OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

SCHEDULING AND HOLDING MEETINGS WITH OUTSIDE PARTIES

I. PURPOSE

This document:

- defines the types of meetings the Office of New Animal Drug Evaluation (ONADE) has with outside parties;
- describes the procedures for scheduling and holding meetings with outside parties;[1] and
- includes information on scheduling meetings on sponsor block days.

II. DEFINITIONS

1. Early response letter (ERL): A letter provided only for virtual presubmission conferences (PSCs) where the new animal drug product discussed is under an investigational new animal drug file (INAD) or new animal drug application (NADA) (a.k.a. pioneer product).[2]
2. Meeting: A meeting is any substantive oral discussion, whether by telephone, videoconference, or in person.[3] As part of requesting a meeting, the outside party specifies their proposed venue.

[1] For meetings with Division of Animal Bioengineering and Cellular Therapies (DABCT), see DABCT SOP 1243.106.002 "Procedures for Developer Meetings with DABCT" and ONADE SOP "Veterinary Innovation Program: Review Team Process".
[2] Generic products (generic investigational new animal drug files (JINADs) and abbreviated new animal drugs (ANADAs) are not eligible for the process that would result in the ERL. Therefore, no ERL would ever be prepared for a generic product.
[3] Note that we do not consider brief exchanges seeking clarification to be meetings for the purpose of this document. However, you should document these exchanges in the administrative record.

3. Memorandum of conference (MOC): An MOC is a document prepared by CVM personnel that documents the nature and substance of a meeting with an outside party.[4] The MOC is the official record of the meeting (see P&P 1243.3025). Outside parties are referred to as the sponsor for the remainder of this document.

4. Scheduler: The scheduler is the CVM individual responsible for scheduling the meeting. The scheduler may be the primary reviewer (PR) assigned to the meeting request or another person designated by office or division procedures.

III. TYPES OF MEETINGS

Meetings requested by a sponsor are coded as Z submissions in our Corporate Database Portal's (CDP's) Submission Tracking and Reporting System (STARS). Meetings we initiate are coded as Q submissions in STARS. All meeting requests have the subclass code of OM. The meeting request is designated as presubmission conference, method demonstration, or other ONADE meeting in the STARS Meeting Type Indicator (MTI) field. This field is populated based on the meeting scope selected in eSubmitter.

Sponsors can elect to have a meeting in-person or virtually. In-person (also called "hybrid") meetings are where attendees from CVM and outside party(ies) may attend in person or virtually. Virtual meetings are where all CVM and outside party attendees attend virtually.

A. Presubmission Conference (PSC)

A PSC (in-person or virtual) is an entitlement granted to any potential applicant under the Federal Food, Drug and Cosmetic Act in Section 512(b)(3), with the details spelled out in 21 CFR 514.5. A PSC is a meeting to discuss submission or investigational requirements, including the number and types of studies or information that will be submitted to support the approval of an application. PSC questions are typically some form of, "Will my proposed development plan support approval of this product?"

Where possible in a PSC, we try to reach agreement with the sponsor on requirements. PSC agreements[5] are binding upon us and the sponsor, and the legislative history[6] points out that agreements provide sponsors assurance about applying their time and resources to development work. However, classifying a meeting as PSC or other ONADE meeting is not based upon whether agreements are likely. If the purpose of the meeting fits the criteria described above, the MTI should be classified as PS in STARS.

A virtual PSC with an ERL is a process in which the sponsor[7] opts to receive a written response from CVM to their agenda questions at least six (6) calendar days prior to their scheduled PSC. After receiving the ERL, the sponsor can choose to hold the

[4] An outside party is a person(s) from outside the FDA who has requested a meeting with us. An outside party may be a potential applicant, a representative of industry or special interest group, or any other external constituent. Potential applicant is defined in 21 CFR 514.3.

[5] Agreements are predicated on the accuracy and completeness of the information presented and discussed at the time of the meeting. The agreements may be modified by mutual agreement or if substantiated scientific requirements essential to the determination of safety or effectiveness appear after this meeting.

[6] Legislative history refers to the progress of a bill through the legislative process and to the documents created during that process. Attorneys, judges, and others often turn to these documents to learn why Congress enacted a particular law or to aid in the interpretation of a law.

[7] Generic products are not eligible for a virtual PSC with an ERL.

scheduled meeting or cancel it. Binding agreements (§512(b)(3)) can only be made if a meeting is held and an MOC is sent. A PSC with an ERL is not an option for sponsors requesting an in-person meeting, or for sponsors requesting a meeting for generic new animal drug products. For more information, see P&P 1243.3025.

B. Method Demonstration Meetings

A method demonstration meeting is a meeting held for the sponsor to validate an official method for determining new animal drug residues in food-producing animal tissues (see SOP 1243.150.007).

C. Other ONADE Meetings

Other ONADE meetings are any meetings other than a PSC or method demonstration meeting type. Examples of other ONADE meeting topics include: details of a protocol,[8] labeling, inclusion/exclusion criteria for a data submission, sponsor responsibilities following a conditional approval (per P&P 1243.5076), and lessons learned meetings (per P&P 1243.3023). Meetings held under General Correspondence files, including portfolio overview meetings (per P&P 1243.3021) and pre-INAD meetings (see below), and meetings held under Type VII Veterinary Master Files (VMFs) are other ONADE meetings.

D. Meetings That Do Not Require Z Submissions

Divisions may discuss issues with a sponsor informally and document the discussion in a Q submission (see P&P 1243.3250).

IV. PRE-INAD MEETINGS UNDER A GENERAL CORRESPONDENCE (GC) FILE

We sometimes receive questions from sponsors about the availability of “pre-INAD meetings.” CVM may meet with a sponsor under a GC file before the sponsor proceeds with establishing an INAD. Specific parameters for pre-INAD meetings, which have another ONADE meeting type, are described below. Sponsors who are unsure whether their desired agenda is appropriate for a pre-INAD meeting should contact their assigned project manager (PM) or CVM.ONADE.PM@fda.hhs.gov.

Pre-INAD meetings are available for high-level discussion of a limited number of questions (typically one or two) for which the sponsor needs CVM’s feedback to form their proposed development plan. Examples of potential topics include:

- feedback on a novel indication,
- advice for working through specific challenges before finalizing the proposed development plan for a particular technical section, and
- feedback on the sponsor's eligibility for expanded conditional approval (see P&P 1243.2100).

[8] Note that we will not concur on a protocol in a meeting. A sponsor may ask targeted questions about specific aspects of the protocol or seek to confirm they’re on the right track with their overall design. For a detailed protocol evaluation, the sponsor must submit the protocol for review as an E submission.

Internal information redacted.

CVM does not issue an MOC for pre-INAD meetings. We normally close out the meeting request with internal documentation of the discussion (FNR/MEMO). We may choose instead to issue an acknowledgement letter to the sponsor (ACK) if we want to convey information in writing.

V. INITIAL PROCESSING OF A MEETING REQUEST

Upon receipt, the PR determines if the request has the correct MTI according to the definitions above. If the MTI is incorrect, the PR determines whether it is necessary to void the submission and ask the sponsor to resubmit using the correct meeting type in eSubmitter.[9]

The PR also determines if we have sufficient information from the sponsor to schedule the meeting. For PSC requests, the PR confirms the sponsor filled out eSubmitter completely and correctly to provide a detailed agenda and supporting materials, including:

- the purpose of the meeting and/or expected outcomes,
- how the sponsor proposes to address the technical sections (TSs) selected, and specific questions they want CVM to address for each of those TSs,
- a copy of any materials the sponsor will present at the meeting, and
- copies of materials the sponsor evaluated or referenced relative to the items in their request.

If the PR or any other member of the review team identifies that the sponsor has included Early Information (EI) in the meeting request rather than in an A-0000 or H submission followed by a meeting request, the PR follows up with the sponsor as described in P&P 1243.2200.

Finally, the PR checks whether the sponsor is requesting a virtual or an in-person meeting. For an in-person meeting, the PR confirms the sponsor has included a list of planned in-person attendees from their side and identified any foreign visitors.

Note: We do not meet with sponsors to discuss a submission that is under review, except for an associated H submission (see P&P 1243.4092 “H Submissions Preceding Meetings and Protocols), because granting such a meeting may require us to review the submission outside the normal timeframes and queues.

VI. SPONSOR BLOCK DAYS FOR SCHEDULING SPONSOR MEETINGS

ONADE has implemented specific days that we use to optimize our scheduling of sponsor meetings. We refer to these days as sponsor block days. We have also

[9] There are specific eSubmitter templates for method demonstration and pioneer PSC meetings, so we need sponsors to populate eSubmitter using the correct meeting type and associated templates for those meetings.

established meeting times on those sponsor block days to ensure there is time on those days for breaks between meetings to accommodate things like lunch. Sponsor block days are the Wednesday and Thursday in the second and fourth week of every month. To facilitate the use of sponsor block days for meetings with sponsors, it is an ONADE expectation that we do not schedule regular or recurring meetings or non-sponsor meetings on sponsor block days. Every ONADE employee should have the sponsor block days indicated on their calendars. The meeting time slots on sponsor block days are as follows:

8:00 - 9:50 a.m.

10:00 - 11:50 a.m.

12:30 - 2:20 p.m.

2:30 - 4:20 p.m.

Meetings can be scheduled for up to 1 hour and 50 minutes, within the specified time slots. Not every meeting needs to be scheduled for the full time. Meetings must start and end on time; this is the responsibility of the meeting organizer.

Sponsor meetings have priority on sponsor block days, and as such, they can be scheduled over other meetings. Meetings set up by or on behalf of the Center or Office Director, continuing education (including courses through CVM's Talent Development Learning Center), and official leave will not be scheduled over on a sponsor block day. Sponsor meetings that need to be scheduled on non-sponsor block days can be scheduled over the following meetings: ONADE Roundup, Leadership Forum, CVM All-Hands, and 1-1 meetings. For all other meetings, schedulers will confirm with required participants before scheduling over conflicting meetings on non-sponsor block days.

VII. PRESUBMISSION CONFERENCE MEETING PREPARATION

For a PSC, 21 CFR 514.5(b) requires that the sponsor submit the request in a signed letter. That letter must include a proposed agenda that clearly outlines the PSC scope, purpose, and objectives, and a list of the names and positions of the representatives who will attend the PSC on behalf of the sponsor. The report file for a complete pioneer PSC request made using eSubmitter fulfills this regulatory requirement.

A PM is the assigned PR for investigational new animal drug or new animal drug application (a.k.a. pioneer) PSC requests when the sponsor states in eSubmitter that:

- this is the first meeting to address the development plan for this project or approval effort (i.e., this meeting serves as a kickoff meeting for the project);
- their proposal represents a change to aspects of the approval effort discussed in a previous meeting (e.g., changes to formulation, dosage form, dose, duration, route of administration, species and class, indication, or science/regulatory policy), and they wish to revisit their development plan across all TSs based on the change; or
- they request to discuss requirements for more than one TS or component that is handled by more than one ONADE division as primary (e.g., for a meeting to discuss Effectiveness and Chemistry, Manufacturing and Controls; however, a meeting to

discuss Effectiveness and Target Animal Safety would be assigned to the target animal division).[10]

Pioneer products sponsors must identify in the eSubmitter template which TSs or components (for Human Food Safety) they seek to involve. For meetings they identify as either the first meeting to address the development plan or a request to revisit the development plan, the sponsor is prompted to select one of the following for each TS or component as appropriate:

- "To Discuss at Current Meeting"
- "CVM to Confirm, but Not for Discussion"
- "To Discuss at a Future Meeting"
- "Already Complete"
- "Not Applicable"

Meetings held following the receipt of an ERL will only either clarify CVM's comments in the ERL or establish binding agreement(s) (§ 512(b)(3)). For CVM and the sponsor to have either a meaningful discussion regarding a complex situation or a high-level discussion, CVM may recommend the sponsor request an in-person or virtual PSC. Examples of meeting topics that involve a complex situation or a high-level discussion which may be beyond the scope of a virtual PSC with ERL could include:

- detailed questions on Real World Data (RWD) or Real World Evidence (RWE) protocols or study designs,
- novel or adaptive study designs such as group sequential designs or Bayesian designs,
- 60-day Animal Drug Availability Act (ADAA) combination medicated feeds,
- early information,
- biologics or drug products with novel modes of action, or
- if a consultation is needed from another center within Food and Drug Administration (FDA) or outside of FDA (for example, Center for Biologics Evaluation and Research (CBER) or United States Department of Agriculture (USDA)).

If either CVM or the sponsor is unsure of the level of complexity of the proposed meeting topics, a conversation with a PM is suggested prior to submission of the virtual PSC with ERL meeting request.

[10] For the purposes of meeting assignments, divisions considered will be those groups that have primary responsibility for the evaluation of a TS regardless of the need for a consulting review from another division.

A. Create and Assign Consults

1. For the First PSC, or a PSC to Revisit the Development Plan Across All TSs, for Pioneer Products:

   The PM has two (2) calendar days from the assignment of a complete request to issue consults to all members of the project team to notify them of the new project or change to an existing project. In addition to the PM, the project team consists of at least one representative from each team involved in the review of each applicable major TS. Team leaders (TLs) assign consults within three (3) calendar days from the date the consult is sent by the PM.

   PLEASE NOTE: For the ERL, it is important to assign consults immediately due to the condensed timeline in generating an ERL at least six (6) calendar days prior to the scheduled meeting.

   TSs or components identified by the sponsor in eSubmitter:

   - as “To Discuss at Current Meeting” are discussed at the pre-meeting, in the ERL, and at the sponsor meeting. For any TSs confirmed to be complete at the meeting, the division representative informs the sponsor to provide a copy of either the acknowledgement letter, ERL or MOC in lieu of a TS complete (TSC) letter when they submit their application for approval.

   - as “To Discuss at a Future Meeting” are not discussed at the pre-meeting or the sponsor meeting, and CVM will not generally transmit feedback for that component in the acknowledgement letter to the sponsor.

   - as “CVM to Confirm, but Not for Discussion” are not discussed at the pre-meeting or sponsor meeting. However, this designation means the sponsor wants feedback outside of the meeting discussion. Therefore, the appropriate division representative or consulting reviewer (CR) provides feedback in the acknowledgement letter or ERL commensurate with the level of detail provided to CVM.

   - as either complete or not applicable (i.e., “Already Complete” or “Not Applicable”) are not discussed at the pre-meeting or sponsor meeting, but CVM provides feedback in the acknowledgement letter or ERL that CVM agrees, disagrees, or cannot confirm the sponsor’s assessment. For any TS confirmed to be complete outside of the meeting, the acknowledgement letter or ERL language informs the sponsor they should provide a copy of the acknowledgement letter for the PSC or of the ERL in lieu of a TSC letter when they submit their application for approval.

The table below summarizes expectations related to the sponsor's selections:

Sponsor selection for TS or component	Consults sent?	Scheduled for meeting and pre-meeting?	Reviewer expectations
To discuss at Current Meeting	Yes	Yes	Participate at pre-meeting and meeting; Provide MOC and acknowledgement letter text, as applicable; OR Provide ERL or MOC and acknowledgement letter text commensurate with level of detail provided, as applicable
To Discuss at a Future Meeting	Yes	No	Acknowledge if desired
CVM to Confirm, but Not for Discussion	Yes	No	Provide feedback in acknowledgement letter/ERL that CVM agrees, disagrees, or cannot confirm the sponsor's assessment
Already Complete *OR* Not Applicable	Yes	No	Provide feedback in acknowledgement letter/ERL that CVM agrees, disagrees, or cannot confirm the sponsor's assessment

When the sponsor identifies that either the Effectiveness or Target Animal Safety TSs will be part of the meeting discussion, the PM issues consulting reviews to members of the Biostatistics and Clinical Pharmacology Teams.[11] Other consults (e.g., for policy, microbiology) are identified by the PM or requested by a TL and relayed to the PM within this timeframe.

If a requested review group has a question about attending, they should discuss this with the PM within two (2) calendar days of receiving a consult. The PM discusses options with the sponsor and other review groups, if needed.

2. For All Other PSCs[12]

   The PR has two (2) calendar days from the assignment of a complete request to issue consults. TLs assign consults within three (3) calendar days.

[11] For ADAA (Animal Drug Availability Act of 1996) combination project PSCs, consults are not issued to Clinical Pharmacology and Biostatistics teams. For DABCT this may not be the case for all the submissions.
[12] For PSCs led by the Division of Animal Bioengineering and Cellular Therapies (DABCT), see DABCT SOP 1243.106.002.

3. For In-Person PSCs

   Upon assignment of an in-person meeting, the PR and CRs determine with their management whether they will attend in-person or virtually, guided by ONADE's Expectations and Best Practices document.[13]

B. Schedule Pre-Meeting and Meeting

1. For Pioneer Products

   The scheduler schedules the internal pre-meeting and the sponsor meeting based on the TSs or components selected by the sponsor for discussion and on the availability of assigned review staff in a systematic order. For virtual pioneer PSC meetings with an ERL, the scheduler targets the pre-meeting date to occur no earlier than 39 days prior to the scheduled PSC date.

   For pioneer PSCs, the scheduler targets the meeting date to occur no later than 60 calendar days from receipt of a complete request. Follow this same timing for PSCs that reference EI in a completed A or H submission (per P&P 1243.2200). For pioneer PSCs that reference EI submitted in a pending A or H submission, the scheduler contacts the review team of the EI submission to confirm the appropriate timing for the meeting. Depending on the content of the EI submission, the meeting date may be targeted to occur on approximately the due date of the A or H submission.[14]

   If an in-person meeting is requested, the scheduler considers the sponsor's audio-visual (A/V) and connection requirements in identifying an appropriate conference room, and will reserve that room through Outlook.[15, 16] Note that in-person CVM A/V support is currently available only on Tuesdays, Wednesdays, and Thursdays (the A/V technicians are available to help remotely on Mondays and Fridays). Schedulers should consider the need for in-person A/V support when scheduling in-person meetings. If an in-person meeting cannot be scheduled within 60 days due to conference room and/or A/V support unavailability, the scheduler should offer the sponsor both the first available date for an in-person meeting and the first available date (within 60 days) for a virtual meeting.

   Generally, a meeting should not exceed two hours. If the agenda is divided into more than one meeting, the scheduler attempts to schedule the meetings for the same day or over consecutive days at the sponsor's request, for the convenience of out-of-town attendees.

   For the pre-meeting:

   - Preferred scenario: Meeting is scheduled around assigned consulting reviewers (CRs) and their TLs; if not possible, proceed to next scenario.

[13] Internal information redacted.

[14] ADUFA IV performance goals letter (page 8) https://www.fda.gov/media/116001/download

[15] The conference room should be large enough to hold the expected attendees comfortably. The meeting should not be in an area where trade secret or commercial confidential information is stored or where outside parties can overhear conversations involving trade secret or commercial confidential information.

[16] If appropriate, reserve the appropriate teleconference or virtual meeting resources.

- Second scenario: Meeting is scheduled around CRs only (TLs included as optional).

For the meeting:

- Preferred scenario: Meeting is scheduled around assigned CRs and their TLs on a sponsor block day (per SOP 1243.186.001); if not possible, proceed to next scenario.
- Second scenario: Meeting is scheduled around assigned CRs and their TLs on a non-sponsor block day; if not possible, proceed to next scenario.
- Third scenario: Meeting is scheduled around CRs only (TLs included as optional) on a sponsor block day; if not possible, proceed to next scenario.
- Fourth scenario: Meeting is scheduled around CRs only (TLs included as optional) on a non-sponsor block day.

2. For Generic Products

   Please refer to the Division of Generic Animal Drugs (DGAD) meetings SOP 1243.170.003.

C. Confirm Meeting Date

The scheduler contacts the sponsor and confirms the meeting date and time.

After the meeting date is confirmed, the scheduler updates the meeting date in Appian. If the proposed date for a pioneer PSC exceeds 60 days, the Appian workflow prompts the scheduler to select whether CVM is unable to accommodate a meeting date within 60 days or the sponsor is unable to meet with CVM at the offered times within 60 days.

- For pioneer PSCs that reference EI in a pending A or H submission and are scheduled beyond 60 days to allow sufficient review of the EI, select the option that the sponsor is unable to meet with CVM at the offered times within 60 days.[17]
- For in-person pioneer PSCs that are scheduled beyond 60 days due to conference room or A/V support unavailability, select the option that the sponsor is unable to meet with CVM at the offered times within 60 days.[18]
- For virtual PSCs with an ERL, the ERL is sent six (6) calendar days prior to the scheduled sponsor meeting. The sponsor has three (3) calendar days to respond with an amendment to the Z submission in eSubmitter, letting CVM know if they still want to proceed with the scheduled sponsor meeting or to cancel the meeting. If the sponsor does not respond within three (3) calendar days, the PR or PM sends a reminder notification via email. It is important to note that if the sponsor does not confirm whether they want to hold the scheduled sponsor meeting, CVM will proceed with holding the meeting.

[17] We may update the wording in the future but choose this option to reflect that the sponsor is not able to meet earlier because the meeting relies on review of the EI in a pending submission.
[18] This acknowledges that the sponsor was given the option to meet sooner virtually.

D. Ensure the Clearance of Foreign Visitors (When Applicable)

For in-person meetings, the scheduler confirms with the sponsor whether their group includes any foreign visitors. A person is considered to be a foreign visitor if they are not a US citizen, a Legal Permanent Resident, or a Green Card holder.

If any foreign visitor will be present at the meeting, the scheduler follows the process for foreign visitors.[19] Foreign visitors must be cleared in advance, so the scheduler should confirm with the sponsor and begin the process immediately after scheduling the meeting date. Any foreign visitor who is not cleared through this process will be denied entry to the building.

E. Conduct the Pre-Meeting and Any Follow-up

1. For In-Person and Virtual Meetings (With No ERL):

   The purpose of the pre-meeting is to plan for the meeting with the sponsor. At the pre-meeting, participants:

   - finalize the agenda (e.g., establish the speaking order and agree how to move through the sponsor's materials);
   - share their prepared talking points and identify any anticipated agreements;
   - decide whether any questions for the sponsor will be posed before or during the meeting;
   - discuss any questions or points participants have for one another to ensure alignment;
   - confirm whether any participants will leave the meeting early after addressing their agenda items;
   - confirm whether any CR whose input is not required to discuss the sponsor's proposal will not attend the meeting (e.g., Biostatistics and Clinical Pharmacology Teams); and
   - identify if any follow-up, internal or with the sponsor, is needed before the meeting with the sponsor.

2. For an In-Person Meeting, Participants Also Confirm the Following:

   - who will attend in person and who will attend virtually, as determined following ONADE's Expectations and Best Practices document;[20] and
   - among the in-person attendees, who will act as onsite host. To ensure efficient use of ONADE's travel resources, the onsite host will be a person who is already required to attend the meeting in person.

[19] See foreign national visitor clearance process: Internal information redacted.

[20] Internal information redacted.

3. The PR or Scheduler Follows Up With the Sponsor After the Pre-Meeting to:

   - share the final agenda;
   - confirm expectations for the sponsor's speaking role in the meeting. Typically, after introductions, we move to the discussion, but we may allow them to give a brief opening statement or request that they speak to specific items in their meeting materials;
   - ask any questions or clarifications that will facilitate a more effective meeting;
   - for virtual and hybrid meetings and also virtual PSC meeting with ERL, confirm the virtual connection information with the sponsor. Typically, CVM generates the remote connection. The scheduler can email the dial in information in a separate email or separate Outlook invite to the sponsor; and
   - for in person meetings, provide directions to the meeting location to the sponsor (if necessary) and remind their representatives to arrive about 15 minutes early to clear security.

4. For Virtual PSC Meetings With an ERL:

   The purpose of the pre-meeting is to discuss the draft response(s) to the sponsor's questions that will be sent in the ERL, or to determine if the questions can't be answered in the ERL. At the time of the pre-meeting, CVM will not know if the sponsor meeting will be held; however, the pre-meeting will be used to discuss a plan for the potential sponsor meeting. It may be an option to cancel the pre-meeting if the draft responses can be shared and agreed upon by all reviewers, ahead of the pre-meeting. If a premeeting is held, the participants:

   - discuss any questions or points participants have for one another to ensure alignment;
   - discuss CVM's responses to be included in the ERL;
   - decide if any follow-up, internal or with the sponsor, is needed before sending the ERL; and
   - establish the potential speaking order, agree how to move through the sponsor's materials, share prepared talking points, and identify any anticipated agreements (these may change based on the sponsor's need for clarification). Refer to Section XIII for more details about holding the meeting.

VIII. METHOD DEMONSTRATION MEETING PREPARATION

Method demonstration meeting requests should identify the CVM submission in which CVM agreed that an analytical method may proceed to a method demonstration meeting, a list of sponsor attendees, and include the method standard operating procedure and method trial protocol as attachments (see SOP 1243.150.007).

A. Create and Assign Consults

The Division of Human Food Safety Residue Chemistry Team (HFV-151) reviewer assigned to the meeting sends a consult to the Office of Applied Science's (OAS) Division of Residue Chemistry (HFV-510). In consultation with their TL, CRs, and HFV-510 management, the PR determines who to invite to the meeting.

Upon assignment of an in-person meeting, the PR and CRs will determine with their management who will attend in person and who will attend virtually, guided by ONADE's Expectations and Best Practices document.[21]

B. Schedule Meeting

CVM has asked that the sponsor not request the method demonstration meeting until the date has been agreed upon between CVM and the sponsor. CVM and the sponsor will agree on the date based on the availability of staff and equipment at OAS. The PR verifies that the meeting date included in the eSubmitter meeting request matches the agreed upon date.

C. Confirm Meeting Date and Attendees

The PR contacts the sponsor to confirm the meeting date, time, and attendees.

In the Outlook meeting invite, the PR lists the names of the CVM attendees who are expected to attend in person. For in-person meetings, this is how we will meet the agency requirement to notify remote employees in writing when they need to come into the office.

D. Ensure the Clearance of Foreign Visitors (When Applicable)

For in-person meetings, the scheduler confirms with the sponsor whether their group includes any foreign visitors. A person is considered to be a foreign visitor if they are not a US citizen, a Legal Permanent Resident, or a Green Card holder.

If any foreign visitor will be present at the meeting, the scheduler follows the process for foreign visitors.[22] Foreign visitors must be cleared in advance, so the PR confirms with the sponsor and begins the process immediately after scheduling the meeting date. Any foreign visitor who is not cleared through this process will be denied entry to the building. OR laboratory visits by foreign visitors require written justification from the respective division director for the visit as part of the application.

E. Conduct the Pre-Meeting

A pre-meeting is generally not necessary for the method demonstration meeting. The PR communicates with the HFV-510 CR to ensure that the laboratory is prepared for the method demonstration.

[21] Internal information redacted.

[22] See foreign national visitor clearance process: Internal information redacted.

F. Manage Logistics with the Sponsor

1. For In-Person Meetings

   The PR provides directions to OR to the sponsor (if necessary) and reminds the sponsor to have their representatives arrive a few minutes early to clear security. The PR or HFV-510 CR provides a list of the non-FDA attendees and a phone number of an office contact (escort) to the building security staff for the building in which the meeting will occur the morning of the meeting (or earlier) so that the security staff can prepare visitor badges more quickly.

2. For Virtual Meetings

   The PR confirms the virtual connection information with the sponsor. Typically, CVM generates the remote connection.

IX. OTHER ONADE MEETING PREPARATION

If the meeting is not a PSC or a method demonstration meeting, the sponsor should provide at a minimum a detailed agenda that identifies the general areas of discussion and allows us to evaluate who from FDA should attend the meeting and provide enough background information to ensure a productive meeting.

As with PSCs, a PM is the PR for other ONADE meetings that discuss more than one TS that is handled by more than one ONADE division as primary. For those meeting requests that require the feedback from one primary review division or for meeting requests for generic drugs, the PR is a member of that division.

A. Create and Assign Consults

The PR determines who to invite to the meeting in consultation with the TL. Generally, at least two people from ONADE attend a meeting with a sponsor.

Because there are no defined minimum criteria for other ONADE meeting requests in eSubmitter, CRs carefully evaluate the sponsor's submission materials to ensure that the information is adequate to allow for a productive discussion. If the sponsor did not provide sufficient information and context for a productive discussion, CVM may request additional information and possibly reschedule or postpone the meeting. CRs discuss the need for additional information with the PR.

Upon assignment of an in-person meeting, the PR and CRs will determine with their management who will attend in person and who will attend virtually, guided by ONADE's Expectations and Best Practices document.[23]

B. Schedule Pre-Meeting and Meeting

The scheduler schedules the internal pre-meeting and the sponsor meeting based on the proposed agenda and the CVM expertise needed to address the request.

[23] Internal information redacted.

If an in-person meeting is requested, the scheduler considers the sponsor's A/V and connection requirements in identifying an appropriate conference room, and will reserve that room through Outlook.[24,25] Note that in person CVM A/V support is currently available only on Tuesdays, Wednesdays, and Thursdays (A/V technicians are available to help remotely on Mondays and Fridays). Schedulers should consider the need for in person A/V support when scheduling in-person meetings.

C. Confirm Meeting Date

The scheduler contacts the sponsor and confirms the meeting date and time. After the meeting date is confirmed, the scheduler updates the meeting date in STARS using the ONADE Update Meeting Date/Type workflow in Appian.

D. Ensure the Clearance of Foreign Visitors (When Applicable)

For in-person meetings, the scheduler confirms with the sponsor whether their group includes any foreign visitors. A person is considered to be a foreign visitor if they are not a US citizen, a Legal Permanent Resident, or a Green Card holder.

If any foreign visitor will be present at the meeting, the scheduler follows the process for foreign visitors.[26] Foreign visitors must be cleared in advance, so the scheduler confirms with the sponsor and begins the process immediately after scheduling the meeting date. Any foreign visitor who is not cleared through this process will be denied entry to the building.

E. Conduct the Pre-Meeting and Any Follow-up

The purpose of the pre-meeting is to plan for the meeting with the sponsor.

1. At the Pre-Meeting, Participants:

    - finalize the agenda (e.g., establish the speaking order and agree how to move through the sponsor's materials);
    - share each speaker's prepared talking points;
    - decide whether any questions for the sponsor will be posed before or during the meeting;
    - discuss any questions or points participants have for one another to ensure alignment;
    - confirm whether any participants will leave the meeting early after addressing their agenda items;

[24] The conference room should be large enough to hold the expected attendees comfortably. The meeting should not be in an area where trade secret or commercial confidential information is stored or where outside parties can overhear conversations involving trade secret or commercial confidential information.
[25] If appropriate, reserve the appropriate teleconference or virtual meeting resources.
[26] See foreign national visitor clearance process: Internal information redacted.

- confirm whether any CR whose input is not required to discuss the sponsor's proposal will not attend the meeting (e.g., Biostatistics and Clinical Pharmacology Teams); and

- identify any follow-up, internal or with the sponsor, needed before the meeting with the sponsor.

2. When the Pre-Meeting is for an In-Person Meeting, Participants Also Confirm:

   - who will attend in person and who will attend virtually, as determined following ONADE's Expectations and Best Practices document;[27] and

   - among the in-person attendees, who will act as onsite host. To ensure efficient use of ONADE's travel resources, the onsite host will be a person who is already required to attend the meeting in person.

3. The PR or Scheduler Follows Up With the Sponsor After the Pre-Meeting to:

   - share the final agenda;

   - confirm expectations for the sponsor's speaking role in the meeting; typically, after introductions we will move to the discussion, but we may allow them to give a brief opening statement or request that they speak to specific items in their meeting materials;

   - ask any questions or clarifications that will help us have a more effective meeting;

   - for virtual and hybrid meetings, confirm the virtual connection information with the sponsor. Typically, CVM generates the remote connection. The scheduler can email the dial in information in a separate email or separate Outlook invite to the sponsor; and

   - for in-person meetings, provide directions to the meeting location to the sponsor (if necessary) and remind their representatives to arrive about 15 minutes early to clear security.

X. MANAGING LOGISTICS FOR IN PERSON MEETINGS TO BE HELD AT METROPARK NORTH 2 (MPN2)[28]

A. List In-Person Attendees in the Outlook Invite

After receiving confirmation in the pre-meeting, the scheduler updates the body of the Outlook meeting invite to list the names of the CVM attendees who are expected to attend in person. This is how we will meet the agency requirement to notify remote employees in writing when they need to come into the office.

[27] Internal information redacted.

[28] 7500 Standish Place, Rockville, MD 20855

B. Submit a Request for Audio-Visual (A/V) Support

The scheduler submits a completed Audio-Visual Request Form[29] to request conference room support. Note that in-person CVM A/V support is currently available only on Tuesdays, Wednesdays, and Thursdays (A/V technicians are available to help remotely on Mondays and Fridays). The A/V request form should be submitted as soon as possible after the meeting date is confirmed but no later than 48 hours before the meeting date.

Note: If all CVM in-person attendees want their laptops fully available for their own use during the meeting (e.g., to refer to or take notes, to message with other attendees), the scheduler can request a loaner laptop for use by the onsite host during the meeting to connect to the conference room projection system. The scheduler does this by completing the following steps.

Specify in the Audio-Visual Request Form that a loaner laptop is requested.

1. Email our CVM IT Liaison[30] requesting they confirm whether user profiles need to be added to the loaner laptops and provide the names of the onsite host and backup onsite host. The CVM IT Liaison will add the profiles if needed so the hosts can log into McAfee using their normal login information.

   If a user is close to a scheduled password change, they may be prompted to do that on the loaner. If a user recently changed their password, they may need to enter the previous password on the loaner.

2. Loaner laptops can be picked up after 8:00 a.m. on the day of the meeting from the A/V offices (N117 and N126), or the A/V technicians will bring one with them to the meeting setup.

C. Notify FDA Physical Security of the Upcoming Meeting and Expected Outside Attendees (Visitors)

The scheduler notifies FDA Physical Security as described in the CVM SOP "MetroPark North (MPN) Visitors and Visitor Badge Process."[31] The scheduler will copy the onsite host on this email. Per the SOP, this should be done 2-14 days prior to the meeting.

D. Provide FDA Physical Security with Prepared Badges and List of Visitors

The onsite host provides FDA Physical Security with badges printed or hand-written with visitors' names, in plastic badge holders or with plastic clips, as described in the CVM SOP "MetroPark North (MPN) Visitors and Visitor Badge Process." Per the SOP, this should be done the day before or the day of the meeting. Badging supplies

[29] Internal information redacted.

[30] Internal information redacted.

[31] Internal information redacted.

are located in MPN2 room E128. There is a CVM template that should be used to create badges.[32]

The onsite host also provides FDA Physical Security with a physical list of the expected visitors, specifying any who are foreign nationals. If the email sent in the previous step includes the required information (name and foreign visitor status), the online host can print it or handwrite a list based on it.

As stated in the CVM SOP, the onsite host will need to collect all of the issued badges from visitors before they leave the building, shred the paper badges, and return the badge holders or clips to their designated location.

XI. HANDLING AMENDMENTS

A. For Pioneer Products

1. CVM-Initiated Amendments

   a. It is appropriate to request amendments if they are minor in nature (e.g., providing cited publications or summaries of pilot data, clarifying discrepancies between eSubmitter information and meeting materials); see P&P 1243.3026. If CVM representatives consider the information that would be requested by amendment necessary to have a meaningful discussion to be a major amendment, the PR closes the meeting request using the final action Postponed Meeting; Insufficient materials; Letter Sent (PSTPN MTG) and advises the sponsor to resubmit the request when the information is available.

   The PR coordinates any CVM-initiated amendment request with the CRs expected to participate at the meeting with the sponsor. CRs not scheduled to participate at the meeting are not expected to contribute to an amendment request.

   CVM's amendment request clearly identifies the information needed, the deadline for receiving the amendment, and what will happen if CVM does not receive the amendment by the deadline (see next paragraph). The deadline is determined by the review team on a case-by-case basis and may depend on the time left between the pre-meeting and meeting dates.

   b. If the amendment is received on time and addresses CVM's request, it is reviewed and discussed at the meeting. If the amendment is received late, the PR does not send consults for the amendment, the information will not be reviewed, and the meeting is still held based on the original submission. If the amendment does not adequately address CVM's request, CVM's meeting discussion is commensurate with the information provided. If the amendment provides more information than was requested, only the requested information is reviewed; the unsolicited information is not reviewed. The group(s) to whom the extraneous information was provided document what information was reviewed and what was not.

[32] The template is called MPN FSC Badge Template, and it can be found on the following SharePoint page: Internal information redacted.

2. Unsolicited Amendments

   a. For PSC and other ONADE meeting types, the eSubmitter template contains language warning sponsors that an unsolicited amendment will result in our rescheduling the meeting. Sponsors who want to submit additional information that CVM did not request should contact the scheduler.

      The options for unsolicited amendments include:

      - move forward with the scheduled meeting utilizing the information in the amendment,
      - void the amendment (hold the meeting as it was first submitted and if the information in the amendment is needed for the sponsor to move forward with their development another meeting request will need to be submitted), or
      - reschedule the meeting. If a sponsor proceeds with submitting an unsolicited amendment with additional information for review, we inform the sponsor that to have adequate time to review the additional information, we'll need to reschedule the meeting. When updating the meeting date in Appian for a rescheduled PSC, the scheduler selects the option that the sponsor is unable to meet with CVM at the offered times within 60 days.

   b. For method demonstration meetings, unsolicited amendments from sponsors will not be accepted.

B. For Generic Products

Please refer to the DGAD meetings SOP 1243.170.003.

XII. POSTPONING, RESCHEDULING, CANCELLING, OR MEETING NOT HELD

A. Postponing (Using the Final Action Code)

Inadequate submissions are closed using the final action code Postponed Meeting; Insufficient materials; Letter Sent (PSTPN MTG). This final action is equivalent to refuse to review/file; we cannot apply the refuse to review/file final action code to meeting requests. We close out a submission with this final action if, for example:

- the meeting is a presubmission conference and the sponsor did not submit the required information as described above in the "Presubmission Conference Meetings" section; or
- we determine that the information the sponsor submitted does not contain sufficient detail (e.g., because it does not identify specific questions, proposals, or issues, or does not explain how the materials support their position with respect to the agenda items) to have a productive discussion.

B. Rescheduling

We reschedule a pioneer product meeting if the sponsor submits an unsolicited amendment with additional information for review as described above. It is extremely rare that we would reschedule a meeting in any other circumstances; these would be exceptional situations such as realizing we have a significant policy issue that requires extensive internal discussion or being confronted with a major and unsolvable scheduling conflict. Any decision to reschedule is only made after discussion between the PR and impacted CVM participants in consultation with their supervisors.

If we decide to reschedule a meeting, the scheduler contacts the sponsor promptly to explain the reason for rescheduling and propose a new meeting date and time. For a rescheduled presubmission conference or other ONADE meeting, the scheduler changes the date in STARS using the Appian Update Meeting Date/Type workflow and notifies the CRs and other internal meeting attendees of the change. For a rescheduled method demonstration meeting, the scheduler sends an email to the EDSR Mailbox to change the meeting date.[33] The subject line for the email should be Change Method Meeting Date. The ONADE Business Informatics Team manages the mailbox. When the change in STARS has been made, the requestor will get a notification email from the EDSR Mailbox.

C. Cancelling

Meetings can be cancelled if the sponsor agrees. Cancelled meetings are closed as either a submission filed with review documentation (FNR/MEMO) or with an acknowledgement letter, depending on division procedure. The PR will write the memorandum or letter and the documentation will contain an explanation for why we did not hold the meeting.

D. Meeting Not Held (Virtual Presubmission Conference with an Early Response Letter (ERL) Only)

For virtual meetings with an ERL where the sponsor provides notification to CVM that the meeting is not needed because the ERL addressed their questions, the submission is closed out.[34]

XIII. HOLDING THE MEETING

A. Meetings for Virtual Presubmission Conference (PSC) with an Early Response Letter (ERL)

Meetings will be focused on clarifying the comments sent in the ERL and providing any PSC agreements. New topics will not be discussed, as they will be considered outside the scope of the meeting. All review team members should keep the meeting invite on their calendars until the sponsor's notification is received confirming which questions need clarification. Each division should assess whether they need to attend the meeting based on the sponsor's notification of questions that need clarification. It is best practice to let the PR know if you no longer plan to attend the meeting. If we

[33] CVM.ONADE.EDSR.SUPPORT@fda.hhs.gov
[34] See ONADE P&P 1243.3025 for the close out procedure if a meeting is no longer needed following the receipt of a virtual PSC with an ERL.

do not receive the sponsor's notification, then the review team should attend the meeting. If the sponsor does not join the meeting within 15 minutes of the scheduled start time, CVM concludes the meeting, and the submission is finalized with an FNR/MEMO.

B. Confirm the List of Meeting Participants

For in person and virtual meetings (including those with an ERL), the PR or designee is responsible for creating a list of attendees from both CVM and outside parties. The meeting participant list, including sponsor and CVM representatives and their affiliations, is reflected in the MOC.

C. Welcome Attendees

The PR welcomes the meeting attendees, states the purpose and goals of the meeting, and reminds participants of the time allotted for the meeting. The PR asks all participants to introduce themselves.

D. Lead the Discussion

The PR either leads the discussion portion of the meeting or turns the lead over to the sponsor or another CVM attendee. The PR ensures the meeting remains cordial and professional at all times, focuses the discussion on the agenda items, and keeps the meeting on schedule.

CVM attendees who have a limited amount of feedback to provide may speak first and leave the meeting early if this was arranged and agreed to at the pre-meeting.

Note: Sponsors are welcome to take notes during the course of the meeting. We do not allow sponsors to record audio or video of our meetings and CVM participants are not to consent to a recording.[35] If a sponsor is concerned about missing key points, we can reassure them that the MOC (or acknowledgement letter for a pre-INAD meeting when applicable) will contain the details discussed.

E. Summarize the Meeting

At the end of the meeting, or following each portion of the discussion if some participants leave early the PR or another attendee summarizes: key discussion points, any agreements reached in a PSC, and any action items identified, such as assignments of responsibility and how CVM will respond to our action items (e.g., in the acknowledgement letter or in a future meeting).

The PR also gives the sponsor the opportunity to identify items in our summary that they do not agree with or have questions about. The PR reminds the sponsor that:

- For in person and virtual meetings (with no ERL), the details of the meeting will be documented in the MOC (or acknowledgement letter for a pre-INAD meeting, when applicable) that is sent within 45 days of the meeting.

[35] In accordance with 21 CFR 10.65(e) and FDA policy, meetings with sponsors and applicants may not be electronically recorded. The official record of the meeting will be the FDA-generated meeting minutes.

- For virtual PSC meetings with an ERL, the details of the meeting will be documented in the MOC that is sent within 30 days of the meeting.

XIV. POST-MEETING (FOLLOW-UP) TASKS

A. Prepare Documentation

The PR or meeting preparer[36] prepares documentation following P&P 1243.3025. If we require the sponsor to conduct more than one field study to establish effectiveness, the PR consults their supervisor about the need for an earlier response (see 21 CFR 514.5(f)(2)).

B. Address Action Items

CVM follows up on any action items assigned to us at the meeting and includes responses in the acknowledgement letter accompanying the MOC as described in P&P 1243.3025, as appropriate.

XV. REFERENCES

The Federal Food, Drug and Cosmetic Act

Section 512(b)(3)

Code of Federal Regulations (Title 21)

Part 10 – Administrative Practices and Procedures

§10.65, Meetings and correspondence

§10.70, Documentation of significant decisions in administrative file

Part 514 – New Animal Drug Applications

§514.3, Definitions

§514.5, Presubmission conferences

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.2100 - Eligibility for Conditional Approval Under the Expanded Conditional Approval (XCA) Criteria

1243.2200 - Submission and Review of Early Information (EI) Prior to Presubmission Conferences and Protocol Review

1243.3021 - Portfolio Overview Meetings with Sponsors of New Animal Drug Application Projects

1243.3023 - Lessons Learned Meetings for New Animal Drug Application Projects

[36] The preparer is the PR assigned to the Z submission or any other individual designated by office, division, or team procedures as responsible for preparing the meeting documentation.

1243.3025 - Preparing Meeting Documentation (i.e., Early Response Letter, Memorandum of Conference, Acknowledgement Letter, Other Review Documentation)

1243.3026 - Assessing Submission Quality and Amending and Resetting the Clock on Submissions

1243.3029 - Closing Out Consulting Reviews for Submission Tracking and Reporting System (STARS) Submissions

1243.3200 - Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

1243.3250 - Q Submissions: Agency-Initiated Actions

1243.4060 - Review of Protocols

1243.5706 - Meeting to Discuss Post-Approval Responsibilities for Sponsors of Conditional Approvals

CVM Standard Operating Procedures

Metro Park North (MPN) Visitors and Visitor Badge Process

Internal information redacted.

CVM template for badges.docx

Internal information redacted.

ONADE Resources

ONADE's Expectations and Best Practices

Internal information redacted.

XVI. VERSION HISTORY

December 8, 2005 – original version

August 10, 2006 – revised to clarify the definition of other meeting approved by ONADE Management August 2006, and to add a Summary of Procedure section.

May 23, 2012 – revised to reflect current practice, including changes to the administrative process due to the implementation of Appian and eSubmitter, and to remove the Summary of Procedure section since that does not follow the current template.

September 6, 2016 – revised to current format, to incorporate the policy for clearance of foreign visitors, to reflect the change from sub-class codes to meeting types, and to

reflect the Appian workflow replacing the STARS correction form for changing meeting type and meeting date.

April 10, 2018 – Revised to remove exemption of Green Card holders from the Clearance of Foreign Visitors process. Green Card holders must follow the Foreign Visitor Clearance Process of FDA.

October 1, 2018 – Revised the document to represent a new process for pioneer PSCs and additional clarifications. The changes reflect a more structured eSubmitter template for pioneer PSC requests to provide a complete agenda.

March 15, 2019 – Revised to fix broken hyperlink in internal version.

May 21, 2019 – Updated to include Appendix 1 that contains information on the beta test ONADE will be conducting for scheduling presubmission meetings on sponsor block days. This is a 6-month beta test that will be from now until December 2019.

April 20, 2020 – Removed reference to EI submitted in a Z submission, consistent with 1243.2200. Created a new section that explains about scheduling meetings on sponsor block days to replace the previous Appendix 1.

October 15, 2020 – Revised to include the consistent use of the term sponsor and updated links and titles of referenced files. Also revised to appropriately represent the applicable SOPs for the Divisions of Animal Bioengineering and Cellular Therapies, Human Food Safety, and Generic Animal Drugs.

November 24, 2020 – Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

December 1, 2020 – Updated to include updated language about foreign visitors as requested by Office of Security Operations (OSO).

February 8, 2021 – Updated to specify that for pioneer PSCs referencing EI in a pending A or H submission, the meeting is no longer automatically scheduled to occur near the due date of the A or H submission. The scheduler will confirm the appropriate timing with the review team.

May 5, 2021 – Updated to link to the CVM Office of Management SOP entitled “Visitor Badge Format MPN SOP” for meetings at Metro Park North with in-person visitors.

July 20, 2021 – Updated to incorporate information from the following office policies: “Differences between a Pre-Submission Conference (PS) and ONADE Other (OO) Meeting Request” (added a more detailed definition of a presubmission conference and updated examples of OO meetings), “Meetings with Outside Stakeholders under General Correspondence (GC) Files” (identified processes unique to pre-INAD OO meetings under General Correspondence (GC) files), “Pre-Submission Conference Expectations” (added details regarding pre-meeting expectations and potential follow-up tasks), and “ONADE Policy on Recording Meetings” (specified that CVM does not permit sponsors to record meetings). Noted ONADE’s expectation that the U.S.-based employee or U.S. agent representative attend any formal meetings between CVM and a foreign sponsor. Added information about managing logistics for virtual meetings. Moved duplicate information about “Handling Amendments” within each meeting type to be a standalone

section covering all three meeting types. Added clarification about circumstances in which we would reschedule a meeting.

August 9, 2021 – Updated Section IV to remove one of the examples. Updated to fix minor formatting issues.

February 14, 2022 – Updated to remove the expectation that the U.S.-based employee or U.S. agent attend any formal meetings between CVM and a foreign sponsor. Change made in conformance with the updated communication expectations in P&P 1243.2020 United States (U.S.)-Based Employee and U.S. Agent Representation of Foreign Sponsors.

July 21, 2022 – Quality systems review for minor formatting updates.

April 17, 2023 – Updated with new logistics for in person meetings: Specific reference to "hybrid" meetings; the need to determine soon after assignment who will attend in person and who will attend virtually, following ONADE's Expectations and Best Practices document; how to handle requested in person PSCs that cannot be scheduled within 60 days; the current onsite schedule for A/V support; pre-meeting tasks of confirming in person attendees and the onsite host; and a new section with specific logistics for MPN2 in person meetings including the updated link for requesting A/V support and references to CVM's new badging SOP. Added the CVM SOP on visitors and the visitor badge process to the references section. As part of this process update, the ONADE Meeting Sign-In Sheet template is no longer necessary, and it was retired. The font of this document was changed from Verdana 10-point font to Arial 11-point font. In order to bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font.

September 29, 2023 – Contents were placed into the most recent template. Updated to include the virtual PSC meeting with an Early Response Letter (ERL) process as a type of meeting resulting from ADUFA V negotiations. This update is reflected in multiple sections of the document (i.e., Sections II Definitions, III Types of Meetings, V Initial Processing of a Meeting Request, XI Handling Amendments, XII Postponing, Rescheduling, Cancelling or Meeting Not Held, and XIII Holding the Meeting). This update also includes the procedure for requesting a loaner laptop and the link to the CVM SOP "MetroPark North (MPN) Visitors and Visitor Badge Process." A reference was added to include the P&P 1243.4092 "H Submissions Preceding Meetings and Protocols".

December 6, 2023 – Updated sections XII. B. The STARS Correction Request Form has been retired. The instructions are that the scheduler will send an email to the EDSR Mailbox asking to change the method demonstration meeting date.

January 11, 2024 – Updated to redact information in section IV and to remove the redaction the PM email address since it is available publicly.