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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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**"Q" SUBMISSIONS: AGENCY-INITIATED ACTIONS**

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**I. PURPOSE**

The purpose of this document is to describe how to add documents or other information to the administrative record of a new animal drug application or abbreviated new animal drug application (A)NADA, investigational new animal drug file or generic investigational new animal drug file (J)INAD, and veterinary master files (VMF) when the documents are not associated with an open or pending submission provided by the sponsor.

**II. BACKGROUND**

Before August 1994, Submission Tracking and Reporting System-tracked (STARS) submissions were restricted to submissions from the sponsor (or outside agencies) to a file or application. If the Center for Veterinary Medicine (CVM) or the agency initiated work that was not associated with a sponsor's submission, there was no readily available and searchable record of that work. The records resulting from that work (e.g., letters and memoranda) were filed in the administrative record of the associated application or file and could only be found by a manual search or direct knowledge of the record in an administrative file.

We established the Q submission type in STARS to enable us to track and search for CVM-initiated actions in STARS.

**III. TYPES OF "Q" SUBMISSIONS**

"Q" submissions are most commonly created to:

- prepare a Freedom of Information (FOI) Summary when a (J)INAD project is nearing completion.<sup>1</sup>
- document internal meetings to discuss the status of each technical section for a (J)INAD project at the beginning or end (end-game) of the project.<sup>2</sup>

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<sup>1</sup> See P&P 1243.5760 (ANADA) or P&P 1243.5761 (NADA) for further information about creating a "Q" submission for an FOI Summary.

<sup>2</sup> See P&P 1243.3050 and 1243.3051 for further information about creating a "Q" submission for these meetings.

- document telephone or e-mail correspondence with a sponsor that occurs regarding an application or file but unrelated to an open or pending submission.
- capture any other record CVM initiates and creates that is not directly related to the review of an open or pending submission from a sponsor and is relevant to one or more applications or files. (i.e., reviews of VMF submissions that have been finalized with an FNR or ACK final action code, and not previously reviewed).

#### **IV. CREATING THE “Q” SUBMISSION**

##### **A. When do we create a “Q” submission?**

Create a “Q” submission when the need is first identified. Set a reasonable CVM due date for completion of review and preparation of review documentation, taking into consideration any consulting review due dates (75% of the STARS due date) or the due date for any related submissions.

##### **B. How do we create a “Q” submission?**

To create a “Q” submission, use the “ONADE Create Q Submission” workflow in Appian. Access this workflow from the “Actions” tab. Enter the required information into the fields and select an appropriate due date. In the “Purpose of Submission” field on the Entry Form, select an option from the drop down list. If none of the items in the list are applicable, select “Other” and enter a short descriptive phrase (e.g., “document stats analysis discussion for Study 1234” rather than just “memo to file”) into the text field provided. Adding an accurate description will help identify the purpose of submission in STARS. There is a limit of 73 characters when creating a custom purpose of submission. You may assign the submission to yourself or request that it be assigned to someone else. You may also choose to send a notification to others that the submission has been created. As the initiator of the workflow, you will automatically receive an email confirmation. If you choose to have the submission assigned to yourself, STARS will automatically assign it to you. If you request to have the submission assigned to someone else, the submission will appear as unassigned in the STARS “Primary Reviewer Assignments” screen of the division selected during the workflow.

##### **C. Preparing review documentation and final action processing for the new “Q” submission**

Proceed with the review and processing of the “Q” submission in a manner similar to other submissions, recognizing its due date and potential priority within CVM. Q submission due dates can be updated at any time during the review cycle. Complete (“final out”) the final action package for the submission in a manner consistent with current policy.<sup>3</sup> “Q” submissions most commonly result in a final action of “Submission filed with review documentation; no letter sent (FNR w/memo)” or “Submission reviewed; letter sent (acknowledgement letter)”.

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<sup>3</sup> See P&P 1243.3030.

**V. REFERENCES**

CVM Program Policy and Procedures Manual:

1243.3030 – Completing Final Action Packages for STARS Submissions

1243.5761 – Freedom of Information Summary for Original and Supplemental NADA

1243.3050 – Identifying and Documenting Technical Section Requirements for Approval

1243.3051 – Verifying Scope and Technical Section Status for Phased Review ([J]INAD) Projects in the End Game

**VI. VERSION HISTORY**

March 29, 2011 – original version

July 25, 2011 – Updated to Verdana font, clarified location of the Agency-Initiated Action Submission Form, updated the types of Q submissions

August 26, 2014 - Updated to reflect the addition of an Appian workflow for the creation of Q submissions.

June 15, 2016 – Updated format

August 6, 2018 - Revised to remove reference to a P&P that was retired. Updated to current P&P format and update section IV. B. to reflect current Appian information.