CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761436Orig1s000
761436Orig2s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

IND 153805

MEETING PRELIMINARY COMMENTS

Paul V. Thomas
U.S. Agent for Biocon Biologics UK Limited
245 Main Street
2nd Floor
Cambridge, MA 02142

Dear Paul Thomas:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Bmab 1000-P and Bmab 1000-X.

We also refer to your March 6, 2024, correspondence, requesting a meeting to seek the Agency's advice and opinion on product development aspects to support licensure of Bmab 1000 as a proposed biosimilar to US-Licensed Prolia and US-licensed Xgeva, under the 351(k) pathway.

Our preliminary responses to your meeting questions are enclosed.

You should provide, to the Regulatory Project Manager, an electronic version of any materials (i.e., slides or handouts) to be presented and/or discussed at the meeting.

In accordance with FDA policy, you should not make audio or visual recordings of the discussion at this meeting. Consistent with 21 CFR 10.65(e), the official record of this meeting will be the FDA-generated minutes.

If you have any questions, call me at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

Jennifer Johnson
Regulatory Health Project Manager
Endocrinology
Division of Regulatory Operations for
Cardiology, Hematology, Endocrinology, and
Nephrology
Office of Regulatory Operations
Center for Drug Evaluation and Research

ENCLOSURE:
Meeting Preliminary Comments

U.S. FOOD & DRUG ADMINISTRATION

PRELIMINARY MEETING COMMENTS

Meeting Type:	Biosimilar
Meeting Category:	BPD Type 4
Meeting Date and Time:	Tuesday, April 30, 2024, 12:30 – 1:30 pm EDT
Meeting Location:	Videoconference
Application Number:	IND 153805
Product Name:	Bmab 1000-P and Bmab 1000 X
Indication:	Bmab 1000-P and Bmab 1000 X are being developed for the same indications as those approved for US-licensed Prolia (US-Prolia) and US-licensed Xgeva (US-Xgeva)
Sponsor Name:	Biocon Biologics UK Limited
Regulatory Pathway:	351(k) of the Public Health Service Act

FDA ATTENDEES (tentative)

Office of New Drugs (OND), Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN)

Division of General Endocrinology

Olivia Easley, MD, Clinical Reviewer
Shivangi Vachhani, MD, Clinical Team Leader
Marina Zemskova, MD, Deputy Director for Safety
Naomi Lowy, MD, Deputy Director
Theresa Kehoe, MD, Director

Division of Pharmacology/Toxicology for Cardiology, Hematology, Endocrinology and Nephrology

Sree Rayavarapu, PhD, Nonclinical Reviewer
David Carlson, PhD, Supervisory Toxicologist
Daniel Minck, PhD, Team Lead

Office of Translational Sciences (OTS), Office of Clinical Pharmacology

Chongwoo Yu, PhD, Clinical Pharmacology Reviewer
Li Li, PhD, Acting Clinical Pharmacology Team Leader

OTS, Office of Biostatistics

Kiya Hamilton, PhD, Biometrics Reviewer
Feng Li, PhD, Biometrics Team Leader

Office of Pharmaceutical Quality (OPQ), Office of Product Quality Assessment III, Division of Product Quality Assessment XV
Joao Pedras-Vasconcelos, PhD, Product Quality Assessor
Hailin (Sheena) Wang, PhD, Product Quality Team Leader

OPQ, Office of Program and Regulatory Operations (OPRO), Division of Regulatory and Business Process Management I
Melinda Bauerlien, Senior Regulatory Business Process Manager

Office of Therapeutic Biologics and Biosimilars (OTBB)
Raquel Tapia, MD, Scientific Reviewer
Cristina Ausin, PhD, Scientific Reviewer
Alexander Cristaudo, JD, Policy Reviewer
Ruby (Chi-Ann) Wu, PharmD, MPH, CAPT/USPHS, Labeling Reviewer
Emanuela Lacana, PhD, Deputy Director

OND, Office of Regulatory Operations, Division of Regulatory Operations for Cardiology, Hematology, Endocrinology, and Nephrology
Jennifer Johnson, Regulatory Health Project Manager, Endocrinology
Elisabeth Hanan, MS, Chief, Project Management Staff

Office of Surveillance and Epidemiology, Office of Medication Error Prevention and Risk Management, Division of Risk Management
Theresa Ng, Risk Management Reviewer
Yasmeen Abou-Sayed, Risk Management Team Leader

SPONSOR ATTENDEES
Global Regulatory Affairs
Arlene Wolny, Ph.D., Head, Global Regulatory Affairs
Raja Sekhar Vanga, M.Sc., Vice President, Global Regulatory Affairs
Yoganandareddy G, M.Sc., General Manager, Global Regulatory Affairs
Neha Mohandas, M. Tech., Global Regulatory Lead for Bmab 1000 program

Research and Development
Anuj Goel, Ph. D., Chief Scientific Officer
Dinesh B, M.S., Global Portfolio Lead
Anita Krishnan, Ph.D., Analytical Science Lead
Sandhya S, M.Sc., Analytical Project Group Lead
Rishikesh Gawade, M. Tech., Process Project Group Lead

Clinical Development and Medical Affairs
Elena Wolff-Holz, M.D., Global Head of Clinical Development, Medical Affairs
Subramanian L, M.D., Head Clinical Sciences
Pawan Kumar Singh, M.D., Medical Lead

Introduction:
This material consists of our preliminary responses to your questions and any additional comments in preparation for the discussion at the meeting scheduled for Tuesday, April 30, 2024, 12:30 – 1:30 pm EDT between Biocon Biologics UK Limited and the Division of General Endocrinology. We are sharing this material to promote a collaborative and successful discussion at the meeting. The meeting minutes will reflect agreements, important issues, and any action items discussed during the meeting and may not be identical to these preliminary comments following substantive discussion at the meeting. If you determine that discussion is needed for only some of the original questions, you have the option of reducing the agenda and/or changing the format of the meeting (e.g., from face to face to teleconference). Contact the Regulatory Project Manager (Jennifer Johnson) if there are any major changes to your development plan, the purpose of the meeting, or the questions based on our preliminary responses, as we may not be prepared to discuss or reach agreement on such changes at the meeting.

1.0 BACKGROUND

Biocon Biologics UK Limited is developing Bmab 1000-P and Bmab 1000-X for the same indications as those approved for US-Prolia and US-Xgeva, respectively.

The purpose of the requested meeting is to seek the Agency's advice and opinion on product development aspects to support licensure of Bmab 1000 as a proposed biosimilar to US-Licensed Prolia and Xgeva, under the 351(k) pathway.

FDA may provide further clarifications of, or refinements and/or changes to these preliminary responses and the advice provided at the meeting based on further information provided by Biocon Biologics UK Limited and as the Agency's thinking evolves on certain statutory provisions regarding applications submitted under section 351(k) of the Public Health Service Act (PHS Act).

2.0 DISCUSSION

Your questions are repeated below with our responses followed in **bold.**

2.1. Chemistry, Manufacturing and Controls (CMC)

Question 1: For initial BLA submission, Biocon intends to submit available long term (5ºC±3ºC) and accelerated (25ºC±2ºC) stability data from at-scale development/clinical campaign drug product batches and a 3-month long-term (5ºC±3ºC) stability data and accelerated stability(25ºC±2ºC) from process validation drug product batches. Additional stability data of process validation drug product

batches (6 months) and development/clinical batches will be provided during the BLA review period as part of 120-day update.

Does the Agency agree with the proposed submission approach of stability data of Bmab 1000-X and Bmab 1000-P batches as part of initial BLA and during BLA review period?

FDA Response to Question 1:
Your proposal to submit available long term (5ºC±3ºC) and accelerated (25ºC±2ºC) stability data from development/clinical campaign drug product (DP) batches and 3-months long-term (5ºC±3ºC) and accelerated (25ºC±2ºC) stability data from process validation drug product (PVDP) batches followed by stability update for PV DP batches (6-months) and non-PVDP batches of both Bmab 1000-X (vial) and Bmab 1000-P (PFS) as described in Table 3 of the meeting package appears reasonable. Note that whether the submitted non-PVDP batch data can be used to establish shelf life of DP in both vial and PFS presentations will be a review issue based on the totality of information and data provided in the BLA submission (e.g., whether all relevant comparability of DS and DP is successfully established, the container closure system of non-PV batches is representative of commercial DP, etc.).

Question 2: Based on demonstration of comparability in stability trends between Bmab 1000-X and Bmab 1000-P, Biocon intends to determine the shelf life of Bmab 1000-X based on available stability data of Bmab 1000-P and Bmab 1000-X.

Does the Agency agree with the proposed stability establishment approach?

FDA Response to Question 2:
Your plan to establish the shelf life of Bmab 1000-X based on available stability data of Bmab 1000-P and Bmab 1000-X appears reasonable provided Bmab 1000-P can be consider a worst-case presentation for stability evaluation, and all relevant comparability for DS and DP is successfully established including stability profiles for the two presentations, and residual risks from differences (e.g., head space-to-volume and surface area to volume) between the two presentations are adequately addressed to support quality and stability of the two products. Final determination of whether Bmab 1000-X and Bmab 1000-P can be considered comparable for shelf life establishment will be a review issue.

Question 3: Biocon Biologics is conducting shipping validation study for Bmab 1000-P and Bmab 1000-X. A shipping study protocol is being prepared and this study protocol will be submitted as a part of initial BLA. The shipping validation study

will be ongoing in parallel to BLA review. The shipping validation study data will be submitted during BLA review period (as part of 120-day update).

Does the Agency agree to Biocon's proposal of submitting shipping validation study protocol at the time of initial BLA and provide the shipping study report during BLA review period?

FDA Response to Question 3:
Your plan to submit the shipping validation protocol with the initial BLA submission and provide the shipping validation study data as part of the 120-day BLA update appears reasonable.

The shipping validation study conditions should be representative of the commercial Bmab 1000-P and Bmab 1000-X shipping conditions. Results from these studies (including assessment of product quality attributes, container closure integrity, device functionality, etc.) should be provided to the BLA to support that the product quality, device performance and microbial attributes remain intact after exposure to shipping conditions during commercial shipping.

2.2. Clinical Development

Question 4: Biocon proposes to submit the following clinical package during the initial submission of Bmab 1000 Biological License Application (BLA):

- Submission of complete Phase 1 CSR including the primary PK, secondary PD, safety and immunogenicity endpoints
- Submission of primary Phase 3 CSR including the primary efficacy endpoint along with the secondary endpoint of pharmacodynamic, pharmacokinetics, safety and immunogenicity data till week 52
- Submission of Phase 3 addendum CSR including transition data (post single switch) for a subset of population

Biocon proposes to submit the complete 78-week Phase 3 CSR including transition data of all the eligible subjects during the BLA review period (as part of 120-day update).

Does the Agency agree with this submission approach of clinical package for Bmab 1000 BLA?

FDA Response to Question 4:
Your proposal for the PK/PD similarity study is reasonable.

However, we do not agree with your proposal for the comparative clinical study. As proposed, the initial BLA submission will only include transition data for a subset of the population. All data from the single transition phase of the study are critical for the review of the application. Therefore, the completed 78-week comparative clinical study report should be included with the initial BLA submission.

Additional Comments:
We remind you there is currently an approved REMS for US-Prolia. Bmab 1000-P will need to be submitted with a proposed REMS that contains the same REMS elements to inform healthcare providers and patients about specific risks as currently available for Prolia. Please note the recently approved modification to the Prolia REMS on March 5, 2024. Your REMS proposal for Bmab 1000-P should align with the recent changes (see updates on FDA's website, REMS@FDA[1]).

3.0 ADDITIONAL INFORMATION

DISCUSSION OF THE CONTENT OF A COMPLETE APPLICATION

The original 351(k) application will be subject to "the Program" under BsUFA III. Therefore, at this meeting be prepared to discuss and reach agreement with FDA on the content of a complete application, including preliminary discussions regarding the approach to developing the content for risk evaluation and mitigation strategies (REMS), where applicable, patient labeling (e.g., Medication Guide and Instructions For Use) and, where applicable, the development of a Formal Communication Plan. You and FDA may also reach agreement on submission of a limited number of minor application components to be submitted not later than 30 days after the submission of the original application. These submissions must be of a type that would not be expected to materially impact the ability of the review team to begin its review. All major components of the application are expected to be included in the original application and are not subject to agreement for late submission.

Discussions and agreements will be summarized at the conclusion of the meeting and reflected in FDA's meeting minutes. If you decide to cancel this meeting and do not have agreement with FDA on the content of a complete application or late submission of any minor application components, your application is expected to be complete at the time of original submission.

In addition, we remind you that the application is expected to include a comprehensive and readily located list of all clinical sites and manufacturing facilities.

Information on the Program is available at FDA.gov.[2]

[1] https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
[2] https://www.fda.gov/forindustry/userfees/biosimilaruserfeeactbsufa/default.htm

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain a pediatric assessment to support dosing, safety, and effectiveness of the product for the claimed indication unless this requirement is waived, deferred, or inapplicable.

Section 505B(l) of the FD&C Act, added by section 7002(d)(2) of the Affordable Care Act, provides that a biosimilar product that has not been determined to be interchangeable with the reference product is considered to have a "new active ingredient" for purposes of PREA, and a pediatric assessment is required unless waived, deferred, or inapplicable.

FDA encourages prospective biosimilar applicants to submit an initial pediatric study plan (iPSP) as early as practicable during product development. FDA recommends that you allow adequate time to reach agreement with FDA on the proposed iPSP prior to initiating your comparative clinical study.

Sections 505B(e)(2)(C) and 505B(e)(3) of the FD&C Act set forth a process lasting up to 210 days for reaching agreement with FDA on an iPSP. FDA encourages the sponsor to meet with FDA to discuss the details of the planned development program before submission of the iPSP. You must address PREA for every indication for which you seek licensure, and we encourage you to submit a comprehensive iPSP that addresses each indication. For additional information on how you may fulfill the requirement for pediatric assessments or investigations under PREA, see question and answer I.16 in the guidance for industry, *Questions and Answers on Biosimilar Development and the BPCI Act*.

After the iPSP is submitted, a sponsor must work with FDA to reach timely agreement on the plan, as required by section 505B(e)(2)-(3) of the FD&C Act. For additional guidance on the timing content, and submission of the iPSP, including an iPSP Template, please refer to the guidance for industry, *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans*[3]. In addition, you may contact the Division of Pediatric and Maternal Health at 301-796-2200 or email Pedsdrugs@fda.hhs.gov. It should be noted that requested deferrals or waivers in the initial PSP will not be formally granted or denied until the product is licensed.

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pediatric-study-plans-content-and-process-submitting-initial-pediatric-study-plans-and-amended

PRESCRIBING INFORMATION

In your application, you must submit proposed Prescribing Information (PI) that conforms to the content and format regulations found at 21 CFR 201.56(a) and (d)[4] and 201.57[5] including the Pregnancy and Lactation Labeling Rule (PLLR). As you develop your proposed PI, we encourage you to review the labeling review resources on the following websites:

- *Biological Products – Specific Labeling Resources*[6] which includes the guidance for industry*: Labeling for Biosimilar Products* (July 2018).
- *Prescribing Information Resources*[7]

For other prescription drug labeling resources such as those for FDA-approved patient labeling, carton and container labeling, labeling databases, and product databases, visit *FDA's Labeling Resources for Human Prescription Drugs* website.[8]

- Pursuant to the PLLR, you should include the following information with your application to support the changes in the *Pregnancy*, *Lactation*, and *Females and Males of Reproductive Potential* subsections of labeling. The application should include a review and summary of the available published literature regarding the drug's use in pregnant and lactating women and the effects of the drug on male and female fertility (include search parameters and a copy of each reference publication), a cumulative review and summary of relevant cases reported in your pharmacovigilance database (from the time of product development to present), a summary of drug utilization rates amongst females of reproductive potential (e.g., aged 15 to 44 years) calculated cumulatively since initial approval, and an interim report of an ongoing pregnancy registry or a final report on a closed pregnancy registry. If you believe the information is not applicable, provide justification. Otherwise, this information should be located in Module 1. Refer to the draft guidance for industry *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format*.[9]

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[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.56&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=21%20CFR%20201.56&utm_content=1
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.56&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=21%20CFR%20201.56&utm_content=1
[6] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/biological-products-specific-labeling-resources
[7] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/biological-products-specific-labeling-resources
[8] https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs
[9] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Prior to submission of your proposed PI, use the Selected Requirements for Prescribing Information (SRPI) checklist to ensure conformance with the format items in regulations and guidances.

NONPROPRIETARY NAME

On January 13, 2017, FDA issued a final guidance for industry *Nonproprietary Naming of Biological Products*, stating that, for certain biological products, the Agency intends to designate a proper name that includes a four-letter distinguishing suffix that is devoid of meaning.

Please note that certain provisions of this guidance describe a collection of information and are under review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA). These provisions of the guidance describe the submission of proposed suffixes to the FDA, and a sponsor's related analysis of proposed suffixes, which are considered a "collection of information" under the PRA. FDA is not currently implementing provisions of the guidance that describe this collection of information.

However, provisions of the final guidance that do not describe the collection of information should be considered final and represent FDA's current thinking on the nonproprietary naming of biological products. These include, generally, the description of the naming convention (including its format for originator, related, and biosimilar biological products) and the considerations that support the convention.

Your proposed 351(k) BLA would be within the scope of this guidance. As such, FDA intends to assign a four-letter suffix for inclusion in the proper name designated in the license at such time as FDA approves the BLA.

MANUFACTURING FACILITIES

All facilities should be registered with FDA at the time of the 351(k) BLA submission and ready for inspection in accordance with 21 CFR 600.21 and 601.20(b)(2). Manufacturing and testing facilities will be subject to the CGMP standards as described in 21 CFR 601.20, including but not limited to the good manufacturing practice requirements set forth in 21 CFR 210, 211, and 600 of this chapter.

Manufacturing facilities should be in operation and manufacturing the product under review during the inspection, 2-7 months after the submission of the BLA. A manufacturing schedule for the drug substance and the drug product should be provided in Module 1 of the BLA to facilitate planning of pre-license inspections during the review cycle. For a BLA submission, when providing the preliminary manufacturing

schedule, we encourage you to bear in mind the anticipated time frame for the late-cycle meeting for applications subject to "the Program" under BSUFA III.

To facilitate our inspectional process, we request that you clearly identify *in a single location*, either on the Form FDA 356h, or an attachment to the form, all manufacturing facilities associated with your application. Include the full corporate name of the facility and address where the manufacturing function is performed, with the FEI number, and specific manufacturing responsibilities for each facility.

Also provide the name and title of an onsite contact person, including their phone number, fax number, and email address. Provide a brief description of the manufacturing operation conducted at each facility, including the type of testing and DMF number (if applicable). Each facility should be ready for GMP inspection at the time of submission.

Consider using a table similar to the one below as an attachment to Form FDA 356h. Indicate under Establishment Information on page 1 of Form FDA 356h that the information is provided in the attachment titled, "Product name, BLA 012345, Establishment Information for Form 356h."

Site Name	Site Address	Federal Establishment Indicator (FEI) or Registration Number (CFN)	Drug Master File Number (if applicable)	Manufacturing Step(s) or Type of Testing [Establishment function]
(1)				
(2)				

Corresponding names and titles of onsite contact:

Site Name	Site Address	Onsite Contact (Person, Title)	Phone and Fax number	Email address
(1)				
(2)				

To facilitate our facility assessment and inspectional process for your marketing application, we refer you to the instructional supplement for filling out Form FDA 356h[10] and the guidance for industry, *Identification of Manufacturing Establishments in*

[10] https://www.fda.gov/media/84223/download

Applications Submitted to CBER and CDER Questions and Answers[11]. Submit all related manufacturing and testing facilities in eCTD Module 3, including those proposed for commercial production and those used for product and manufacturing process development.

OFFICE OF SCIENTIFIC INVESTIGATIONS (OSI) REQUESTS

The Office of Scientific Investigations (OSI) requests that the items described in the draft guidance for industry *Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions* (February 2018) and the associated Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications be provided to facilitate development of clinical investigator and sponsor/monitor/CRO inspection assignments, and the background packages that are sent with those assignments to the FDA ORA investigators who conduct those inspections. This information is requested for all major trials used to support safety and efficacy in the application (i.e., phase 2/3 pivotal trials). Please note that if the requested items are provided elsewhere in submission in the format described, the Applicant can describe location or provide a link to the requested information.

Please refer to the draft guidance for industry *Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions* (February 2018) and the associated *Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications*.

RECOMMENDATIONS FOR FORMATTING OF CLINICAL PHARMACOLOGY SUBMISSIONS FOR APPLICATIONS

If you are planning to include a clinical pharmacology study as part of your 351(k) BLA marketing application, we have the following general best practice recommendations for you to keep in mind as you prepare your submission, including guides for formatting your submission.

1. As it relates to clinical pharmacology-related sections of the application, apply the following advice when preparing the 351(k) BLA:
   a. Include the rationale for the selected dose used in the PK (and PD similarity, when applicable) study(ies) in the BLA (e.g., eCTD Module 2.7.2 Summary of Clinical Pharmacology).
   b. Include a summary evaluation of the impact of immunogenicity on the activity (e.g., efficacy/PD), safety, and pharmacokinetics, as is applicable,

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identification-manufacturing-establishments-applications-submitted-cber-and-cder-questions-and

for the studies included in the BLA (e.g., eCTD Module 2.7.2 Summary of Clinical Pharmacology).

c. Present the PK (and PD, when applicable) parameter data as geometric mean with coefficient of variation, mean ± standard deviation, and median with range in the study reports and throughout the BLA.
d. Provide analysis data sets for all concentration-time and derived PK (and PD, when applicable) parameter datasets as SAS transport files (*.xpt). A description of each data item should be provided in a define.pdf file. Any concentrations or subjects that have been excluded from the analysis should be flagged and maintained in the datasets.

2. Include the following information in a tabular format in the 351(k) BLA for each of the completed clinical studies:
    a. Site number
    b. Principal investigator
    c. Site Location: Address (e.g., Street, City, State, Country) and contact information (i.e., phone, fax, email)
    d. Location of Principal Investigator: Address (e.g., Street, City, State, and Country) and contact information (i.e., phone, fax, email). If the Applicant is aware of changes to a clinical investigator's site address or contact information since the time of the clinical investigator's participation in the study, we request that this updated information also be provided.
3. Submit all PK (and PD, when applicable) bioanalytical method validation reports and bioanalytical study reports. In addition, complete the summary tables using the templates available in the 'Bioanalytical Methods Templates' Technical Specifications Document[12] to provide the information regarding the bioanalytical methods for pharmacokinetic and/or biomarker assessments used in clinical pharmacology studies and their life-cycle information pertaining to the studies. Submit the tables in the Appendix of the Summary of Biopharmaceutics located in eCTD 2.7.1.

[12] https://www.fda.gov/media/131425/download

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JENNIFER L JOHNSON
04/26/2024 03:27:35 PM