PROCESS FOR PREPARING AN EXECUTIVE SUMMARY FOR A FREEDOM OF INFORMATION SUMMARY

I. PURPOSE

The purpose of this document is to describe the procedures to request the preparation of an executive summary (ES) to be incorporated into the Freedom of Information (FOI) Summary as part of the process reviewers follow to prepare the approval package documentation for a new animal drug approval. This process applies to all original and supplemental new animal drug applications (NADAs) and abbreviated or generic original and supplemental applications (ANADAs) for which an FOI summary is prepared with the following exceptions: It does not apply to new animal drug applications submitted and approved in accordance with the Animal Drug Availability Act (i.e., ADAA medicated feed combinations), generic medicated feed combinations, or ANADAs for which the bioequivalence requirement was satisfied with a biowaiver.[1]

II. BACKGROUND

In 2019, there was discussion among the Center and Office of New Animal Drug Evaluation (ONADE) leadership about how to improve communication regarding the basis for new animal drug approvals. It was proposed that ONADE implement the use of an ES as a standard section of the FOI Summary prepared for (A)NADA original and supplemental approvals. An ES is not necessary for ADAA or generic medicated feed combinations or ANADAs for which the bioequivalence requirement was satisfied with a biowaiver. The division directors from the target animal divisions agreed that an ES would be prepared by a Communications Writer in CVM's Office of the Director (referred to as Writer in this document). Beginning in January 2020, the ES will be inserted at the beginning of the FOI Summary and is intended to be a short overview of the scientific basis for approval.

[1] In rare cases, the preparation of an executive summary for one of the excluded submission types may be appropriate. The primary reviewer, in consultation with Division and ONADE management, will determine whether an executive summary should be prepared. If there is agreement on the preparation of an ES, the reviewer should initiate the process described in Section III.

III. PREPARATION OF THE EXECUTIVE SUMMARY

A. Triggering the ES Process

The ES writing process is triggered by the primary reviewer upon receipt or creation of a submission that will result in the preparation of a final FOI Summary such as:

1. Initiation of the Q submission to prepare an FOI summary for a phased new animal drug approval when a sponsor submits an M submission(s) in the end game
2. Submission of an original (A)NADA for a traditional new animal drug approval
3. Submission of a supplemental (A)NADA drug application

B. Timing for the ES Initiation

The timing of the ES process initiation is flexible to provide ample time for the primary reviewer to collate all sections of the FOI, or if necessary, complete review of a technical section. Because projects can be in different stages with different technical sections completed, it is important for the primary reviewer (and other consulting reviewer(s)) to communicate early and often with the Writer.

1. If the ES process will be initiated under a Q submission, the primary reviewer should provide the FOI Summary materials no later than 70 days from the due date of the Q submission.
2. If the ES process will be initiated under a traditional (A)NADA timeline (with no shortened review timeframe), the primary reviewer should provide the material for the ES by day 110.
3. If the ES process will be initiated under a traditional (A)NADA timeline with shortened review timeframe, the primary reviewer should provide the material for the ES by day 80.

If the reviewers find it difficult to meet the above timelines, they should reach out to the Writer before these times and provide a status. The Writer can usually be flexible with timelines as long as they know that a submission is coming. This helps to prioritize work and manage upcoming workload.

C. Meeting with the ES Writer

Before initiation of the ES (i.e., providing documents by the due date stated above to the Writer), it may be helpful to schedule a brief meeting with the Writer early in review of the submission. Although not required, it could serve to open lines of communication and provide for a seamless process. The following items are potential topics of discussion:

1. Timelines: This may include information on when the FOI Summary will be available.

2. Outstanding technical sections or known issues that may impact the status of the file or application, or likelihood of project moving towards completion.

3. Sponsor's version of the FOI Summary: Providing this version of the ES may be helpful in cases where there are outstanding technical sections that impact the FOI summary.

4. The need for additional meetings later in the writing process.

When the primary reviewer initiates communication with the Writer, they should provide the portions of the FOI Summary that are available to write the ES (e.g., drafts of previously completed sections), or the complete FOI Summary. Please note that the complete version does not need to be polished, or reviewed by TL/DD, but serves to provide substance to the Writer to draft the ES. Additionally, if a section of the FOI Summary is still under review and not yet drafted, it may still be desirable to initiate the ES process so that the Writer is aware of the project. The reviewer(s) should communicate with the Writer and discuss how best to finalize the outstanding section.

D. How to Initiate the ES Process

Once part(s) of or the complete FOI Summary has been assembled, the primary reviewer should place a copy of these documents into the Executive Summary SharePoint website (in a folder named according to the submission identifier (X-XXXXXX-X-XXXX).[2] The primary reviewer will email the Writer Internal information redacted and copy the human food safety reviewer, when applicable, to notify them of a new task and include some brief contextual background information for the approval.[3]

The primary reviewer will include in the email brief answers (a few sentences) to the following questions and/or indicate the important information in the FOI on which the Writer should focus. A restatement of the FOI is not needed.

1. Is there anything different or new about the approval? Is this a new class of compound? Is this a new indication for this species? Is this the first generic copy of the drug product?
2. Were there any serious adverse drug events (ADEs) reported and, if so, why do we still consider the drug to be safe?
3. Is there anything controversial about the approval?
4. Are there special concerns for user safety (e.g., precautions for pregnant women)? Does the user need to take any special precautions while administering the drug?
5. Is there any other information that will be helpful for the Writer to focus on?
6. What is the anticipated date of approval?

A copy of these questions is provided in the SharePoint website to help draft the email.

[2] Internal information redacted

[3] This email will also initiate the process to notify the Strategic Communications staff to assess the approval and determine if external communication materials should be prepared. See SOP 1243.100.004 for more details.

E. Writer Drafting of the ES

While the Q submission, original, or supplemental applications are under review, the Writer will draft the ES based on the text of the draft FOI Summary. The ES is drafted separately from the FOI Summary and will be incorporated into the final FOI Summary under the Executive Summary heading. The Writer, primary reviewer, and consulting reviewers (if needed) should be in contact during the drafting process to address questions or to notify the Writer of any additions or significant changes to the FOI Summary.

If the primary reviewer of the application or one of the technical section submissions determines it will be incomplete or there's any change in due date, the primary reviewer should inform the Writer as soon as possible. This will help the Writer determine ES priorities across the Office. The primary reviewer and Writer should determine whether the ES should continue to be drafted, and its priority relative to other ES in queue, after the application or submission is closed out. Drafting may continue unless the incomplete information significantly impacts the entire FOI Summary.

If one of the major technical sections that impacts the FOI Summary is still pending but it is likely that the application will be approved, there may not be sufficient time left in the review clock to complete the ES before closing the Q submission. If the writing of the ES is not complete at the time the Q submission is closed, the TAD PR should notify the Writer when the administrative (A)NADA is received and to update the due date of the ES as necessary. In addition, there is boilerplate language available in the ES section of the FOI template to indicate that the ES will be added to the FOI Summary once available. If the ES is complete at the time the Q submission is closed, it may be shared with the sponsor according to division policy. If the timeframe for completing the ES changes (e.g., a technical section will be incomplete), the Writer should be notified as soon as possible and informed of any changes to the timelines.

F. Revision of the Draft ES

As sections of the draft ES are completed, they will be reviewed by the TAD primary reviewer and the reviewers of each technical section (e.g., human food safety reviewers), as applicable, for accuracy and completeness. Comments should be added directly to the draft ES on the SharePoint site. The Writer will revise the ES to address any style and format concerns. The reviewers involved in the process will revise the ES to address any scientific or legal concerns. The revision process should be a collaboration between the Writer and the relevant reviewer(s) to ensure that the ES is accurate and in agreement with the FOI summary. While the Writer is writing the ES, portions of the ES may be shared as they are completed. Because the open technical sections, and their potential impact on the drafting of the ES, will vary by project, the drafting and revision process between the Writer and the reviewers may be fluid. Note that the Writer may also request clarifications on other portions of the FOI summary during the ES writing process. While revisions to the FOI summary are not required, a discussion with the Writer is encouraged to evaluate whether changes to the FOI summary may improve the clarity of both the ES and the FOI summary.

G. Timeframes for Completion of the Draft ES

The Writer will notify the primary reviewer and when applicable, the human food safety reviewer, when the final draft ES is complete. This should occur on or before:

1. **Day 21** for administrative (A)NADAs
2. **Day 145** for traditional NADAs
3. **Day 105** for traditional NADAs – shortened reactivation offered
4. **Day 194** for traditional ANADAs
5. **Day 74** for traditional ANADAs – shortened reactivation offered

H. Placement of the ES in the FOI Summary

When completed, the primary reviewer ensures that the ES is placed into the final version of the ONADE FOI Summary, including it before the FOI Summary's table of contents.

I. Final Revisions and Completion of the ES Process

Once the completed draft ES has been incorporated into the FOI Summary, it will be reviewed for accuracy and completeness by the appropriate division management as part of the FOI Summary review process. The TAD primary reviewer and, where applicable, the consulting reviewer(s), will work with the Writer to revise the ES to address concerns. If additional changes are made prior to finalizing the ES, these changes should be communicated to the Writer.

IV. REFERENCES

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

1243.3250 "Q" Submissions: Agency-Initiated Actions

1243.5761 Freedom of Information (FOI) Summary for Original and Supplemental New Animal Drug Applications (NADA)

ONADE Standard Operating Procedures

1243.100.004 Process for Preparing Communications about New Animal Drug Approvals

V. VERSION HISTORY

January 20, 2020 – Original version.

June 26, 2020 - Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

March 5, 2021 - Updated section III to add reference to the ONADE SOP 1243.100.004 on preparing communications about new animal drug approvals.

May 3, 2021 - Updated the timelines section III A. to revise the information about the timing of the initiation of the process and to include the step of having an optional meeting with the Writer. Updated the revision process for greater clarity.

May 10, 2021 – Revised to include information to section III. A. about applications where no shortened review timeframe is involved and some formatting adjustments.

September 2, 2021 – Revised to clarify that if there is a change in due date the Writer should be notified of the new date to allow better management of the ES queue.

October 8, 2021 – Revised to change the name of the Strategic Initiatives staff to the Strategic Communications staff. Referenced in footnote number three.

January 28, 2022 – Revised to add additional information incorporating consulting reviewers into the ES preparation process.