PORTFOLIO OVERVIEW MEETINGS WITH SPONSORS OF NEW ANIMAL DRUG APPLICATION PROJECTS

I. PURPOSE

The purpose of this document is to explain the process by which the Office of New Animal Drug Evaluation will hold a portfolio overview meeting with a new animal drug application sponsor.

II. BACKGROUND

ONADE holds portfolio overviews to provide an opportunity for sponsors to share their current and future new animal drug application (NADA) development plans. We believe it is a way to foster open communication in identifying issues that need attention and to discuss ways to move forward toward approval. Portfolio overviews also alert ONADE to developing technologies, so ONADE can align training and professional development activities for our review staff with anticipated projects.

III. OBJECTIVES

Portfolio overview meetings are arranged and facilitated by the ONADE Project Management Teams. The project manager (PM) assigned the meeting will advise the sponsor to present a "big picture" of the status and upcoming submissions for active projects, including target approval dates. The sponsor does not need to give an overview of each project they are working on but should highlight projects they wish ONADE to be aware of (e.g., high priority projects, projects with constraints such as targeted approval during a specific season).

The discussion may also include one or more of the following:

1. Sponsor overview, including organizational structure changes
2. Sponsor's regulatory approach, high-level challenges, and opportunities to collaborate
3. High-level process-oriented questions that impact a sponsor's ability to move projects forward toward approval
4. Highlight high-priority projects and international projects, including USA-Canada Regulatory Cooperation Council (RCC) projects

5. Overview of projects currently in research and development; preview new technologies for ONADE

IV. OVERVIEW OF THE PROCESS

The PM will advise the sponsor that to request a portfolio overview meeting, the sponsor will need to establish a General Correspondence (GC) file (A-0000 submission to a new GC file) using CVM eSubmitter.[1] The PM will instruct the sponsor that once a GC file is established, all future meeting requests ("Z" submissions; "OO" meeting type) for portfolio overview meetings should be submitted to that GC file. Meeting requests must be submitted using eSubmitter and include the full agenda, all meeting documentation, and information whether the sponsor is requesting an in-person or virtual meeting.

The PM is responsible for inviting all pertinent members of the CVM staff. Generally, the invited ONADE attendees are those Office Leadership Team (OLT) and Joint Office Leadership Team (JOLT) members required by the agenda, in addition to the ONADE Director, Deputy Director, and Senior Advisor for Science and Policy. Portfolio overview meetings 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.

If a sponsor's meeting request includes information on generic projects, the PM will work with the Division of Generic Animal Drugs to determine whether to include generic projects in the meeting or split the meeting into two separate meetings.

Consults will not be sent for portfolio overview meetings. While portfolio overview meetings are generally conducted in-person, JOLT members that will be attending may ask that a call-in number be established so division/team staff may attend virtually.

The PM will follow the steps outlined in P&P 1243.3024 to schedule a portfolio overview meeting. The PM will schedule a 1-hour premeeting with ONADE attendees to prepare for the portfolio overview meeting and a 2-hour sponsor meeting. The PM will target a day when at least some of each division's leadership can be present, considering whether there are specific teams with whom the sponsor works most frequently, and based on the sponsor's agenda. Either the Office Director or Office Deputy Director should be available to attend the portfolio overview meeting. The Director for the Division of Business Information Science and Management and the appropriate PM Team Leader should also be included in the portfolio overview meeting.

The PM will provide a list of sponsor attendees to the guard station 1-2 days before the meeting. Foreign visitors must be cleared in advance, so the scheduler should confirm with the outside party and begin the process immediately after scheduling the

[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

meeting date. Any foreign visitor who is not cleared through this process will be denied entry to the building.[2] During the meeting, the PM will facilitate the portfolio overview meeting, including introducing the sponsor, ensuring attendees stick to the agenda, prompting participation of CVM attendees as needed, and contributing questions and comments.

After the meeting is held, the PM will close the "Z" submission in Appian with the final action: submission filed with NO review documentation; no letter sent (FNR).[3] No memorandum of conference or acknowledgment letter will be generated for the meeting, and no documentation will be issued to the sponsor.

V. REFERENCES

CVM Program Policies and Procedure Manual

1243.3024 – Scheduling and Holding Meetings with Outside Parties

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

VI. VERSION HISTORY

April 6, 2020 – Original version.

[2] Foreign national visitor clearance process: Internal information redacted

[3] See P&P 1243.3030 Completing Final Action Packages for Submission Tracking and Reporting System (STARS) Submissions