OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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

I. PURPOSE

The document describes the procedures for:

- Providing sponsors or other addressees with copies of official communications previously issued by ONADE[1], and
- Responding to requests for copies of our administrative files.

II. REQUESTS FOR COPIES OF ISSUED OFFICIAL COMMUNICATIONS

Official communications include signed letters we issue to convey actions (non-final or final) taken with regard to submissions as well as e-mails conveying a non-final action that we send to the sponsor as part of our established End Review Amendment (ERA) review procedures.

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 should use the following procedure to respond:

- Navigate to the submission folder in CDMS and copy the appropriate files to their desktop. For letters, use the version with "dsign" appended to it, as this contains the electronic signature of the signator only. For files without signatures to be transmitted to the sponsor (ERA requests, FOI summaries, etc.), use the version with the file name only (not an "esign" appendage). Email the requested file(s) to the sponsor 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.

[1] For paper submissions, 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.

- If the file is not available in CDMS, make a photocopy of the original official communication from the best available source and stamp it "COPY."[2] For paper submissions, the best available copy is a copy of the date-stamped file (pink) copy from the DCU paper archive. For official ERA-related e-mails, the best available copy is the copy printed and stored in the DCU paper archive. Fax or scan the copy to the requestor and shred the copy once the requestor confirms receipt.

III. REQUESTS FOR ADMINISTRATIVE DOCUMENT FILES

Periodically, sponsors request copies of a significant portion, or all, of their administrative file for a particular document. 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 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. You may 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.

[2] The copy of the letter should not include the internal tracking information beneath the cc: block from the copy of the letter. The copy of the letter must include any enclosures or other attachments that we originally issued to the sponsor.

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

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