Michael J. Smith -S4

Digitally signed by Michael J. Smith -S4
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0014080934, cn=Michael J. Smith -S4
Date: 2022.01.10 16:18:07 -05'00'

From: Naik, Ramachandra
Sent: Thursday, January 6, 2022 7:17 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Sutkowski, Elizabeth M. <Elizabeth.Sutkowski@fda.hhs.gov>; Wollersheim, Susan <Susan.Wollersheim@fda.hhs.gov>; Lee, Lucia <Lucia.Lee@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Wang, Xiao <Xiao.Wang@fda.hhs.gov>; Cheung, Anissa <Anissa.Cheung@fda.hhs.gov>; Peden, Keith <Keith.Peden@fda.hhs.gov>; Yang, Ye <Ye.Yang@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Thompson, Deborah <Deborah.Thompson@fda.hhs.gov>; Niu, Manette <Manette.Niu@fda.hhs.gov>; Yang, Ye <Ye.Yang@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Ravenell, Kanaeko <Kanaeko.Ravenell@fda.hhs.gov>; Edwards, Char-Dell <Char-Dell.Edwards@fda.hhs.gov>; Cato, Dennis <Dennis.Cato@fda.hhs.gov>; Elekwachi, Oluchi <Oluchi.Elekwachi@fda.hhs.gov>; Stockbridge, Lisa L <Lisa.Stockbridge@fda.hhs.gov>; Baldwin, Brenda <Brenda.Baldwin@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Reindel, Rebecca <Rebecca.Reindel@fda.hhs.gov>; Levis, Robin <Robin.Levis@fda.hhs.gov>; Weir, Jerry P. <Jerry.Weir@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Lee, Shiowjen <Shiowjen.Lee@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Mampilly, Carrie <carrie.Mampilly@fda.hhs.gov>; Sausville, Robert <Robert.Sausville@fda.hhs.gov>
Cc: Yogurtcu, Osman <Osman.Yogurtcu@fda.hhs.gov>; Funk, Patrick <Patrick.Funk@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Hess, Maureen <Maureen.Hess@fda.hhs.gov>; Anderson, Steven (Steven.Anderson@fda.hhs.gov) <Steven.Anderson@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sharma, Nikunj <Nikunj.Sharma@fda.hhs.gov>; Vujcic, Luba <Luba.Vujcic@fda.hhs.gov>; MaguireThon, Meghan <meghan.maguirethon@fda.hhs.gov>
Subject: STN 125742/45 - Efficacy supplement to COMIRNATY BLA for extending the indication to adolescents 12 through 15 years of age: First Committee Meeting

Dear COMIRNATY sBLA review committee and managers,

Welcome to the Review team for the efficacy supplement (STN 125742/45) for COVID-19 Vaccine, mRNA (COMIRNATY) to extend the indication to adolescents 12 through 15 years of age. This efficacy supplement is available in docuBridge and you may use the Link to Submission in docuBridge to access the submission.

I am the Chair, and I will be working with Mike Smith and Laura Gottschalk as your review management team. This e-mail serves as our First Committee Meeting. **Mike, Laura and I would appreciate if the immediate review team members (Susan Wollersheim – Clinical; Ye Yang – Statistics; Xiao Wang – Serology Assays; Deborah Thompson – PVP-Epidemiology; Oluchi Elekwachi – APLB; Kanaeko Ravenell – BIMO; and Brenda Baldwin – CDISC Consult) could confirm receipt of this e-mail (by replying to us only).** If the information regarding your supervisor, or any other information on the list (attached), is not correct, please let us know. **Please**

include Mike, Laura and me on all e-mails regarding this supplement. Please let us know of any major review issues that you have uncovered immediately.

This supplement has been designated as a 6-month Priority Review. Therefore, the action due date for this submission is **June 17, 2022**. At this time, we do not anticipate presenting this application at a VRBPAC meeting. The final decision will be made at the Filing Meeting or later.

This supplement will be managed through RMS-BLA. Please reach out to the review management team if you have any questions regarding navigation of RMS-BLA or you need assistance with completing tasks, such as uploading documents.

The Filing Meeting is scheduled for Monday, January 31, 2022. Thanks to CBER ADRM excusing us from having to complete the filing checklists for this sBLA, the discipline reviewers do not need to complete the filing checklists. However, please enter your filing determination in the  Sharepoint document by COB January 25, 2022 to help us determine who else needs to be invited to the Filing Meeting.

We are planning to schedule monthly committee meetings as well as labeling meetings soon. Therefore, please keep your calendars updated.

Please see the attached Review Committee-Meeting Dates-Milestones document for more information such as the list of reviewers (and supervisors) on the Review Committee, Review Timetable, Explanation of Milestones, Explanation of Roles and Responsibilities, Documentation of review, Communication plan, etc. Please notify Mike, Laura and me if there are any issues with the submission contents or if your role or supervisor indicated in the attached document is incorrect.

Thank you,

Ram

U.S. FOOD & DRUG ADMINISTRATION

FIRST COMMITTEE MEETING SUMMARY

To:	The File
Date:	January 6, 2022
STN #:	125742/45
Submission Type:	Efficacy Supplement
Reason for the Submission:	To extend the indication to adolescents 12 through 15 years of age
Applicant:	BioNTech Manufacturing GmbH
Product:	COVID-19 Vaccine, mRNA (COMIRNATY)
Meeting Chair:	Ramachandra Naik, PhD

Table 1: Review Committee

Review responsibility	Committee Member	Team Leader / Supervisor	Division Director (and DDD
Chair	Ramachandra Naik, PhD	BC: Elizabeth Sutkowski, PhD	DD: Loris McVittie, PhD SA: Kirk Prutzman, PhD
Regulatory Project Managers	CAPT Mike Smith, PhD Laura Gottschalk, PhD	BC: Elizabeth Sutkowski, PhD	DD: Loris McVittie, PhD SA: Kirk Prutzman, PhD
Clinical	Susan Wollersheim, MD	TL: Lucia Lee, MD BC: Maria Allende, MD	DD: Doran Fink, MD, PhD Douglas Pratt, MD SA: Rebecca Reindel, MD
DVP – Serology assays	Xiao Wang, PhD	S: Keith Peden, PhD Anissa Cheung, MSc	DD: Jerry Weir, PhD DDD: Robin Levis, PhD
Statistics – Clinical (Safety/ Efficacy, and Assays, if needed)	Ye Yang, PhD	TL: Lei Huang, PhD BC: Tsai-Lien Lin, PhD	DD: John Scott, PhD DDD: Shiowjen Lee, PhD
Epidemiology/ Pharmacovigilance	Deborah Thompson, MD, MSPH	BC: Manette Niu, MD	DD: Narayan Nair, MD DDD: Meghna Alimchandani, MD
Benefit-Risk Assessment	Hong Yang, PhD Cc: Osman Yogurtcu, PhD Cc: Patrick Funk, PhD	Sup: Richard Forshee	
BIMO	Kanaeko Ravenell Cc: Char-Dell Edwards	BC: Dennis Cato	DD: Carrie Mampilly, MPH
APLB Labeling reviewer	CAPT Oluchi Elekwachi, PharmD, MPH	BC: Lisa Stockbridge, PhD	DD: Robert Sausville
CDISC consult	Brenda Baldwin, PhD	BC: Elizabeth Sutkowski, PhD	DD: Loris McVittie, PhD

Review Timetable (PDUFA Milestones are in blue, * indicates dates that are TBD or to be scheduled)

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:	12-FEB-2022
Deficiencies Identified:	28-FEB-2022
Primary Draft Reviews & Reviewer Reports Due (4 days prior to Mid-Cycle meeting):	12-MAR-2022*
Mid-Cycle Meeting (Internal):	16-MAR-2022*
Determine if Advisory Committee Meeting is Necessary	16-MAR-2022
PeRC Briefing materials due:	05-APR-2022*
Notify Safety Working Group (SWG)	18-APR-2022
PeRC Meeting:	19-APR-2022*
Labeling Comments to Applicant:	18-MAY-2022
Finalize Discipline Review memo 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
Obtain Lot Release Clearance	18-MAY-2022
Obtain Compliance Check	18-MAY-2022
Final reviews & addenda signed & uploaded:	12-JUN-2022
PDUFA ADD:	17-JUN-2022

Explanation of Milestones:

First Committee Meeting:	Committee must meet by this date to discuss the review of the sBLA.
Filing Meeting:	Meeting at which the review committee determines whether or not the sBLA can be filed. Reviewers must determine whether the information included in the sBLA is sufficient to allow the reviewer to conduct an adequate review. The purpose is not to determine the acceptability of the data but rather to determine whether the appropriate information was submitted to allow the reviewer to conduct a meaningful review.
Filing Action:	Date by which a filing letter (either accepting or refusing to file the sBLA) must be issued.
Deficiencies Identified:	Date by which a letter must be issued in which review issues identified to date are conveyed to the applicant.
Mid-cycle Meeting:	Meeting at which each reviewer is expected to document their review progress and discuss the relevant content of the submission and present an overview. A draft review memorandum identifying key issues should be completed by the time of the meeting. First line supervisors for each review discipline as well as the Director and Deputy Director for DVRPA and OVRR, or their representative, should be in attendance at the meeting.
Action Due Date:	Date by which final action regarding the sBLA must be conveyed to the applicant (issue Approval or Complete Response letter, depending on review decision). All review memos, regardless of

the Action being taken, must be signed and uploaded to the EDR prior to the date of Action.

Explanation of Roles and Responsibilities (See CBER SOPP 8401 for more detail)

- Chair – Manages the administrative processing of reviews and ensures the regulatory and scientific content of submissions and their reviews are appropriate.
- Director and/or Deputy Director – the Signatory Authority who signs action letters and is responsible for content of reviews.
- Regulatory Project Manager (RPM) – Manages the review of submissions, including reviewing assigned portions, performing quality control checks, capturing review committee communications, and ensures that the review and review file is administratively complete. The RPMs work in tandem with the Chair to ensure that amendments are disseminated to the appropriate reviewers and that a meaningful short summary is entered into RMS-BLA. Throughout the review cycle, the RPMs ensure that all FDA documents are uploaded into the CBER Connect as they are generated and the documentation review memo is maintained in real-time.
- Review Committee – Perform review of all assigned areas of submissions, participate in review meetings, and perform and document a review of the submission that is scientifically sound and follows Good Review Management Principles. Documentation of a discipline review may be in the form of a primary review, discipline review letter, and a review addendum. It is imperative that the review committee endeavor to follow the review timetable and finish reviews in a timely manner to allow for adequate supervisory review. It is critical that the review committee keeps management, including senior management, abreast of any significant review issues.
- Supervisors – Ensure the overall content of reviews are appropriate, all administrative processing steps are being completed, including database data entry, and all deadlines are met. Reviews and approves employees' review memos and other submission documents per CBER policies and procedures. Supervisory review is considered the Secondary Review.

Documentation of Review

Each discipline reviewer is expected to prepare a written review documenting their review of the file. Timely submissions are imperative to allow time for adequate management review. The following is recommended:

- Identify all materials assigned for review and include an executive summary in each final or complete review memo.
- List and summarize all material reviewed. The summary should identify each amendment reviewed and include a list of the submission dates, sections and page numbers etc., as applicable.
- A list of questions communicated to the applicant, in letter-ready format, along with the responses received and reviewed should be clearly identified.
- A recommendation for action, approval or CR, based upon the review summary should be clearly stated.
- Draft reviews should be prepared and discussed with the reviewer's supervisor and a copy should be given to the Chair by the draft due date(s). Draft reviews should not be uploaded to the EDR.
- Reviewer's and supervisor's electronic signatures should be placed on the final PDF version of the review. A Word version should be attached, and the PDF should be certified and locked to prevent modification. The review should be entered into RMS-

BLA using the date of the Reviewer's approval stamp as the date of the memo and the certified PDF should be uploaded into the CBER Connect.

- If a Complete Response (CR) Letter is issued, a complete written review is expected and should reflect all amendments that have been reviewed through the date of the CR decision. The final signed and certified PDF version of the review should be uploaded by the date of the CR action.

Communication Plan

We can communicate with the applicant via several methods such as telecon, secure e-mail, and letter. The following is recommended:

- All communication in regard to requests for information or advice for the applicant will be coordinated by the RPMs and communicated either via telecon or secure email. Please contact **Ramachandra Naik** (Chair), **Mike Smith** and **Laura Gottschalk** (RPMs) if you need to communicate with the applicant.
- Although every effort should be made to include the RPMs and/or Chair when communicating with the applicant, in rare instances it may be appropriate, with permission from Ramachandra Naik and/or Mike Smith and Laura Gottschalk, to communicate some requests for information (e.g., something that is relatively simple) to the applicant via a telecon. Please ensure that all such communication is formally documented (i.e., write up a telecon memo and send it to the RPMs to include in the file).
- Formal telecons with the applicant can be scheduled to address issues for which a direct discussion is helpful. The RPMs will coordinate this if/when it is needed.
- Letters can also be used to communicate review issues to the applicant. Although both secure e-mail and letters provide the necessary documentation for the file, letters are a more formal process than secure e-mail (letters must go through more levels of supervisory review and concurrence) so typically letters are reserved for communication of policy or serious review issues.
- Please "Cc" the Chair on significant e-mail communication and meetings (internal and external). It is helpful for the Chair to have a general overview of the review status and review issues in the various disciplines (allows for more effective communication with internal upper level management and the applicant when necessary).
- Supervisory concurrence will be sought, when appropriate, prior to sending communications to the applicant (e.g., memos with request for information, providing advice, etc.).