OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

RESPONDING TO REQUESTS FOR COPIES OF INDIVIDUAL OFFICIAL COMMUNICATIONS OR ADMINISTRATIVE DOCUMENT FILES

I. PURPOSE

This document describes the procedures for:

- providing sponsors or other addressees with copies of official communications previously issued by the Office of New Animal Drug Evaluation (ONADE),[1] and
- responding to requests for copies of our administrative files.

II. REQUESTS FOR COPIES OF OFFICIAL COMMUNICATIONS

Official communications consist of signed letters we issue to convey final actions taken with regard to submissions, and any enclosures included with those letters.

Sponsors or other addressees of letters issued by ONADE occasionally request a copy of an official communication that we previously issued to them. A person requesting a copy of a letter previously issued by ONADE will typically direct their request to the review division that issued the letter, or to their assigned project manager. The group that receives the request will use the following procedure to respond:

A. Verify that the requestor is authorized to receive the copy. The requestor should either be an employee (or U.S.-based employees of foreign sponsors) of the sponsor company (making the request through their company email address), or an authorized consultant or for foreign sponsors a United States (U.S.) agent (authorized through a submission to the file).[2]

   If the requestor is not an employee of the sponsor company or an authorized consultant or U.S. agent, respond to the requestor that CVM does not have an authorization from the sponsor on file for them. They can follow up with the sponsor about submitting an authorization or make a Freedom of Information (FOI) request as described below.

B. If the requestor is authorized to receive the copy, respond to them and copy CVM's eSubmitter help desk (Internal information redacted), asking for the response to be reissued electronically. The eSubmitter help desk will then ask the Electronic

[1] For paper submissions, the Document Control Unit (DCU) will issue letters to sponsors acknowledging receipt of the original submission to each file. If the sponsor requests a copy of such a letter, DCU will follow the DCU procedures for re-issuing the letter and date it with the date of the original letter that acknowledged receipt of the submission.
[2] For more information on U.S.-based employees and U.S. agents see P&P 1243.2020.

Submission Gateway (ESG) help desk to reissue the response electronically via the gateway; the ESG help desk will work directly with the requestor from this point. This is ONADE's preferred approach for providing copies of our responses to submissions as it ensures that files are transmitted securely using the gateway and allows the ESG help desk to work with the requestor if troubleshooting is required.

C. If an electronic reissue does not resolve the problem (e.g., if the requestor is asking for a copy because the electronic recipient is no longer at the company, if the submission is a Q submission,[3] or if the help desk requests this because they cannot promptly reissue the response due to technical issues), send a copy of the response using email. Navigate to the submission folder in the Corporate Document Management System (CDMS) and copy the appropriate file(s) to the desktop. For letters, use the version with "dsign" appended to it, as this contains the digital signature of the signator only. For enclosures[4] without signatures that will be transmitted to the sponsor (FOI summaries, etc.), use the version with the file name only (not an "esign" appendage). Email the requested file(s) to the requestor as an attachment. Because the electronic copies in CDMS are the official copies of the files, there is no need to reissue a hard copy to a requestor, even if that is how CVM's response was initially issued to them.

D. If the request is for an older file that is still in paper format and therefore not available in CDMS, tell the requestor they will need to make an FOI request as described below.

III. REQUESTS FOR ADMINISTRATIVE DOCUMENT FILES

Periodically, sponsors request copies of a significant portion, or all, of their administrative file for a particular document. This may include copies of submissions, extensive copies of official communications, or both. The administrative file we maintain is the government's official record and the sponsor remains responsible for establishing and maintaining their own records required by the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Under 21 CFR 20.23, any written request to FDA for records not prepared for routine distribution to the public is deemed to be a request for records under the Freedom of Information (FOI) Act. Thus, if a sponsor requests a copy of an administrative file, we should direct the sponsor to make an FOI request under 21 CFR 20.40. The sponsor must make such a request in writing to the Freedom of Information (FOI) Staff (HFI-35). The FOI Staff will make a record of the request and the action taken on the request. FDA may charge a fee for the search and reproduction of the information requested. Direct the sponsor to FDA's website, https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request, which contains instructions on how to make an FOI request and discusses charges.

[3] Q submissions are agency-initiated submissions, meaning the sponsor did not make a submission the Electronic Submission Gateway can respond to. Therefore, any communication we issue to a sponsor using a Q submission is sent as a hard copy through the mail. The only way to send an electronic copy to the sponsor is through email.

[4] In addition to the signed letter, send a copy of any document listed in the letter as an "enclosure." Any other files are for internal use only.

IV. REFERENCES

Code of Federal Regulations (Title 21)

Part 20 – Public information

20.23 – Request for existing records

20.40 – Filing a request for records

CVM Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.2020 United States (U.S.)-Based Employee and U.S. Agent Representation of Foreign Sponsors

V. VERSION HISTORY

March 17, 2008 – Original version

June 28, 2010 – Edited to make provisions for providing copies of ERA-related e-mails and include the office policy on faxing letters from packages that have not yet been finalized.

August 21, 2013 – Updated to reflect the change from faxing to emailing official copies, now that these records are electronic.

August 26, 2019 – Updated to new P&P format. Updated FDA.gov URL links to new directed links due to migration of new FDA.gov Website.

April 16, 2021 – Updated to remove references to the end-review amendment (ERA) process, to add steps for verifying that the requestor is authorized to receive the response and for electronically reissuing the response, and to update the process for providing copies of responses available only in paper.

October 16, 2023 - Quality system review conducted of the document and no updates or revisions were necessary at this time. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.