CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761355Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

IND 12462

MEETING MINUTES

Regeneron Pharmaceuticals, Inc.
Attention: Donato M. Forlenza PharmD, MBA
Senior Director, Regulatory Affairs
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

Dear Dr. Forlenza:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for EYLEA (aflibercept) Injection. We also refer to the Type-B, Pre-BLA teleconference between representatives of your firm and the FDA on September 26, 2022.

A copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes. If you have any questions, please contact Michael Puglisi, Regulatory Project Manager, at michael.puglisi@fda.hhs.gov or at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

Enclosure:
Meeting Minutes

U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM OF MEETING MINUTES

Meeting Type/Category: Type-B, Pre-BLA

Meeting Date and Time: September 26, 2022, from 12:00-1:00 pm (Eastern)

Meeting Location: Teleconference

Application Number: IND 12462

Product Name: Eylea (aflibercept) Injection

Indication: Treatment of neovascular age-related macular degeneration (AMD), diabetic macular edema (DME), and diabetic retinopathy (DR)

Sponsor Name: Regeneron Pharmaceuticals, Inc.

Regulatory Pathway: 351(a) of the Public Health Service Act

Meeting Chair: Wiley Chambers, MD
Meeting Recorder: Michael Puglisi

FDA PARTICIPANTS:

Charles Ganley, MD	Director, OND/Office of Specialty Medicine (OSM)
Wiley Chambers, MD	Director, Division of Ophthalmology/ Office of Specialty Medicine (DO/OSM)
William Boyd, MD	Deputy Director, DO/OSM
Rhea Lloyd, MD	Clinical Team Leader, DO/OSM
Jennifer Harris, MD	Clinical Team Leader, DO/OSM
Sonal Wadhwa, MD	Clinical Reviewer, DO/OSM
Martin Nevitt, MD	Clinical Reviewer, DO/OSM
Courtney Evans, PhD	Team Leader, Center for Devices and Radiological Health (CDRH)/ Office of Product Evaluation and Quality (OPEQ)/ Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, Office of Product Evaluation and Quality (OHTIII)/ Division of Health Technology 3C (DHTIIIC)
Sreya Tarafdar, PhD	Reviewer, CDRH/OPEQ/OHTIII/DHTIIIC
Greg Soon, PhD	Statistical Team Leader, Office of Biometrics (OB)/ Division of Biometrics IV (DBIV)
Solomon Chefo, PhD	Statistical Reviewer, OB/DBIV

Anshu Rastogi, PhD	Product Quality Team Leader, Office of Biotechnology Products (OBP)/Division of Biotechnology Review and Research I (DBRRI)
Ping Ji, PhD	Acting Clinical Pharmacology Team Leader, Office of Clinical Pharmacology (OCP)/Division of Inflammation and Immune Pharmacology (DIIP)
Lei He, PhD	Clinical Pharmacology Reviewer, OCP/DIIP
Roy Blay, PhD	Consumer Safety Officer, Office of Scientific Investigations/ Division of Clinical Compliance Evaluation/Good Clinical Practice Assessment Branch
Sofanit Getahun, PharmD, BCPS	Pharmacist, Office of Surveillance and Epidemiology (OSE)/ Office of Medication Error Prevention and Risk Management (OMEPRM)/ Division of Medication Error Prevention and Analysis 1 (DMEPA1)
Jason Flint, MBA, PMP	Associate Director for Human Factors, OSE/ OMEPRM)/DMEPA 1
Oyinlola Fashina, PharmD	Senior Regulatory Project Manager, Project Management Staff, OSE
Michael Puglisi	Regulatory Project Manager, ORO/DROSM

SPONSOR PARTICIPANTS:

Boaz Hirshberg, MD, MBA	Senior Vice President, Clinical Sciences, General Medicine, Regeneron
Robert Vitti, MD, MBA	Vice President, Clinical Sciences, Ophthalmology, Regeneron
Benjamin Drosman, RPh, MBA	Vice President, Regulatory Affairs, Regeneron
Jennifer McNay, PhD	Senior Vice President CMC Regulatory Sciences and Industrial Affairs, Regeneron
Leah Fenley, MS	Manager, CMC Program Management, Regeneron
Peter Petrochencko, PhD	Senior Manager, CMC and Combination Product Regulatory Affairs, Regeneron
Kellie Taylor, PharmD, JD, MPH	Senior Director, CMC and Combination Products Regulatory Affairs, Regeneron
Alyson Berliner, MD, PhD	Executive Medical Director, Clinical Sciences, Ophthalmology, Regeneron
Suzanne Green, MBChB, FPM	Senior Director, Global Patient Safety, Regeneron
Kimberly Reed, OD, FAAO	Senior Medical Director, Clinical Sciences, Ophthalmology, Regeneron
Donato Forlenza, PharmD, MBA	Senior Director, Regulatory Affairs, Regeneron
Jinghua (James) Jia, PhD, PPM	Senior Manager, Regulatory Affairs, Regeneron
Rabih Slim, MS, PhD, DABT	Senior Director, Toxicology, Regeneron
Kenneth Turner, PhD	Senior Group Director, Clinical Pharmacology, Regeneron
Maeve Byrne, PhD	Director, CMC Regulatory Affairs, Regeneron
Wei Sun, PhD	Director, Biostatistics, Regeneron

Sergio Leal, MD	Director, Global Clinical Development, Ophthalmology, Bayer AG
Theodore L. Drell, PhD, MDRA	Global Regulatory Strategist, Bayer AG
Thomas Schmelter, PhD	Expert Statistician Ophthalmology, Statistics Bayer AG

MEETING OBJECTIVE:
The Sponsor requested this meeting to discuss the upcoming BLA submission for Aflibercept Injection, 8 mg for treatment of neovascular age-related macular degeneration (AMD), diabetic macular edema (DME, and diabetic retinopathy (DR).

SUMMARY OF DISCUSSION:
Agency preliminary responses (see text in italics below) to the question outlined in the August 26, 2022, background package (see bolded text below) were provided to the Sponsor in a letter dated September 20, 2022. This meeting served to clarify the Agency responses. Discussion during the meeting is reflected in regular font.

QUESTIONS FOR THE AGENCY:

Regulatory/Clinical

1. **Does the Agency agree with cross-referencing all applicable sections (e.g., Module 4; preclinical study reports; Module 3) of the IAI 8mg BLA to the relevant sections of the previously submitted IAI 2 mg BLA submission packages, including the proposed content and organization of Module 3.2 Body of Data?**

   Agency Response: Although you can bundle multiple indications in one BLA efficacy supplement it is also acceptable to submit separate efficacy supplements for each indication. In either case it is acceptable to cross-reference applicable sections. Any sections that have additional or new information pertaining to the IAI 8 mg product should be submitted to the Module 3.2 and clearly outlined as new/additional information.

   Your intent to include 510(k) approval numbers of FDA-cleared device components co-packaged in the kit, is acceptable. However, since the co-kitted devices (syringe and needle) will be intended to be used for intravitreal administration, please ensure that the intended use of the administration components of the injection kit are in accordance with their original approved/cleared indication for use. Please provide information supporting the appropriate intraocular injection specifications for the devices being kitted with your product, including, for example, bacterial endotoxins (FDA Guidance Endotoxin Testing Recommendations for Single- Use Intraocular Ophthalmic Devices, https://www.fda.gov/media/88615/download), sterilant residuals (ISO 10993-7, Clause 4.3.6), USP 789 particulates, ocular irritation (ISO 10993-23), etc. Information should include a combination of data assuring product

meets appropriate ocular specifications, and controls to assure that any future lots will continue to meet these specifications. Assurance that future lots meet these specifications may be accomplished through a combination of release tests, quality agreements, or other appropriate controls to assure conformance to device specifications.

In your meeting request package content, you have stated that kit components (b) (4) *Please note, in order to support your claim, you should also demonstrate and /or provide supporting evidence* (b) (4)

Additionally, you must also demonstrate that the transportation studies on your final finished combination product (commercially packaged kit) does not negatively impact the primary packaging and thus the sterility of the individual pre-approved components within the kit.

Meeting Discussion: The Agency clarified that it is acceptable to submit the application for the 8 mg product as a new BLA or as an efficacy supplement to the existing BLA for Eylea. The Agency confirmed that their preliminary meeting comments would apply, regardless of how the application is submitted.

Regeneron stated their intent to submit a Human Drug Application Utilizing a Material Threat Medical Countermeasure Priority Review Voucher for this application. The Agency confirmed it has no concerns about the use of the priority review voucher.

The Agency recommended that Regeneron submit a new, proposed initial PSP which states their intent to request a waiver for pediatric studies in the BLA and provides the formulation of the proposed product. The Agency confirmed that it does not expect any change in past policy of granting pediatric study waivers for the proposed indications.
The Agency confirmed that the draft Table of Contents provided in Regeneron's meeting briefing package appears reasonable.

In preparation for the meeting, Regeneron submitted to the IND, a description of the components of their proposed convenience kit, including the status and numbers of the related 510(k) submissions. Regarding the preliminary comments about potential device components, the Agency cited the Genus legal decision for its departure from previous advice about requirements for these components. Eylea was approved solely as a biologic product. The new product will be regulated as a combination product if marketed with a convenience kit or copackaged with a filter-needle. A vial-alone presentation would be regulated solely as a biologic product.

Regeneron provided the regulatory approval information about the device components of the 8 mg kit and indicated that it intended leveraging information from the 2mg vial kit. Based on Regeneron's statement that the device components are identical between the 2 mg and the 8 mg kits, the Agency noted that the regulations have changed and the product would be reviewed under the current regulations.

2. **Regeneron requests that the Agency waive the requirement (21CFR 314) to submit a pooled analysis for integrated efficacy and safety. Considering the BLA will comprise separate indications derived from individual clinical trials [one pivotal trial in nAMD (PULSAR), one pivotal trial in DME/DR (PHOTON)], can the Agency confirm that the Sponsor's approach to Modules 2.7.3 and 2.7.4 (presenting a summary of efficacy and safety from each individual trial without pooled analysis) is sufficient for filing?**

   Agency Response: Yes, since these are single studies for separate indications, pooling of the safety and efficacy data (ISS and ISE) is not applicable.

   Meeting Comment: There was no discussion of this matter during the meeting.

3. **Does the Agency agree with the content, structure, and version of the electronic submission datasets and analysis datasets proposed to be included in the BLA?**

   Agency Response: Acceptable.

   Meeting Comment: There was no discussion of this matter during the meeting.

4. **The Sponsor proposes** (b) (4) [redacted]

   Agency Response: No, we do not agree. You should submit narratives for all SAEs (b) (4) [redacted]

   Meeting Comment: There was no discussion of this matter during the meeting.

5. **Does the Agency agree that the Sponsor may include, in the BLA application, a request for indication of diabetic retinopathy (with or without DME) for the IAI 8mg BLA, supported by the pre-specified secondary endpoint of proportion of patients with ≥2-step improvement in DRSS in the PHOTON study?**

Agency Response: *The pre-specified secondary endpoint of ≥2 step improvement in DRSS for the indication of DR in PHOTON study is acceptable for filing. Whether this study also supports the indication of DR in addition to the DME indication would be a review issue.*

For the secondary endpoint of the proportion of subjects who achieve ≥2-step improvement in DRSS from baseline at Week 48, you propose a noninferiority (NI) margin of 15%. A NI margin of 15% is not acceptable. We recommend that a NI margin of 10% be used to establish noninferiority. Please note that, based on your hierarchical testing strategy in the PHOTON study, this endpoint will be tested only if noninferiority of HDq12 to 2q8 followed by noninferiority of HDq16 to 2q8 in the primary efficacy endpoint of the mean change in BCVA from baseline at Week 48 are established.

Meeting Discussion: The Agency clarified that the proposed secondary endpoint of a ≥2-step improvement in DRSS in the PHOTON study is likely to be acceptable for BLA **filing** for the indication of DR. Approvability would be a review issue.

6. (b) (4)

Agency Response: Disagree. (b) (4)

Meeting Comment: There was no discussion of this matter during the meeting.

7. Regeneron is submitting the proposed packaging for review in the BLA. Does the Agency have any comments or advice to the sponsor at this time to help ensure that there is acceptable differentiation between EYLEA 2mg and IAI 8mg products?

Agency Response: *Your design approach to differentiate between the two products appears reasonable; however, the acceptability of the container label and carton labeling for your proposed product will be a review issue under the BLA submission.*

Meeting Comment: There was no discussion of this matter during the meeting.

CMC:

Clinical Pharmacology

10. **Does the Agency agree on the proposed content of Module 2.7.2, as well as the Clinical Pharmacology data package, to support the BLA submission?**

Agency Response: We agree that the proposed content and clinical pharmacology data package appear reasonable. The final determination of the adequacy will be a review issue.

Meeting Comment: There was no discussion of this matter during the meeting.

11. Does the Agency agree with the proposed dataset to be used as the basis of the population PK model and analysis, as well as the proposed covariates to explain sources of variability?

Agency Response: We agree that the proposal appears reasonable. The final determination of the adequacy will be a review issue.

Meeting Comment: There was no discussion of this matter during the meeting.

(b) (4)

(b) (4)

(b) (4)

a. Following submission and approval of nAMD, DME and DR with aflibercept 8 mg, (b) (4)

Agency Response: Approvability is a review issue and can only be determined once a complete BLA is submitted and reviewed. (b) (4)

1 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

(b) (4)

Additional comments regarding PHOTON and PULSAR protocols:

- *In PHOTON and PULSAR studies, we note that you are treating the three treatment arms differently. The dosing regimen modification only applies to the two high dose arms and not to the 2mgQ8 arm. We do not agree with the three treatment arms being treated differently.*

- *In your primary efficacy analysis in PHOTON and PULSAR studies, treatment comparisons will be made using MMRM model based on all randomized subjects assuming that subjects adhere to treatment during the study under a hypothetical estimand strategy. Under this strategy, missing data due to occurrence of intercurrent events (such as, discontinuation from study/study treatment due to adverse events [AEs] or lack-of-efficacy [LoE] or receiving rescue/prohibited therapy) or due to other reasons will be considered as missing at random and implicitly imputed by the MMRM under a missing at random missing data mechanism. Your primary analysis approach would be acceptable if the number of subjects with occurrence of intercurrent events and/or missing data are minimal and balanced between the treatment groups.*

  A reasonable strategy(ies) for handling intercurrent events and/or missing data should be specified in the protocol if the number of subjects with intercurrent events and/or missing data are more than minimal or unbalanced between the treatment groups. For example, a trimmed mean analysis approach (https://www.ncbi.nlm.nih.gov/pubmed/27523396) could be considered. In this analysis approach, subjects who discontinue the study/study treatment due to AEs or LoE and have no post-discontinuation data and those who receive any prohibited/rescue therapy during the study be considered as having worse BCVA outcome post-discontinuation and trimmed from the analysis. For subjects who discontinue the study treatment due to AEs or LoE but continue the study without receiving any prohibited/rescue therapy after treatment discontinuation, we recommend that their efficacy data after treatment discontinuation be collected and used in the primary analysis under a treatment policy estimand strategy.

  To assess the robustness of the primary efficacy analysis, we recommend that potential supporting analyses (e.g., using a treatment policy estimand

strategy) and sensitivity analyses (e.g., a tipping point analysis) be specified in the protocol and statistical analysis plan.

For the analysis of the key secondary efficacy endpoint of the proportion of subjects with a ≥2-step improvement in DRSS at Week 48 in PHOTON study, please specify in the protocol and statistical analysis plan strategies for the handling of potential intercurrent events and/or missing data in the analysis.

- *Your assumed dropout rate of 19% used in the sample size calculation in PHOTON study appears to be high. Thus, you should make every effort to minimize dropout/missing data during the study and encourage subjects who discontinue treatment due to adverse events or lack-of-efficacy to stay in the study for efficacy and safety assessment at all the scheduled visits.*

  Meeting Discussion: The Agency discussed the problems, particularly unmasking of the subjects when the treatment arms are dosed with different frequencies. The Agency stated it has repeatedly recommended that multiple arms be treated with the same frequency to preserve masking and to provide better data. The Agency agreed that the PHOTON and PULSAR trials may be sufficient for BLA filing, but approvability would be a review decision.

Additional Agency Comments:

DISCUSSION OF THE CONTENT OF A COMPLETE APPLICATION
As stated in our July 27, 2022, communication granting this meeting, if, at the time of submission, the application that is the subject of this meeting is for a new molecular entity or an original biologic, the application will be subject to "the Program" under PDUFA VI. Therefore, at this meeting be prepared to discuss and reach agreement with FDA on the content of a complete application, including preliminary discussions on the need for risk evaluation and mitigation strategies (REMS) or other risk management actions 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.[1]

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 an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Please be advised that under the Food and Drug Administration Safety and Innovation Act (FDASIA), you must submit an Initial Pediatric Study Plan (iPSP) within 60 days of an End-of-Phase-2 (EOP2) meeting. In the absence of an EOP2 meeting, refer to the draft guidance below. The iPSP must contain an outline of the pediatric study or studies that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation, and any previously negotiated pediatric plans with other regulatory authorities. The iPSP should be submitted in PDF and Word format. Failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

For additional guidance on the timing, content, and submission of the iPSP, including an iPSP Template, please refer to the draft guidance for industry Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.[2] *In addition, you may contact the Division of Pediatric and Maternal Health at 301-796-2200 or email Pedsdrugs@fda.hhs.gov. For further guidance on pediatric product development, please refer to FDA.gov.*[3]

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) and 201.57 including the Pregnancy and Lactation Labeling Rule (PLLR) (for applications submitted on or after June 30, 2015). As you develop your proposed PI, we encourage you to review the labeling review resources on the PLR Requirements for Prescribing

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[1] https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm

[2] 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.

[3] https://www.fda.gov/drugs/development-resources/pediatric-and-maternal-health-product-development

Information[4] and Pregnancy and Lactation Labeling Final Rule[5] websites, which include:

- *The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products.*
- *The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information related to pregnancy, lactation, and females and males of reproductive potential.*
- *Regulations and related guidance documents.*
- *A sample tool illustrating the format for Highlights and Contents, and*
- *The Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances.*
- *FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.*

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.

Prior to submission of your proposed PI, use the SRPI checklist to ensure conformance with the format items in regulations and guidances.

MANUFACTURING FACILITIES
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

[4] https://www.fda.gov/drugs/laws-acts-and-rules/plr-requirements-prescribing-information
[5] https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

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, NDA/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[6] and the guidance for industry, Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers[7]. 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, and the associated conformance guide, 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

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

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

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.

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.

To the extent that your proposed 351(a) BLA is within the scope of this guidance, FDA will assign a four-letter suffix for inclusion in the proper name designated in the license at such time as FDA approves the BLA.

Meeting Comment: There was no discussion of the Additional Agency Comments during the meeting.

ACTION ITEM:
The Agency agreed to provide minutes of the meeting within 30 days.

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/

WILEY A CHAMBERS
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