U.S. FOOD & DRUG ADMINISTRATION

FILING MEETING SUMMARY

Application number: BLA STN 125742/45
Product name: COVID-19 Vaccine, mRNA (COMIRNATY)
Proposed Indication: Active immunization to prevent coronavirus disease 19 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older
Applicant: BioNTech Manufacturing GmbH
Meeting date & time: January 31, 2022; 12:00 - 1:00 PM EST
Committee Chair: Ramachandra Naik, Ph.D.
Meeting Recorders: CAPT Michael Smith, Ph.D. and Laura Gottschalk, Ph.D.

Ramachandra Naik -S

Digitally signed by Ramachandra Naik -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001232361, cn=Ramachandra Naik -S
Date: 2022.02.09 14:16:40 -05'00'

Background:
COMIRNATY (COVID-19 Vaccine, mRNA) was originally approved on August 23, 2021, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The current application, received on December 16, 2021, is an efficacy supplement from BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.) for COMIRNATY to extend the indication to adolescents 12 through 15 years of age.

The purpose of this meeting was to discuss 1) the completeness of the sBLA submission and, 2) whether it is acceptable to be filed.

Table 1: Review Committee and Discipline Filing Decision Summary

Discipline/Organization	Name	Attended meeting	Fileable	RTF	Deficiencies Identified
Regulatory Project Managers	CAPT Michael Smith, PhD Laura Gottschalk, PhD	✓ ✓	✓		
Chair	Ramachandra Naik, PhD	✓	✓		
Division Director – Clinical Scientific Advisor – Clinical	Doran Fink, MD, PhD Rebecca Reindel, MD	✓ ✓			
Division Director – Regulatory Scientific Advisor – Regulatory	Loris McVittie, PhD Kirk Prutzman, PhD	✓ ✓			
Office Director (acting)	Peter Marks, MD, PhD				
Clinical Reviewer	Susan Wollersheim, MD	✓	✓		
CMC Reviewer	Xiao Wang, PhD	✓	✓		
OCBQ/APLB Reviewer	CAPT Oluchi Elekwachi, PharmD, MPH	✓			

Discipline/Organization	Name	Attended meeting	Fileable	RTF	Deficiencies Identified
OCBQ/BIMO Reviewers	Kanaeko Ravenell Char-Dell Edwards	✓ ✓	✓		
Statistical Reviewer of clinical and non-clinical data	Ye Yang, PhD	✓	✓		
Postmarketing Safety Epidemiological/Pharmacovigilance Reviewer	Deborah Thompson, MD, MSPH	✓	✓		
CDISC Consult	Brenda Baldwin, PhD	✓	✓		

Other Attendees:
Meghna Alimchandani, Maria Allende, Dennis Cato, Anissa Cheung, Nicolette Devore, Karen Farizo, Theresa Finn, Helen Gemignani, Maureen Hess, Brynn Hollingsworth, Lei Huang, Hector Izurieta, Lucia Lee, Shiowjen Lee, Robin Levis, Tsai-Lien Lin, Meghan MaguireThon, Carrie Mampilly, Narayan Nair, Manette Niu, Cassandra Overking, Keith Peden, David Rouse, John Scott, Nikunj Sharma, Lisa Stockbridge, Elizabeth Sutkowski, Qun Wang, and Hong Yang

Review Timetable (PDUFA Milestones are in blue)

Review Milestone	Target Due Date
Submitted:	16-DEC-2021
Received:	16-DEC-2021
Committee Assignment:	30-DEC-2021
First Committee Meeting:	06-JAN-2022
Filing reviews complete:	25-JAN-2022
Confirm BIMO (GCP) Inspection Sites	30-JAN-2022
Filing Meeting:	**31-JAN-2022**
Filing Action:	14-FEB-2022
Deficiencies Identified:	28-FEB-2022
Primary Draft Reviews & Reviewer Reports Due (4 days prior to Mid-Cycle meeting):	31-MAR-2022
Mid-Cycle Meeting (Internal):	06-APR-2022
Determine if Advisory Committee Meeting is Necessary:	06-APR-2022
PeRC Briefing materials due:	xx-APR-2022
Notify Safety Working Group (SWG)	18-APR-2022
PeRC Meeting:	xx-APR-2022
Labeling Comments to Applicant:	18-MAY-2022
Final draft primary reviews with supervisory Concurrence (upload not required):	18-MAY-2022

Notify OCOD of pending approval:	18-MAY-2022
Notify Applicant of PMC/PMR:	18-MAY-2022
Final reviews & addenda signed & uploaded:	12-JUN-2022
PDUFA ADD:	**17-JUN-2022**

Table 2: Scheduled Meetings

PDUFA Meetings:
• **First Committee Meeting:** January 6, 2022 (by email)
• **Filing Meeting:** January 31, 2022, 12:00PM – 1:00PM
• **Internal Mid-Cycle:** April 6, 2022, 1:00PM-2:30PM
Monthly Committee Meetings (to be scheduled):
• February 23, 2022
• April 18, 2022
• May 19, 2022
Labeling Meetings:
To occur after the Mid-Cycle Meeting, TBD

UPDATES FROM REVIEW DISCIPLINES:

1. **Chair** (Ram Naik):
   - The Chair provided a brief overview of the submission including review milestone dates.
   - Discipline reviewers are not required to complete filing checklists for this supplement. Reviewers should still perform their due diligence to ensure that the application is complete for the purposes of filing.
   - This application does not trigger PREA. However, it will need to go to PeRC as it includes the pediatric assessment for children 12 through 15 years of age as described in PMR #1 of the August 23, 2021 approval letter for the original COMIRNATY BLA. The PeRC meeting will be scheduled soon.

2. **Regulatory Project Managers** (Mike Smith and Laura Gottschalk):
   - The RPMs summarized the IRs and Amendments to the BLA to date (please see details at end of document).
   - The sBLA is fileable.
   - To ensure the regulatory items were covered in the submission, the RPM Checklist was completed and will be uploaded to the file.

3. **Clinical** (Susan Wollersheim):
   - The sBLA is fileable and the clinical reviewer agrees with the Priority Review designation.

4. **CMC** (Xiao Wang):
   - The sBLA is fileable.

5. **Statistics** (Ye Yang):
    - The sBLA is fileable.

6. **Epidemiology/Pharmacovigilance** (Deborah Thompson):
    - The sBLA is fileable.

7. **BIMO** (Kanaeko Ravenell and Char-Dell Edwards):
    - The sBLA is fileable.
    - Preliminarily investigator sites have been selected for inspection assignments and will be sent to the clinical team for concurrence soon.

8. **APLB** (Oluchi Elekwachi):
    - The sBLA is fileable.

9. **CDISC** (Brenda Baldwin):
    - The sBLA is fileable.

REGULATORY CONCLUSIONS / DEFICIENCIES:

1. **Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and require an RTF letter?**
   The application appears to be suitable for filing.

2. **If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application**:
   No substantive deficiencies or issues were identified.

3. **If RTF, list any substantive deficiencies or issues that would make this application unsuitable for filing:**
   N/A

FILING MEETING DISCUSSION, IF FILED:

4. **Indicate any comments on the status of the proprietary name review (PNR).**
   N/A

5. **Indicate whether the product sh/would be subject to lot release, surveillance, or exempt from lot release. Verify sample availability.**
   N/A

6. **Confirm review schedule for the application. If priority review, include justification from clinical reviewer filing review checklist. [Standard Review, Priority Review, or Expedited Review]**
   The submission is a 6-month Priority Review sBLA with a PDUFA Action Due Date (ADD) of June 17, 2022.

7. **Indicate the decision regarding the need for an Advisory Committee.**

This application does not need to go to VRBPAC - Confirmed by the DVRPA management at the Filing Meeting.

8. **Indicate whether the submission triggers PREA. If yes, a PeRC meeting is needed. Verify whether the applicant has an initial pediatric study plan (iPSP) in place.**
   The submission does not trigger PREA. However, a PeRC meeting is needed as the supplement includes the pediatric assessment for adolescents 12 through 15 years of age from study C4591001 as described in PMR #1 of the August 23, 2021 approval letter for the original COMIRNATY BLA.

9. **Indicate whether the submission contains a proposed REMS. If yes, or if a REMS may be needed as a condition of approval, schedule an internal REMS meeting between the Product Office and OBE/DE.**
   The submission does not contain a REMS.

10. **Is a comprehensive and readily located list of all clinical sites included or referenced in the application?**
    A comprehensive and readily located list of all clinical sites is included in the application.

11. **Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application?**
    N/A. There is no change to the product information and the manufacturing facilities.

12. **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?)**
    None.

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

14. **Is the product an Original Biological Product or a New Molecular Entity (NME) for an NDA?**
    N/A

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

15. **Confirm that any late submission components were submitted within 30 days. List any late submission components that arrived after 30 days.**
    N/A

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

The application was complete upon submission.

ADMINISTRATIVE DETAILS, IF FILED:

17. Review the Milestone Schedule and indicate if there are any issues with the schedule. Note: This is a confirmation to capture any changes made since the First Committee Meeting.

No changes have occurred in the Milestone Schedule since the First Committee Meeting. Please see Review Timetable above.

INFORMATION REQUESTS:

1. 01/19/2022: Three questions regarding datasets.

2. 01/25/2022: Request for an updated FDA form 356h and an Environmental Assessment or claim of Categorical Exclusion.

AMENDMENTS:

1. STN 125742/45.1 (January 28, 2022) – Response to January 25, 2022 request regarding submitting (1) updated Form 356h to include information regarding all establishments and manufacturing facilities, and (2) an Environmental Assessment or Claim of Categorical Exclusion.