RESPONDING TO REQUESTS FOR COPIES OF LETTERS OR REQUESTS FOR COPIES OF ADMINISTRATIVE FILES

I. PURPOSE

This guide describes the procedures for:

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

II. REQUESTS FOR COPIES OF ISSUED LETTERS

Sponsors or other addressees of letters issued by ONADE occasionally request a copy of a letter that we previously issued to them. [2] A person requesting a copy of a letter previously issued by ONADE should direct their request to the project manager assigned to that sponsor.[3]

The project manager should use the following procedures to respond to the request:

[1] DCU is responsible for issuing a letter 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] The faxing of approval letters, and other letters issued in response to a submission, before we process a final action package is handled according to our procedures for faxing letters.
[3] If no project manager is assigned, the request should be made to the project management team leader.

- make a photocopy of the original letter from the best available source and stamp it "COPY."[4] For electronic submissions, the best available copy is the scanned image of the issuing letter found in CDMS. For paper submissions, the best available copy is a copy of the date-stamped file (pink) copy from the DCU paper archive,

- if a hard copy of the letter is requested,

    - address the envelope to the same address as the original letter unless the person requesting the copy directs that the copy should be mailed to another address known to be associated with the sponsor,

    - put the copy of the letter in an envelope, seal it, and deliver it to the mail room to be mailed within 3 business days of the request,

- if a facsimile copy of the letter is requested,

    - confirm the fax number with the requestor, fax the copy of the letter to the sponsor, and then shred the copy once receipt is confirmed, and

- add the following information regarding the current request to the spreadsheet monitoring requests for copies of letters: date of request for copy, name of requestor and address, identity of the letter requested, the date the copy is mailed, and the name of the person who prepared the copy for mailing.

The project management team leader will periodically review the spreadsheet and determine if there are patterns in the requests that can be addressed by corrective action. For example, if the requests consistently come from sponsors in one postal region, we may need to contact the postal service. If the same sponsor is constantly requesting copies, we should work with the sponsor to understand and address the problem.

[4] The copy of the letter should <u>not</u> 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.

III. REQUESTS FOR ADMINISTRATIVE RECORDS

Periodically, sponsors request copies of a significant portion, or all, of their administrative file. 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, *http://www.fda.gov/opacom/backgrounders/foiahand.html*, which contains instructions on how to make an FOI request and discusses charges.

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