

OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

PROCEDURE 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 CVM website has an error requiring correction. The procedure explains how reviewers correct errors identified in 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 will be assigned the submission as a 'G' submission. If CVM initiates the correction, the TAD that approved the product will determine who in the division will be assigned the task of making the needed correction. That TAD will create a Q submission for the (A)NADA in Appian and have it assigned to the designated person in the TAD who will make the needed corrections.
2. Any scientific or major substantive issues will require reexamination of the original review documents, and any major issues will be discussed with the appropriate review division. If necessary, an Appian consult will be sent to the appropriate review division.
3. Prepare a stand-alone submission summary explaining the origin of the correction request and the correction needed to the FOI summary.
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." Change the header on pages 2 until the end of the document to read "Corrected Freedom of Information Summary." Make the appropriate correction in the text of the FOI summary and the remainder of the FOI summary will remain the same as the original.
6. Create an appendix to the FOI summary, using the "Heading 1" 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 FR Notice. Send an email to the Policy and Regulations Team (HFV-6) for batching changes or to request an FR Notice.
8. Determine if any of the changes made will necessitate a revision to the Green Book and/or Animal Drugs @ FDA Website. Prepare a GBAAD form if changes are required.
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 FOI summary does not need to be sent to the Quality Assurance (QA) Team for review.
11. Upload the prepared review 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 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.
 - A GBAAD form if the changes necessitate a revision to the Green Book and/or Animal Drugs @ FDA website. This is an internal document.
12. The appropriate final action for the submission is to issue an "acknowledgement" letter to the sponsor.
13. Once 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 website and update the Green Book database and Animal Drugs @ FDA at the time of the next Green Book monthly update.

III. SAMPLE LANGUAGE FOR THE ACKNOWLEDGEMENT LETTER

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

1. Reference line:
Re: Correction 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.

-
3. We have corrected the original Freedom of Information (FOI) Summary that accompanied the <insert original or supplemental> approval of <insert new animal drug application or abbreviated new animal drug applications (A)NADA> for <insert Proprietary Name (product established name)> approved on <insert the original approval date for the approval in question ex. January 01, 1901>. <Product established name> is approved for <insert approved indication and route> in <insert species/class>.
 4. The second paragraph will detail the specific changes made to the FOI. The details about corrections to the FOI should include the original text and the corrected 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 correction.

Your submission (G-xxxx) alerting us to the error in section XXX or requesting a correction to the FOI was received on <insert date January 01, 1901>.

Subsequently, the following correction(s) was (were) made to the FOI Summary:

Use the following opening sentence to the second paragraph if the correction was initiated by CVM.

The following error(s) was (were) noted and have been corrected:

5. Include the following in the Enclosure section of the letter.
Enclosure:
Corrected Freedom of Information Summary

Figure 1: A sample acknowledgement letter

X-000000-X-0000-XX

Company Name

Additional line for company name. [delete this if not applicable]

Attention: name of person who signed submission letter 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 the Freedom of Information Summary for Proprietary Name

Dear Dr. surname of the person to whom you addressed the letter:

We have corrected the original Freedom of Information (FOI) Summary that accompanied the original approval of New Animal Drug Application NADA for Proprietary Name (product established name) approved on January 01, 1901. Product established name is approved for approved indication, route in species/class.

Your submission (G-xxxx) alerting us to the error in section XXX or requesting a correction to the FOI was received on January 01, 1901. Subsequently, the following correction(s) was (were) made to the FOI Summary:

The following error(s) was(were) noted and have been corrected:

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

Sincerely,

{see appended electronic signature page}

division director or staff leader's name and degrees

Director, division or staff name

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

Enclosure:

Corrected Freedom of Information Summary

Comment [c1]: Use this paragraph if the sponsor requested the FOI correction, and delete the paragraph below. Detail all the specific changes made to the FOI after the introductory sentences, including the original text and how it was modified. State if any changes were made to Animal Drugs @ FDA.

Comment [c2]: Use this paragraph if the correction was initiated by CVM, and delete the paragraph above. Detail all the specific changes made to the FOI after the introductory sentence, including the original text and how it was modified. State if any changes were made to Animal Drugs @ FDA.

IV. VERSION HISTORY

May 10, 2016 - Original version