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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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PROCESS FOR CORRECTING PUBLISHED FREEDOM OF INFORMATION (FOI)  
SUMMARIES

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**I. PURPOSE**

This document applies to cases where an FOI Summary on the Animal Drugs @ FDA (ADAFDA) website has an error requiring correction or requires some sort of change or revision (e.g., BIMO inspection results in official action indicated for an investigator and that investigator and their associated data needs to be removed from the FOI Summary). The procedure explains how reviewers should correct errors identified in or make changes to FOI summaries already posted on the internet.

**II. PROCEDURE**

1. If the sponsor has requested the correction, the target animal division (TAD) that created the FOI Summary will be assigned the submission as a G submission. If the Center for Veterinary Medicine (CVM) initiates the correction or change, the TAD that approved the product will determine who in the division will be assigned the task of making the needed edits. That TAD will create a Q submission for the (abbreviated) new animal drug application ((A)NADA) in Appian and have it assigned to the designated person in the TAD who will make the needed corrections.<sup>1</sup>
2. Any scientific or major substantive issues will require reexamination of the original review documents and will be discussed with the appropriate review division. If necessary, an Appian consult will be sent to the appropriate review division(s).<sup>2</sup>
3. Prepare a stand-alone submission summary explaining the origin of the correction request and the correction needed to the FOI Summary.<sup>3</sup>
4. Use the published FOI Summary as the starting document. The date of approval will not change; therefore, leave the date the FOI Summary was originally approved on the title sheet in the "date of approval" line.
5. Add "CORRECTED" in front of "FREEDOM OF INFORMATION SUMMARY" on the cover page. Change the header on pages 2 until the end of the document to read "Corrected Freedom of Information Summary." Make the appropriate

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<sup>1</sup> See P&P 1243.3250

<sup>2</sup> See P&P 1243.3200

<sup>3</sup> See P&P 1243.3009

correction(s) in the text of the FOI Summary and the remainder of the FOI Summary will remain the same as the original. If the change(s) being made is not a correction of an error but an approved modification (e.g., removal or addition of information such as the addition of the qualification for expanded conditional approval), add the word "UPDATED" in front of "FREEDOM OF INFORMATION SUMMARY" on the title page of the FOI Summary. For this sort of modification, change the header on pages 2 until the end of the FOI to "Updated Freedom of Information Summary."<sup>4</sup>

6. Create an appendix to the FOI Summary, using the Heading 2 format style, that details the changes made. In the appendix, include the original text and the revision, along with the date that the change was made. Update the FOI Summary Table of Contents by right clicking on the Table of Contents, selecting "update field" and "update entire table." The appendix will then appear in the FOI Summary Table of Contents.
7. Determine if any of the changes made will necessitate a revision to the Code of Federal Regulations or FEDERAL REGISTER (FR) Notice. If changes are required, send an email to the Policy and Regulations Team (HFV-6) for batching changes or to request an FR Notice, using the appropriate ONADE outlook template.
8. Determine if any of the changes made will necessitate a revision to the ADAFDA website. Prepare a Green Book and Animal Drugs @ FDA (GBAAD) form if changes are required.<sup>5</sup>
9. Prepare an acknowledgement letter to the sponsor and list "Corrected FOI Summary" as an enclosure. Use the acknowledgement letter template and follow the example in the Appendix.
10. The corrected or updated FOI Summary does not need to be sent to the Quality Assurance (QA) Team for review.
11. Upload the prepared documentation into Appian. The clearance chain should include you, your team leader, and your division director. The following documents should be uploaded into Appian:
  - The acknowledgement letter to be sent to the sponsor.
  - The corrected or updated FOI Summary that will be sent to the sponsor.
  - The stand-alone submission summary explaining the need for correction. This is an internal document and should not be sent to the sponsor.
  - An FR Notice, if applicable.
  - A GBAAD form if the changes necessitate a revision to the ADAFDA website. This is an internal document and should not be sent to the sponsor.

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<sup>4</sup> Make sure the font used in the FOI summary is Verdana 10-point font.

<sup>5</sup> See P&P 1243.3801

- Other pertinent information (e.g., copies of email communications with sponsor, if applicable).
12. The appropriate final action for the submission is to issue an "acknowledgement" letter to the sponsor.
  13. After the submission is closed out, Appian will generate and send an email containing a link to the FOI Summary and GBAAD form, if necessary, to the CVM Green Book and Animal Drugs @ FDA mailbox. The Business Informatics Team will post the revised FOI Summary to the ADAFDA website at the time of the next Green Book monthly update.

### **III. SAMPLE LANGUAGE FOR THE ACKNOWLEDGEMENT LETTER**

Use the ONADE letter template to create an acknowledgement letter. The following sample language can be included in the acknowledgement letter.

1. Reference line:

Re: Correction/Update of the Freedom of Information Summary for <insert Proprietary Name>

2. Opening paragraph:

Modify the opening sentence for the paragraph, as needed, to apply to your submission.

We have corrected/updated the original Freedom of Information (FOI) Summary that accompanied the <insert original or supplemental> approval of the <insert new animal drug application or abbreviated new animal drug applications (A)NADA> for <insert Proprietary Name (drug product established name)> approved on <insert the original approval date for the approval in question ex. January 01, 1901>. <Drug product established name> is approved for <insert approved indication and route> in <insert species/class>.

3. The second paragraph will detail the specific corrections or updates made to the FOI Summary. The details about corrections or updates to the FOI Summary should include the original text and the corrected or updated version of the text. In addition, state if any changes were made to Animal Drugs @ FDA.

Use the following opening sentence for the second paragraph if the sponsor requested the FOI Summary correction.  
Your submission (G-xxxx) alerting us to the error in section XXX of the FOI Summary was received on <insert date January 01, 1901>. Subsequently, the following correction(s)/update(s) was (were) made to the FOI Summary:

Use the following opening sentence to the second paragraph if the correction or update was initiated by CVM.  
The following error(s) was (were) noted in the FOI Summary and have been corrected:

OR

The following update(s) was(were) made to the FOI Summary:

4. Include the following in the Enclosure section of the letter.

Enclosure:

Corrected/Updated Freedom of Information Summary

Figure 1: A sample acknowledgement letter

X-xxxxxx-X-xxxx-XX

Company Name  
Additional line for company name. [delete this if not applicable]  
Attention: name of Responsible Official or U.S. agent and their degrees  
Title [e.g., "Director, Regulatory Affairs"]  
street address or PO Box number  
second line of address. [if unnecessary, delete.]  
City, ST 00000-0000

Re: Correction of/Updates to the Freedom of Information Summary for <Proprietary Name>

Dear Dr. last name of Responsible Official or U.S. agent:

We have corrected/updated the original Freedom of Information (FOI) Summary that accompanied the original approval of the new animal drug application (NADA) for Proprietary Name (drug product established name) approved on January XX, 1901. Drug product established name is approved for <insert indication, route of administration> in <insert species and if applicable, class>.

Your submission (G-xxxx) alerting us to the error in section XXX of the FOI Summary was received on January XX, 1901. Subsequently, the following correction(s)/update(s) were made to the FOI Summary:

The following error(s) was(were) noted in the FOI Summary and have been corrected:

OR

The following update(s) was(were) made to the FOI Summary:

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier at the top of this letter. If you have any questions or comments, please contact name of division contact and their title at phone number or at insert email address. You may also contact name of alternative contact and their title, at alternative contact's phone number or at insert email address. If you have any questions or comments, please contact name of alternative contact and their title, at alternative contact's phone number or at insert email address.

Sincerely,

*{see appended electronic signature page}*  
team leader or project manager's name and  
degrees  
Team Leader, division name  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

Enclosure:

<Corrected/Updated> Freedom of Information Summary

**Commented [CVM1]:** Select either Correction of or Changes to and delete the other.

**Commented [CVM2]:** Insert the type of application for which the FOI was prepared.

**Commented [CVM3]:** Use this paragraph if the sponsor requested correction of the FOI, delete the two paragraphs below. Detail all the specific changes made to the FOI after the introductory sentences, including the original text and how it was modified. Also, note if any changes were made to Animal Drugs @ FDA.

**Commented [CVM4]:** Use either this introductory statement or the one that follows if the revisions were initiated by CVM and delete the paragraph above. Delete the introductory statement that does not apply to your situation. Detail all the specific changes made to the FOI after the introductory statement and how it was modified. State if any changes were made to Animal Drugs @ FDA.

## IV. REFERENCES

CVM Policies and Procedures Manual – ONADE Reviewers Chapter

1243.3009 - Format and Style Conventions for Reviews and Submission Summaries

1243.3200 - Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

1243.3250 – Q Submissions: Agency-initiated Actions

1243.3801 - Completing the Green Book and Animal Drugs @ FDA (GBAAD) Form

**V. VERSION HISTORY**

May 10, 2016 - Original version

March 6, 2020 – Revised to reflect there is no longer a FOI website and to indicate FOI summaries are posted to the Animal Drugs @ FDA website at the next Green Book monthly update. Also, updated to current format.

July 29, 2021 – Revised to allow for the update of FOI summaries, not just for corrections when there are errors but when revisions or changes need to be made.