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 primary 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. Initiation of the ES Process

The ES writing process should be triggered by the primary reviewer within 5 days of receipt of a submission that will result in the preparation of the 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

The complete FOI Summary does not need to be available before beginning the ES writing process. The ES process should be initiated at the same time that drafting of the FOI Summary is initiated. Once part or all of the draft FOI Summary has been assembled, the primary reviewer should place a copy of the FOI Summary into the Executive Summary SharePoint website Internal information redacted in a folder named according to the submission identifier (X-XXXXXX-X-XXXX). The primary reviewer will email the Writer (Internal information redacted.) to notify them of a new task and include some brief contextual background information for the approval.

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.

B. Writer Drafting of the ES

While the 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 and primary reviewer 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, the primary reviewer and Writer (in conjunction with the target animal division (TAD) primary reviewer) should determine whether the ES should continue to be drafted after the application or submission is closed out. Drafting should 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. In this case, 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.

C. Revision of the Draft ES

As sections of the draft ES are completed, they will be reviewed by the TAD primary reviewer and the primary reviewer of each technical section (e.g., human food safety reviewers), as applicable, for accuracy and completeness. 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. 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.

D. Timeframes for Completion of the Draft ES

The Writer will notify the primary 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

E. Placement of the ES in the FOI Summary

The ES, when completed, will be inserted by the primary reviewer into the ONADE FOI Summary Template. The ES is inserted before the FOI Summary's table of contents following the ONADE template.

F. 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 will work with the Writer to revise the ES to address concerns.

Once the approval package has been closed out, the TAD primary reviewer should delete the submission folder from the SharePoint site.

IV. REFERENCES

CVM Program Policies and Procedure Manual

1243.3250 "Q" Submissions: Agency-Initiated Actions

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

V. VERSION HISTORY

January 20, 2020 – Original version.