MEETING TO DISCUSS POST-APPROVAL RESPONSIBILITIES FOR SPONSORS OF CONDITIONAL APPROVALS

I. PURPOSE

This document describes our procedures for requesting a meeting prior to the conditional approval (CA) and the requirements and responsibilities for sponsors who have a conditional approval as they work towards obtaining a full approval.

II. GENERAL INFORMATION

The Office of New Animal Drug Evaluation (ONADE) recognizes that sponsors obtaining a CA may be unfamiliar with the sponsor's post-approval responsibilities after obtaining a CA. The sponsor's assigned project manager (PM) will recommend that the sponsor request a meeting shortly before obtaining CA to discuss these responsibilities. The meeting is intended to answer the sponsor's questions as well as provide an opportunity for ONADE, the Office of Surveillance and Compliance (OSC), and the Office of Minor Use and Minor Species Animal Drug (OMUMS) (if applicable) to clarify the post-approval obligations for sponsors of CA products. This meeting is strongly recommended for sponsors obtaining their first CA; sponsors already familiar with the CA process can determine whether this meeting would benefit them. If during the end-game Day 150 check-in process[1] the project is on track for approval, the PM will follow up with the sponsor about requesting this meeting.

III. CONTENT OF THE SPONSOR'S MEETING REQUEST

The sponsor will include in their meeting request a proposed agenda and detailed questions that the sponsor would like CVM to address. The sponsor should include the following topics at minimum, plus any additional questions that they have:

- the process and timing for CA renewal requests;
- content of CA renewal requests;
- the process and timing for the application for full approval;

[1] See ONADE P&P 1243.3051 Verifying Scope and Technical Section Status for Phased Review Investigational New Animal Drug (INAD) Projects in the End Game

- the sponsor's post-conditional approval obligations; and
- how to maintain designation [if a designated MUMS product].

IV. PROCESS FOR SUBMITTING AND PROCESSING THE MEETING REQUEST

The meeting request will be submitted to the investigational new animal drug (INAD) file as a Z submission, meeting type Other ONADE (OO), using eSubmitter and will be directed to the Division of Business Information Science and Management (HFV-180) for the appropriate project management team. The meeting will be assigned to the PM as the primary reviewer.

The PM will follow the procedures for OO meetings as described in P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties. The PM will issue consult requests based on the content and questions in the meeting materials. Typically, the following divisions, branches and teams will be consulted for the meeting:

1. ONADE
    a. The appropriate target animal division (TAD) team
2. OSC
    a. The Division of Pharmacovigilance and Surveillance (HFV-240) and appropriate branches within that division.
3. OMUMS, if applicable

Following the meeting, the review team will prepare the memorandum of conference (MOC) and acknowledgement letter according to P&P 1243.3025 Preparing Meeting Documentation. The review team will follow up on any action items and include responses in the acknowledgment letter accompanying the MOC as described in P&P 1243.3025, as appropriate.

V. AGENDA FOR MEETING

The agenda will typically consist of the following items and will be expanded, as needed, based on the sponsor's questions.

- The process and timing for CA renewal requests (PM)
- Content of CA renewal requests (TAD)
- Process and timing for the application for full approval (PM)
- The sponsor's post-conditional approval obligations to OSC's Division of Pharmacovigilance and Surveillance (HFV-240)
    - Introduction to the product manager
    - Safety reporting
    - Periodic reporting
    - Advertising and promotion

- Drug listing

- How to maintain designation with OMUMS [if a designated MUMS product]

See section VI below for details of what ONADE will cover in the meeting. OSC and OMUMS will maintain their own talking points.

VI. TOPICS ONADE WILL COVER IN THE MEETING

In addition to answering questions from the sponsor, ONADE will address the points below. Note that CVM will typically follow the order prescribed in Section V as appropriate, but the topics are presented here according to the team that is responsible.

A. The PM Wil Cover the Following Topics During the Meeting:

1. CA renewal requests must be submitted at least 90 days prior to the annual anniversary date for up to the first four years following the CA.

    a. A CA that is not renewed will no longer be in effect and the conditionally approved product may no longer be marketed.

    b. For CA products that qualify under the Expanded Conditional Approval (XCA) criteria, if a renewal request is not submitted on time, there may be user fee implications.

    c. A CA renewal request is submitted as a G submission to the CA application number and has a 90-day due date.[2]

2. The CA renewal request is a separate submission from the annual Minor Changes and Stability Reports (MCSRs) that are submitted to the Division of Manufacturing Technologies (see 21 CFR 514.8).

3. The new animal drug application (NADA) for full approval must be submitted at least 180 days prior to the termination of the fifth 1-year period of CA, regardless of whether it is a 180-day NADA or an administrative NADA.

    a. The statute does not allow for any flexibility in the timing for when a sponsor may submit the NADA for full approval.

    b. If the sponsor does not submit their NADA 180 days prior to the termination of the fifth 1-year period, the sponsor could continue their field study under their INAD; however, the CA will no longer be in effect, so the conditionally approved product could no longer be marketed.

    c. To support an NADA for full approval, the sponsor will need to submit data to support substantial evidence of effectiveness (SEE), Environmental Impact, and updated All Other Information (AOI) and Labeling technical sections.

        i. The PM will discuss the implications of pursuing a 180-day NADA review versus the phased review approach.

[2] Please note that to date, ONADE has not programmed these submissions to have a 90-day review time, so the pending review list will reflect an incorrect date.

ii. For Chemistry, Manufacturing and Controls (CMC) and Target Animal Safety (TAS) technical sections, the sponsor will attach their technical section complete letters (if applicable) and refer to the CA for current CMC information.

iii. If the sponsor misses the deadline, there may be user fee implications for products that qualified for CA under the XCA criteria.

iv. The NADA number for full approval will be a different than the one issued for the CA (either a new number, or an existing number if a supplement).

d. If the CA is no longer in effect for any reason, all sales of the CA must stop, and all CA products must be removed from the market.

B. The TAD Team Will Cover the Content of the CA Renewal Requests in the Meeting

A renewal request must contain information that justifies or demonstrates:

1. That the sponsor is making sufficient progress toward meeting the full approval requirements under Section 512(d)(1)(E) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

   a. The following are examples sponsors could include with their CA renewal requests, as applicable:

      i. Number of investigational sites open for recruitment, number of animals enrolled in total, number of patients enrolled in the past year;

      ii. Enrolled patients versus previous projections; issues encountered with enrollment, and plans for next year's enrollment;

      iii. Quantity of drug shipped for conduct of the clinical effectiveness study through submission of notice of claimed investigational exemption;

      iv. If the study has not yet started, progress may include CVM's review of field effectiveness study protocols or meetings to discuss protocol design.

2. That the quantity of the drug distributed (product sales) is consistent with the conditionally approved intended use and conditions of use. CVM will evaluate the product distribution information for commercial use to ensure that the quantity distributed is consistent with the conditionally approved use, as extra-label use of the drug is prohibited.

   That the same drug in the same dosage form for the same intended use has not received approval under Section 512 of the FD&C Act, or if such drug has been approved, the holder of the approved application is unable to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

C. Other Information the TAD Team May Cover

The TAD Team may also cover other general information related to CA renewal requests, such as:

1. Reminding the sponsor that extra-label use of CA products is prohibited.
2. Reminding the sponsor that Serious Adverse Events (SAE) that occur during the clinical effectiveness study to support SEE must be submitted to both ONADE (under the INAD) and OSC. (this can be conveyed by either ONADE or OSC).

VII. REFERENCES

The FD&C Act

Section 512(d)(1)(E) of the FD&C Act

Section 571(a)(1)(A)(ii) of the FD&C Act

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

1243.3024 Scheduling and Holding Meetings with Outside Parties

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

1243.3051 Verifying Scope and Technical Section Status for Phased Review Investigational New Animal Drug (INAD) Projects in the End Game

VIII. VERSION HISTORY

February 1, 2021 – Original version

September 7, 2021 – Updated to remove the word "holding" from Section I. Purpose.

December 6, 2022 – Updated to remove HFV-212 from the list of OSC contacts on page 2 because that team is not part of the process.

February 15, 2023 – Revised section VI. B to now includes an item 2 and a new section C further clarifying what the target animal division will discuss during these meetings. Made other formatting updates including putting the document in the most recent P&P template.

May 16, 2023 – Updated sections IV and V to reflect the OSC reorganization and include information on the Division of Pharmacovigilance and Surveillance. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

July 13, 2023 – Updated to change all occurrences of the words annual renewal to CA renewal throughout the document.