

---

OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

---

**SCHEDULING AND HOLDING MEETINGS WITH OUTSIDE PARTIES**

I.	Purpose.....	1
II.	Definitions .....	1
III.	Types of meetings .....	2
IV.	Pre-INAD meetings under a general correspondence (GC) file .....	3
V.	Initial processing of a meeting request.....	4
VI.	Sponsor block days for scheduling sponsor meetings .....	4
VII.	Presubmission conference meetings .....	5
VIII.	Method demonstration meetings .....	11
IX.	Other ONADE meetings .....	13
X.	Handling amendments.....	15
XI.	Postponing, rescheduling, or cancelling a meeting .....	17
XII.	Holding the meeting.....	18
XIII.	Post-meeting (follow-up) tasks .....	19
XIV.	References .....	19
XV.	Version history .....	20

**I. PURPOSE**

This document:

- Defines the types of meetings the Office of New Animal Drug Evaluation (ONADE) has with outside parties, and
- Describes the procedures for scheduling and holding meetings with outside parties.
- Includes information on scheduling meetings on sponsor block days.

**II. DEFINITIONS**

**A. Meeting**

A meeting is any substantive oral discussion, whether by telephone, videoconference, or in person.<sup>1</sup>

**B. Memorandum of Conference (MOC)**

An MOC is a document prepared by ONADE personnel that documents the nature and substance of a meeting with an outside party.<sup>2</sup> The MOC is the official record

---

<sup>1</sup> 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.

<sup>2</sup> 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.

of the meeting.<sup>3</sup> Outside parties are referred to as the sponsor for the remainder of this document.

### **C. Scheduler**

The scheduler is the individual in ONADE 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 Submission Tracking and Reporting System (STARS).<sup>4</sup> All meeting requests have the subclass code of OM. The meeting request is designated as presubmission conference (PS), method demonstration (MD), or other ONADE meeting (OO) in the Meeting Type field in STARS. The Meeting Type field is populated based on the meeting scope selected in eSubmitter.

### **A. Presubmission Conference (PS)**

A presubmission conference (commonly referred to as a PSC) 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, which include 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 should try to reach agreement with the sponsor on requirements. PSC agreements are binding upon us and the sponsor, and the legislative history<sup>5</sup> points out that agreements provide sponsors assurance about applying their time and resources to development work. However, classifying a meeting as PS or OO is not based upon whether agreements are likely. If the purpose of the meeting fits the criteria described above, it should be classified as PS in STARS.

### **B. Method Demonstration Meetings (MD)**

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 Division of Human Food Safety SOP 1243.150.007 – Review of Submissions Related to the Official Residue Method.

---

<sup>3</sup> Refer to P&P 1243.3025 Preparing Meeting Documentation (i.e., Memorandum of Conference, Acknowledgement Letter, Other Review Documentation) for details about preparing a memorandum of conference.

<sup>4</sup> Meetings we initiate are coded as Q submissions in STARS.

<sup>5</sup> 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.

### C. Other ONADE Meetings (OO)

Other ONADE meetings are any meetings other than a PS or MD meeting type. Examples of OO meeting types are meetings to discuss the details of a protocol,<sup>6</sup> labeling, inclusion/exclusion criteria for a data submission, sponsor responsibilities following a conditional approval,<sup>7</sup> lessons learned meetings,<sup>8</sup> meetings held under General Correspondence (GC) files including portfolio overview meetings<sup>9</sup> and pre-INAD meetings (see below for details), and meetings held under Type VII Veterinary Master Files (VMFs).

### D. Meetings That Do Not Require Z Submissions

Divisions may discuss issues with a sponsor informally and document the discussion in a Q submission (refer to P&P 1243.3250 for details about Q submissions).

## 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 General Correspondence (GC) file before the sponsor proceeds with establishing an INAD. Specific parameters for pre-INAD meetings, which have an OO meeting type, are described below.

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 in order 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
- Feedback on the sponsor's eligibility for expanded conditional approval<sup>10</sup>

Pre-INAD meetings are not to be used to provide an overview of the approval process or to discuss requirements for approval. (Redact in public version) CVM may make an exception and discuss the approval process and requirements in pre-INAD meetings with sponsors from industries with new or novel technology or that often require more assistance, such as alternatives to antimicrobials, and aquaculture.

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](mailto:CVM.ONADE.PM@fda.hhs.gov).

<sup>6</sup> 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.

<sup>7</sup> 1243.5706 Meeting to Discuss Post-Approval Responsibilities for Sponsors of Conditional Approvals

<sup>8</sup> 1243.3023 Lessons Learned Meetings for New Animal Drug Application Projects

<sup>9</sup> 1243.3021 Portfolio Overview Meetings with Sponsors of New Animal Drug Application Projects

<sup>10</sup> 1243.2100 Eligibility for Conditional Approval Under the Expanded Conditional Approval (XCA) Criteria

CVM will not issue an MOC for pre-INAD meetings. We will 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 will determine if the request has the correct meeting type according to the definitions above. If the meeting type is incorrect, the PR will determine whether it is necessary to void the submission and ask the sponsor to resubmit using the correct meeting type in eSubmitter.<sup>11</sup>

The PR will also determine if we have sufficient information from the sponsor to schedule the meeting. For PSC requests, the PR will confirm 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 selected, and specific questions they want CVM to address for each of those technical sections,
- 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 will follow up with the sponsor as described in P&P 1243.2200.

**Note:** We do not meet with sponsors to discuss a submission that is under review 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 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 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 will not schedule regular or recurring meetings or non-sponsor meetings on sponsor block days. Every ONADE employee should have

---

<sup>11</sup> There are specific eSubmitter templates for MD and pioneer PS meetings, so we need sponsors to populate eSubmitter using the correct meeting type and associated templates for those meetings.

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. Time 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 and commute time. 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 MEETINGS**

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 scope, purpose, and objectives of the PSC, and the 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 assigned as the PR for investigational new animal drug or new animal drug application (a.k.a. pioneer) PSC requests in any of the following circumstances:

- The sponsor states in eSubmitter that this is the first meeting to address the development plan for this project or approval effort. This meeting serves as a kickoff meeting for the project.
- The sponsor states in eSubmitter that 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 that they wish to revisit their development plan across all technical sections based on the change.
- The sponsor requests in eSubmitter to discuss requirements for more than one technical section 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).<sup>12</sup>

Sponsors of pioneer products must identify in the eSubmitter template which technical sections 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 technical section 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"

#### **A. Create and Assign Consults**

1. For the first PSC, or a PSC to revisit the development plan across all technical sections, for pioneer products:

The PM will have 2 business 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 technical section. Team leaders will assign consults within 3 business days from the date that the consult is sent by the PM.

- Technical sections or components identified by the sponsor in eSubmitter as "To Discuss at Current Meeting" will be discussed at both the pre-meeting and the meeting with the sponsor. For any technical sections confirmed to be complete at the meeting, the division representative will inform the sponsor to provide a copy of the MOC in lieu of a technical section complete letter when they submit their application for approval.
- Technical sections or components identified by the sponsor in eSubmitter as "To Discuss at a Future Meeting" will not be discussed at the pre-meeting or the meeting with the sponsor, and CVM will not generally transmit feedback for that component in the acknowledgement to the sponsor.

---

<sup>12</sup> For the purposes of meeting assignments, divisions considered will be those groups that have primary responsibility for the evaluation of a technical section regardless of the need for a consulting review from another division.

- Technical sections or components identified by the sponsor in eSubmitter as “CVM to Confirm, but Not for Discussion” will not be discussed at the pre-meeting or meeting with the sponsor. However, this designation means the sponsor wants feedback outside of the meeting discussion. Therefore, the appropriate division representative or consulting reviewer will provide feedback in the acknowledgement letter commensurate with the level of detail provided to CVM.
- Technical sections or components that the sponsor identifies in eSubmitter as either complete or not applicable (i.e., “Already Complete” or “Not Applicable”) will not be discussed at the pre-meeting or meeting with the sponsor, but CVM will provide feedback in the acknowledgement letter that CVM agrees, disagrees, or cannot confirm the sponsor’s assessment. For any technical sections confirmed to be complete outside of the meeting, the acknowledgement letter language will inform the sponsor they should provide a copy of the acknowledgement letter for the PSC in lieu of a technical section complete letter when they submit their application for approval.

See the table below for a summary of expectations related to the sponsor’s selections:

<b>Sponsor Selection for Technical Section or Component</b>	<b>Consults Sent?</b>	<b>Scheduled for Meeting and Pre-meeting?</b>	<b>Reviewer Expectations</b>
“To discuss at Current Meeting”	Yes	Yes	Participate at pre-meeting and meeting  Provide MOC and letter text, 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 letter commensurate with level of detail provided
“Already Complete” or “Not Applicable”	Yes	No	Provide feedback in letter that CVM agrees, disagrees, or cannot confirm the sponsor’s assessment

The PM will also issue consulting reviews to members of the Biostatistics and Clinical Pharmacology Teams when the sponsor identifies that either the Effectiveness or Target Animal Safety technical sections will be part of the meeting discussion.<sup>13</sup> Other consults (e.g., for policy, microbiology, etc.) will be identified by the PM or requested by a team leader 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 2 business days of receiving a consult. The PM will discuss options with the sponsor and other review groups, if needed.

2. For all other PSCs<sup>14</sup>

The PR will have 2 business days from the assignment of a complete request to issue consults. Team leaders will assign consults within 3 business days.

## **B. Schedule Pre-Meeting and Meeting**

1. For pioneer products

The scheduler will schedule the internal pre-meeting and the meeting with the sponsor based on the technical sections or components selected by the sponsor for discussion and on the availability of assigned review staff in a systematic order. For pioneer PSCs, the scheduler will target the meeting date to occur no earlier than 30 days and no later than 60 days from receipt of a complete request. Follow this same timing for PSCs that reference EI in a completed A or H submission.<sup>15</sup> For pioneer PSCs that reference EI submitted in a pending A or H submission, the scheduler will contact 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.<sup>16</sup>

For the pre-meeting:

- Preferred scenario: Meeting is scheduled around assigned consulting reviewers and their team leaders; if this cannot be done, proceed to second scenario
- Second scenario: Meeting is scheduled around consulting reviewers only (team leaders included as optional)

For the meeting:

---

<sup>13</sup> For ADAA (Animal Drug Availability Act of 1996) combination project PSCs, consults will not be issued to Clinical Pharmacology and Biostatistics teams.

<sup>14</sup> For PSCs led by the Division of Animal Bioengineering and Cellular Therapies (DABCT) see Division SOP 1243.106.002 - Procedures for Sponsor Meetings with the Division of Animal Bioengineering and Cellular Therapies.

<sup>15</sup> See P&P 1243.2200 Submission and Review of Early Information (EI) Prior to Presubmission Conferences and Protocol Review

<sup>16</sup> ADUFA IV performance goals letter (page 8) <https://www.fda.gov/media/116001/download>



- Preferred scenario: Meeting is scheduled around assigned consulting reviewers and their team leaders on a sponsor block day<sup>17</sup>; if this cannot be done, proceed to second scenario
- Second scenario: Meeting is scheduled around assigned consulting reviewers and their team leaders on a non-sponsor block day; if this cannot be done, proceed to third scenario
- Third scenario: Meeting is scheduled around consulting reviewers only (team leaders included as optional) on a sponsor block day; if this cannot be done, proceed to fourth scenario
- Fourth scenario: Meeting is scheduled around consulting reviewers only (team leaders included as optional) on a non-sponsor block day

The scheduler will allow at least 3 weeks between the received date of the complete PSC request and the pre-meeting. Other persons alerted by the consulting reviewers (e.g., division directors or other reviewers) may attend the meetings as their schedule permits, but the meetings will not be rescheduled to accommodate them.

If an in-person meeting is requested, the scheduler will consider the sponsor's audio-visual and connection requirements in identifying an appropriate conference room, and will reserve that room through Outlook.<sup>18,19</sup> Generally, a meeting should not exceed two hours. If the agenda is divided into more than one meeting, the scheduler will attempt 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.

## 2. For generic products

Please refer to the Division of Generic Animal Drugs (DGAD) meetings SOP.<sup>20</sup>

### C. Confirm Meeting Date

The scheduler will contact the sponsor and confirm the meeting date and time. After the meeting date is confirmed, the scheduler will update the meeting date in STARS.<sup>21</sup> If the proposed date for a pioneer PSC exceeds 60 days, the Appian workflow will prompt the scheduler to identify 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 will be scheduled beyond 60 days to allow

<sup>17</sup> See SOP 1243.186.001 Adding Sponsor Block Days to Your Calendar.

<sup>18</sup> 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

<sup>19</sup> If appropriate, reserve the appropriate teleconference or virtual meeting resources.

<sup>20</sup> DGAD SOP 1243.170.003 – Division of Generic Animal Drugs SOP for Meeting Requests.

<sup>21</sup> Using the ONADE Update Meeting Date/Type workflow in Appian.

sufficient review of the EI, select the option that the sponsor is unable to meet with CVM at the offered times within 60 days.<sup>22</sup>

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

For in-person meetings, the scheduler will confirm with the sponsor whether their group will include 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 will follow the process for foreign visitors.<sup>23</sup> 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**

The purpose of the pre-meeting is to plan for the meeting with the sponsor. Items to be addressed include:

- Finalize the agenda; this includes establishing the speaking order and agreeing how to move through the sponsor's materials
- Each speaker will 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 consulting reviewer whose input is not required to discuss the sponsor's proposal will not attend the meeting (e.g., Biostatistics and Clinical Pharmacology Teams)
- Identify if any follow-up, internal or with the sponsor, is needed before the meeting with the sponsor

The PR or scheduler will follow up with the sponsor after the pre-meeting if necessary; items may include:

- Share the final agenda

---

<sup>22</sup> 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.

<sup>23</sup> See foreign national visitor clearance process:  
Internal information redacted.

- 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

## **F. Manage Logistics with the Sponsor**

### **1. For In-Person Meetings**

The scheduler will provide directions to the meeting location to the sponsor (if necessary) and remind their representatives to arrive a few minutes early to clear security.

The scheduler will provide the required advance notification, and will prepare and provide the required visitor badges, to FDA security as outlined in CVM SOP "Visitor Badge Format MPN SOP".<sup>24</sup> The scheduler will use the notification template and the badge template linked in the SOP to complete these steps following the required timeframes.

### **2. For Virtual Meetings**

The scheduler will confirm the virtual connection information with the sponsor. Typically, CVM will generate the remote connection.

## **G. Conduct the Meeting with the Sponsor**

All review staff scheduled to attend the pre-meeting and meeting with the sponsor are expected to attend the meeting unless a consultant's specific expertise is not required (e.g., Biostatistics and Clinical Pharmacology Teams). Any representative whose group has 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.

Refer to Section XII. Holding the Meeting below for more details about conducting the meeting.

## **VIII. METHOD DEMONSTRATION MEETINGS**

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.<sup>25</sup>

<sup>24</sup> Internal information redacted.

specific to the Metro Park North location

<sup>25</sup> See Division of Human Food Safety SOP 1243.150.007 Review of Submissions Related to the Official Residue Method

**A. Create and Assign Reviews**

The Division of Human Food Safety Residue Chemistry Team (HFV-151) reviewer assigned to the meeting will send a consult to the Office of Research's Division of Residue Chemistry (HFV-510). In consultation with their team leader, consulting reviewers, and HFV-510 management, the PR will determine who to invite to the method demonstration meeting.

**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 the Office of Research (OR). The PR will verify that the meeting date included in the eSubmitter meeting request matches the agreed upon date.

**C. Confirm Meeting Date**

The PR will contact the sponsor and confirm the method demonstration meeting date and time, and the list of attendees.

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

For in-person meetings, the scheduler will confirm with the sponsor whether their group will include 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 will follow the process for foreign visitors.<sup>26</sup> Foreign visitors must be cleared in advance, so the PR 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. Laboratory visits to OR by foreign visitors require written justification from the respective division director for the visit to be part of the application.

**E. Conduct the Pre-Meeting**

A pre-meeting is generally not necessary for the method demonstration meeting. The PR will communicate with the HFV-510 consulting reviewer to ensure that the laboratory is prepared for the method demonstration.

**F. Manage Logistics with the Sponsor****1. For In-Person Meetings**

The PR will provide directions to OR to the sponsor (if necessary) and remind the sponsor to have their representatives arrive a few minutes early to clear security. The PR or HFV-510 consulting reviewer will provide a list of the non-

---

<sup>26</sup> See foreign national visitor clearance process: Internal information redacted.

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 will confirm the virtual connection information with the sponsor. Typically, CVM will generate the remote connection.

## **IX. OTHER ONADE MEETINGS**

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, PMs will be the PR for Other ONADE meetings that discuss more than one technical section 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 will be a member of that division.

### **A. Create and Assign Consulting Reviews**

The PR will determine who to invite to the meeting in consultation with the team leader. Generally, at least two people from ONADE should attend a meeting with a sponsor.

Because there are no defined minimum criteria for OO meeting requests in eSubmitter, consulting reviewers should 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 have to request additional information and possibly reschedule the meeting. Consulting reviewers should discuss the need for additional information with the PR.

### **B. Schedule Pre-Meeting and Meeting**

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

### **C. Confirm Meeting Date**

The scheduler will contact the sponsor and confirm the meeting date and time. After the meeting date is confirmed, the scheduler will update the meeting date in STARS.<sup>27</sup>

---

<sup>27</sup> 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 will confirm with the sponsor whether their group will include 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 will follow the process for foreign visitors.<sup>28</sup> 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**

The purpose of the pre-meeting is to plan for the meeting with the sponsor. Items to be addressed include:

- Finalize the agenda; this includes establishing the speaking order and agreeing 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
- Confirm whether any consulting reviewer whose input is not required to discuss the sponsor's proposal will not attend the meeting (e.g., Biostatistics and Clinical Pharmacology Teams)
- Identify any follow-up, internal or with the sponsor, needed before the meeting with the sponsor

The PR or scheduler will follow up with the sponsor after the pre-meeting if necessary; items may include:

- 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

---

<sup>28</sup> See foreign national visitor clearance process:  
Internal information redacted.

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

## **F. Manage Logistics with the Sponsor**

### **1. For In-Person Meetings**

The scheduler will provide directions to the meeting location to the sponsor (if necessary) and remind their representatives to arrive a few minutes early to clear security.

The scheduler will provide the required advance notification, and will prepare and provide the required visitor badges, to FDA security as outlined in CVM SOP "Visitor Badge Format MPN SOP".<sup>29</sup> The scheduler will use the notification template and the badge template linked in the SOP to complete these steps following the required timeframes.

### **2. For Virtual Meetings**

The scheduler will confirm the virtual connection information with the sponsor. Typically, CVM will generate the remote connection.

## **G. Conduct the Meeting with the Sponsor**

All review staff scheduled to attend the pre-meeting and meeting with the sponsor are expected to attend the meeting unless a consultant's specific expertise is not required (e.g., Biostatistics and Clinical Pharmacology Teams). Those representatives 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.

Refer to Section XII. Holding the Meeting below for more details about conducting the meeting.

## **X. HANDLING AMENDMENTS**

### **A. For Pioneer Products**

#### **1. CVM-Initiated Amendments**

- 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).<sup>30</sup> If, however, CVM representatives consider the information that would be requested in an amendment necessary to have a meaningful discussion to be a major amendment, the PR will close the meeting request using the

<sup>29</sup> Internal information redacted.

specific to the Metro Park North location

<sup>30</sup> See P&P 1243.3026 Assessing Submission Quality and Amending and Resetting the Clock on Submissions

final action Postponed Meeting; Insufficient materials; Letter Sent (PSTPN MTG) and advise the sponsor to resubmit the request when the information is available.

The PR will coordinate any CVM-initiated amendment request with the consulting reviewers expected to participate at the meeting with the sponsor. Consulting reviewers not scheduled to participate at the meeting are not expected to contribute to an amendment request.

CVM's amendment request will clearly identify 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 will be determined by the review team on a case-by-case basis and may depend on the time remaining between the pre-meeting and meeting dates.

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

## 2. Unsolicited Amendments

- a. For PS and OO 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. If a sponsor proceeds with submitting an unsolicited amendment with additional information for review, we will 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 will select 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 Division of Generic Animal Drugs (DGAD) meetings SOP.<sup>31</sup>

**XI. POSTPONING, RESCHEDULING, OR CANCELLING A MEETING****A. Postponing (Using the Final Action Code)**

Inadequate submissions will be 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 will 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.
- 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 will 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 will only be made after discussion between the PR and impacted CVM participants in consultation with their supervisors.

If we decide to reschedule a meeting, the scheduler will contact the sponsor promptly to explain the reason for rescheduling and propose a new meeting date and time. For a PS or OO meeting that is rescheduled, the scheduler will change the date in STARS using the Appian Update Meeting Date/Type workflow and ensure the consulting reviewers and other internal meeting attendees are aware of the change. For a rescheduled MD meeting, the scheduler will need to submit a STARS correction form to change the meeting date.

**C. Cancelling**

Meetings can be cancelled if the sponsor agrees.

Cancelled meetings will be closed as either a submission filed with review documentation (FNR/MEMO) or with an acknowledgement letter, depending on

---

<sup>31</sup> DGAD SOP 1243.170.003 – Division of Generic Animal Drugs SOP for Meeting Requests.

division procedure. The memorandum or letter will be written by the PR and will explain why we did not hold the meeting.

## **XII. HOLDING THE MEETING**

### **A. Facilitate Signing In (In-Person Meetings Only)**

The PR or designee will use the office template to prepare a sign-in sheet to record the attendees accurately for the MOC. The PR or designee will provide the outside party with a copy of the completed sign-in sheet upon their request. The list of meeting participants, including the sponsor and CVM representatives and their affiliations, will be reflected in the MOC.

### **B. Welcome Attendees**

The PR will welcome the meeting attendees, state the purpose and goals of the meeting, and remind participants of the time allotted for the meeting. The PR will ask all participants to introduce themselves.

### **C. Lead the Discussion**

The PR will either lead the discussion portion of the meeting or turn the lead over to the sponsor or another CVM attendee. The PR will ensure the meeting remains cordial and professional at all times, focus the discussion on the agenda items, and keep the meeting on schedule.

**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.<sup>32</sup> 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.

### **D. Summarize the Meeting**

At the end of the meeting or following each portion of the discussion if participants will leave early the PR or another attendee will summarize the key discussion points, any agreements reached in a PSC, and any action items identified, including 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 will also give the sponsor the opportunity to identify items in our summary that they do not agree with or have questions about. The PR will remind the sponsor that the details of the meeting will be documented in an MOC (or acknowledgement letter for a pre-INAD meeting when applicable) that will be sent within 45 days of the meeting.

---

<sup>32</sup> The state of Maryland, our official duty station, requires consent from both parties being recorded.

### **XIII. POST-MEETING (FOLLOW-UP) TASKS**

#### **A. Prepare Documentation**

The PR or meeting preparer<sup>33</sup> will prepare documentation following P&P 1243.3025.

If we require the sponsor to conduct more than one field study to establish effectiveness, the PR will consult their supervisor about the need for an earlier response.<sup>34</sup>

#### **B. Address Action Items**

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

### **XIV. 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

---

<sup>33</sup> The preparer is the primary reviewer (PR) assigned to the Z submission or any other individual designated by office, division, or team procedures as responsible for preparing the meeting documentation

<sup>34</sup> See 21 CFR 514.5(f)(2)

1243.3025 - Preparing Meeting Documentation (i.e., 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

## **XV. 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.