LESSONS LEARNED MEETINGS FOR NEW ANIMAL DRUG APPLICATION PROJECTS

I. PURPOSE

The purpose of this document is to explain the process by which either a new animal drug sponsor or an Office of New Animal Drug Evaluation (ONADE) review division may request a lessons learned meeting.

II. BACKGROUND

Upon approval of a new animal drug application (NADA) or B1 supplement to an approved new animal drug application, either the sponsor or an ONADE review division may request a lessons learned meeting. These meetings provide a forum soon after the completion of a project for parties involved to exchange feedback on the project with the expectation of improving future projects. These meetings usually involve ONADE review divisions and sponsor representatives, but when appropriate, other offices within CVM can be invited to participate.

III. OBJECTIVES

The overall objectives of a lessons learned meeting are:

1. Provide a forum for the new animal drug sponsor to present and discuss what they believed went well during the project as well as what could be improved for the next project.

2. Provide ONADE the opportunity to present and discuss what we believed went well during the project as well as what could be improved for the next project.

3. Discuss issues or obstacles experienced during the project so ONADE and the sponsor can develop a high-level action plan for future projects.

IV. OVERVIEW OF THE PROCESS

A. Sponsor-requested Lessons Learned

If after the approval of an original application or B1 supplement to a new animal drug product, a sponsor reaches out to request a meeting to discuss lessons learned, you should advise the sponsor to contact their project manager (PM).

The PM will instruct the sponsor to submit a Z submission (OO meeting type) to the approved new animal drug application (NADA), using eSubmitter,[1] to request a lessons learned meeting. The PM should tell the sponsor to include in the meeting request the full agenda and all meeting documentation.

Lessons learned meetings are arranged and facilitated by the PM assigned to the new animal drug sponsor's portfolio of projects. The CVM attendees will be based on the sponsor's agenda and may include attendees from other CVM Offices (e.g., Office of Minor Use and Minor Species Animal Drug Development [OMUMS], Office of Surveillance and Compliance [OSC]), if relevant, based on the agenda/topics. The PM will send consults to the review team(s) to be invited to the lessons learned meeting according to the procedures outlined in P&P 1243.3024.

The consulting reviewers (CR) will gather a list of topics for discussion with the sponsor. The discussion topics will be based on experience with the project and easily remembered (i.e., deep dive into the records is not expected). Upon request from the CR, the PM will remind both parties of any discussion points (issues) that were documented throughout the course of the project.

The PM will follow the steps outlined in P&P 1243.3024 to schedule the lessons learned meeting. The PM will schedule a 1-hour premeeting with CVM attendees to prepare for the meeting. The PM will target the sponsor meeting to a day when the CRs and team leaders (TLs) are available. The appropriate PM TL also should be included in all lessons learned meetings.

The PM will facilitate the pre-meeting and lessons learned meeting. During the pre-meeting, the PM will ensure the CVM attendees determine their position in regard to the sponsor's topics/information and identify what to share with the sponsor from CVM's point of view regarding what went well and what could be improved next time.

After the lessons learned meeting is held, the CRs will close out their consults with an Appian comment or review summarizing their feedback on the project to the sponsor. The consult will be closed out by the Appian due date according to P&P 1243.3029.

The PM will write a memorandum to file that includes background information, sponsor and CVM attendees, and a high-level summary of topics/issues discussed at the lessons learned meeting. The PM can point to the CR's reviews for detailed discussion. The PM will close out the Z submission with the final action: submission filed with review documentation; no letter sent (FNR w/memo), according to P&P 1243.3030. No memorandum of conference or acknowledgment

[1] eSubmitter is an electronic submission tool designed specifically for animal drugs, the FDA Center for Veterinary Medicine (CVM) eSubmitter program is part of the agency's overall Electronic Document Submission and Review System. The CVM eSubmitter program is a free, question-based tool that allows animal drug sponsors to electronically and securely submit information to the center. More information on CVM eSubmitter can be found here: https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-program-animal-drugs-office-new-animal-drug-evaluation

letter will be generated for the meeting, and no documentation will be issued to the sponsor.

B. Internal Lessons Learned

If the sponsor is not interested in holding a lessons learned meeting, ONADE can decide to hold an internal meeting to discuss and document lessons learned for future process improvements. The PM will create a Q submission to the approved NADA file and send consults to review team(s), to be invited to the internal lessons learned meeting.[2]

The PM and consulting reviewers (CR) will gather a list of topics for the internal discussion. The discussion topics will be based on experience with the project and easily remembered (i.e., deep dive into the records is not expected). The PM will schedule a 1-hour internal meeting for the discussion. The PM will target a day when the CRs and team leaders (TLs) are available. The appropriate PM TL also should be included in all lessons learned meetings.

After the meeting is held, the CRs will close out their consults with an Appian comment or review summarizing their feedback on the project. The consult will be closed out by the Appian due date according to P&P 1243.3029.

The PM will write a memorandum to file that includes background information, CVM attendees, and a high-level summary of topics/issues discussed at the lessons learned meeting. The PM can point to the CR's reviews for detailed discussion. The PM will close out the Q submission with the final action code: submission filed with review documentation; no letter sent (FNR w/memo), according to P&P 1243.3030.

V. REFERENCES

CVM Program Policies and Procedure Manual – ONADE Reviewer's Chapter

1243.3024 – Scheduling and Holding Meetings with Outside Parties

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

1243.3030 - Completing Final Action Packages for Submission Tracking and Reporting System (STARS) Submissions

1243.3250 - Q Submissions: Agency-Initiated Actions

[2] See P&P 1243.3250

VI. VERSION HISTORY

April 6, 2020 – Original version.

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

February 17, 2022 – Updated to remove information on in person meetings and foreign visitors because that information is contained in P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties and this P&P now references 1243.3024.