OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

RECEIVING AND RESPONDING TO INFORMAL COMMUNICATION REQUESTS THROUGH ESUBMITTER

I. PURPOSE

This document describes a process by which Office of New Animal Drug Evaluation (ONADE) reviewers can receive sponsor questions through eSubmitter. It outlines when this process is and is not appropriate to use, and how ONADE will review and respond to these questions.

The process outlined here is intended to be an efficient, secure, and documented means for sponsors to communicate with ONADE about a wide range of issues that may arise during their drug's development process. The process uses eSubmitter, which provides a secure environment to transmit proprietary and trade secret information. Submissions made using this process receive the code Z-####-OM with a purpose of submission of "Informal Communications".

The process described in this P&P may be used for certain sponsor questions directed to ONADE under (abbreviated) new animal drug applications (A)NADA, (generic) investigational new animal drug (J)INAD files, veterinary master files (VMF) or general correspondence (GC) files. These questions should be those which require time and deliberation to fully address, but for which a sponsor meeting is not needed.

Examples of when this process may be used include:

- policy questions related to regulations and legal requirements, patents, marketing status, or controlled substances;
- issues that occur immediately before or during a study such as need for amendments and deviations, product quality issues, interim analysis, unmasking, or addition of study sites;
- scientific questions such as clarification of non-concurrence or incomplete (technical section or supplement) comments, questions on non-pivotal studies (pilot studies, dose characterization, palatability, etc.), or limited study design questions in advance of protocol submission/revision;
- Specific administrative questions related to the content and format of a proposed submission, or inquiries related to submitting a post-approval change;
- other questions requiring consultation with other FDA centers, or questions requiring input from multiple teams or divisions to fully answer; or

- requests for pre- and post-review feedback under processes outlined in CVM Guidance for Industry #283 titled, Priority Zoonotic Animal Drug Designation and Review Process for drugs designated as Priority Zoonotic Animal Drugs (PZAD).[1]

This process is NOT intended to be used for:

- review of information proposed for submission by the sponsor outside of an established pre-review process;
- presenting early information to CVM;
- reaching pre-submission conference agreements as covered by P&P 1243.3050 (type and number of studies required);
- data review;
- informal protocol concurrence;
- official reporting of adverse events during a study; shipment notices or addition of study sites; or
- routine administrative questions surrounding submission order, timing, or logistics, or general notifications.

Submitting inquiries beyond the intended scope outlined here may require the reviewer to reject the submission or convert the inquiry to an ONADE Other (OO) meeting (Z-####-OO).[2]

Note: Advise sponsors that if they have urgent questions requiring a response within 48 hours, they should not use this process and should instead contact their ONADE point of contact directly by phone or email. The sponsor may still be asked to submit their question(s) via this process following initial contact with CVM.

Phone and email to AskCVM at AskCVM@fda.hhs.gov, the VMF support mailbox at VMSTFILE@CVM.FDA.GOV, Project Management Team mailbox at CVM.ONADE.PM@fda.hhs.gov and eSubmitter support mailbox at cvmesubmitter@fda.hhs.gov remain available as means of contacting ONADE for inquires that fall outside this process.

II. QUESTION SUBMISSION

Sponsors or file owners make submissions under this process using the ONADE Communications submission type.[3] Users may initiate communication with ONADE by creating a submission, or ONADE personnel may request that a submission be made following initial contact made through other means (even if an answer has already been provided).

[1] CVM GFI #283 Priority Zoonotic Animal Drug Designation and Review Process | FDA
[2] See P&P 1243.3024
[3] For details on making the submission, sponsors may be referred to: CVM eSubmitter Informal Communication Quick Guide https://www.fda.gov/media/178835/download?attachment

III. RESPONDING TO SPONSOR QUESTIONS[4]

A. Receiving and Assigning the Submission

When a submission is received by ONADE, the following process is applied:

1. The recipient division screens the submission to determine if the question(s) is appropriate for the process outlined herein and that sufficient information is provided for the question to be sufficiently addressed.

2. If appropriate, the submission is assigned to a primary reviewer (PR) and a tentative due date will be established.

   Response times will vary depending on the nature of the question(s). The target due date for a response is 14 days. If a longer response time is expected, the PR informs the sponsor of the estimated timeline for response.

3. If the information provided in the submission is not sufficient, the PR may request an amendment to provide additional information. A due date is not assigned until the amendment is received and the information is considered sufficient to provide a response.

4. If the review team determines that that the question(s) would be best answered by meeting with the sponsor, the submission can be transitioned to an OO meeting. The PR informs the sponsor and discusses scheduling according to existing procedures[5]. The sponsor may be asked to submit an amendment with any additional information needed prior to scheduling. To facilitate this, the amendment tab of the ONADE Communication template in eSubmitter allows the sponsor to enter all of the information normally found on the OO meeting template. Once the meeting is scheduled, the PR updates the meeting date in Appian.

5. For questions not appropriate for the outlined processes, the recipient division or the PR informs the sponsor by email and voids the submission. The PR advises the sponsor on the appropriate process for addressing their question(s).

B. Internal Deliberation and Response Formulation

Note: At this time, Submission Tracking and Reporting System (STARS) due dates will not reflect the target 14-day response time. Internal timelines should be adjusted accordingly.

1. The PR requests consults, as needed, through Appian within two business days. The consult instructions should include a note that this is a request for an informal communication submission, rather than a sponsor meeting, because both submission types are coded Z-####-OO. The PR sends a courtesy email to the recipient Team Leader(s) to inform them of the shortened response timeline.

2. The PR sets a timeline for consult returns and other responses as appropriate.

[4] For pre- and post- review feedback request for products designated for special review processes, the submission should instead be handled in accordance with those processes.
[5] See P&P 1243.3024 “Scheduling and Holding Meeting with Outside Parties”

A suggested timeline is: five calendar days for consulting reviewers to return consults, five days for the PR to incorporate all of the consults into the response, and two days for consulting reviewers to provide concurrence, if needed. Consults outside of ONADE may require additional time.

3. The PR uses the 'Informal Communication Acknowledgment Letter' template to generate the response to be sent to the sponsor.

C. Closing Out the Submission

1. Clearance chain: Clearance follows procedures established by the PR's division. At least two signatures are required to complete final action. Signers are determined by team/division processes.

2. The response is uploaded into Appian as an Acknowledgment letter using the 'Informal Communication Acknowledgment Letter' template.

3. Internal deliberations not captured in the letter may be documented and uploaded to Appian as a submission summary, memo to file, or other review related document as appropriate.

IV. REFERENCES

Guidance for Industry (GFI)

GFI #283 - Priority Zoonotic Animal Drug Designation and Review Process for drugs designated as Priority Zoonotic Animal Drugs (PZAD).

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

1243.3024 - Scheduling and Holding Meeting with Outside Parties

CVM eSubmitter Resource Center

1240.182.U14 CVM eSubmitter Informal Communication Quick Guide

V. VERSION HISTORY

July 31, 2024 – Original version.