Filing Decision Summary

Review responsibility	**Committee Member**	Attended meeting	Fileable	RTF	Deficiencies Identified
Chairperson	Carmen Collazo	X	X		
Regulatory Project Manager	Ramachandra Naik	X	X		
Regulatory Project Manager	Michael Smith	X	X		
Clinical	Paula Agger	X	X		
Clinical	Rebecca Reindel	X	X		
Pharm/Tox	Nabil Al-Humadi	X	X		
Pharm/Tox	Claudia Wrzesinski	X	X		
Product	Shuang Tang	X	X		
Product	Marina Zaitseva	X	X		
Product, Consult assay reviewer	Hang Xie		X		
Product Quality	Simleen Kaur		X		
Product Quality	Tao Pan		X		
Product Quality	Noel Baichoo	X	X		
Product Quality	Marie Anderson	X	X		
Statistics, clinical and assays	Rong Fu	X	X		
Epidemiology/Pharmacovigilance	Ravi Goud	X	X		
DMPQ RPM	Debra Vause	X	X		

Review responsibility	**Committee Member**	Attended meeting	Fileable	RTF	Deficiencies Identified
DMPQ (Facilities, CCIT, Inspector) Reviewer	Jeremy Wally	X	X		
BIMO	Haecin Chun		X		
APLB Labeling and PNR reviewer	Oluchi Elekwachi	X	X		
Labeling	Daphne Stewart		X		

OTHER PARTICIPANTS

Wellington Sun	Meghan Ferris	Robin Levis
Douglas Pratt	Deepa Arya	Andrea Hulse
William McCormick	Elizabeth Sutkowski	Hana Golding

REGULATORY QUESTIONS:

1. **Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and will require a RTF letter?**
   The committee recommended that the application is suitable for filing. Signed Filing Checklists will be uploaded to the EDR.

2. **If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application**:
   The reviewers indicated that the submission is complete for their reviews. Some deficiencies were identified and it was agreed to resolve them through Information Requests (IRs).

3. **If RTF, list any issues that would make this application unsuitable for filing?**
   NA

FILING MEETING DISCUSSION, IF FILED:

4. **Indicate any comments on the status of the proprietary name review.**
   APLB reviewer (Oluchi Elekwachi) recommended that the proposed proprietary name, **SHINGRIX**, is acceptable (refer to Memo dated November 22, 2016).

5. **Indicate whether the product sh/would be subject to lot release, surveillance, or exempt from lot release.**
   The product is subject to lot release, and CBER/OCBQ/DBSQC sent an IR asking the Applicant when the samples will be ready for testing. Also, DBSQC has scheduled a meeting with the Product division to discuss and plan for product testing.

6. **What is the review classification of this application?**
   Standard Review

7. **Indicate the decision regarding the need for an Advisory Committee.**
   VRBPAC will be held on September 13, 2017.

8. **Indicate whether the submission triggers PREA; if yes, a PeRC meeting is needed.**

The submission triggers PREA. The applicant submitted a Request for Waiver of Pediatric Studies.

9. Is a comprehensive and readily located list of all clinical sites included or referenced in the application?
Yes

10. Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application?
Yes

11. Indicate any updates since the first committee meeting on pre-license inspection, pre-approval inspection, or BIMO sites requiring inspections (Is the establishment(s) ready for inspection?)
DMPQ reviewer indicated that they are anticipating waiving inspection of both the manufacturing sites ((b) (4), Belgium and (b) (4)).

12. If the application is affected by the Application Integrity Policy (AIP), has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance?
NA

FOR APPLICATIONS IN THE PROGRAM (PDUFA V) (NME NDAs/Original BLAs), IF FILED

13. Confirm that any late submission components were submitted within 30 days. List any late submission components that arrived after 30 days.
NA

14. Was the application otherwise complete upon submission, including those applications where there were no agreements regarding late submission components?
Yes

ADMINISTRATIVE DETAILS, IF FILED:

15. Review the Milestone Schedule and indicate if there are any issues with the schedule.
VRBPAC meeting will be held on September 13, 2017. As this date is very close to the Action Due Date, milestone dates for PeRC presentation and Late Cycle meeting (that are linked to VRBPAC) will be **changed** to occur before the VRBPAC.

16. Enter the date of the Mid-cycle Meeting, if appropriate (required for NME NDAs/BLAs in "the Program" PDUFA V):
Internal mid-cycle review meeting is scheduled for April 19, 2017.
Mid-cycle communication with the Applicant is scheduled for May 3, 2017.

3.0 DISCUSSION

- Reviewers indicated that the submission is complete for their reviews, and the deficiencies will be resolved through IRs.

- The statistical reviewer indicated that the submission is lacking the Statistical Analysis Plans (SAPs).
- The Clinical reviewers stated that the Integrated Summary of Safety (ISS) contains only tables and does not have any text. If the Summary of Clinical Safety document doesn't have links to all the tables in ISS, CBER may have to contact the Applicant for further information/analysis. The Clinical reviewer was informed of the latest amendment (STN 125614/0.4, dated 12/5/2016) in which GSK provided detailed clarifications regarding the aspects of the BLA structure and other items (ISS, ISE, SCS, ISE datasets and links in SCS to tables in ISS) discussed during the telecon held on November 16, 2016.

4.0 CONCLUSION

During the Filing Meeting, the committee agreed that the application could be filed.

5.0 SUMMARY OF ACTION ITEMS

- Finalize Filing Checklists and upload to EDR.
- Finalize the comments to be provided to the Applicant via an IR.
- Issue the Filing letter on or before December 20, 2016

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