Submissions to FDA

Submissions to FDA: Center for Biologic Evaluation Research (CBER) and Center for Drug Evaluation and Research (CDER)

SOP #: RPS-9	**Next Review Date: 08/2013**
Version #: 1.0	**Review Interval Period: Biennial**
Approved Version #: 1.0 Date: 08/2011	**Policy Reference: FDA SOP 8007**

Purpose: To Provide a Guide for Processing Submissions to CDER and CBER

General Information

1. All IND submissions and amendments must be submitted to the FDA with a signed and dated 1571 form. The initial IND submission is serial #0000. All IND amendments should be consecutively numbered starting with serial #0001.
2. All Drug Master File submissions must consist of the original document and one copy. A 1571 form is not required for DMF submissions.
3. Ensure you are sending submission to the correct division of CBER or CDER prior to sending.

STEP 1: Creating a Submission

1. Create the components of the submission
    - All regulatory documents (applications, amendments) should be three-hole punched on the left side of the page. The left margin should be at least three fourths of an inch to assure text is not obscured in the fastened area.
    - U.S. standard paper size (8-1/2 by 11 inches) is preferred. However, it may occasionally be necessary to use individual pages larger than standard paper size to present a floor plan, synthesis diagram, batch formula, or manufacturing instructions. These pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved.
    - Paginate submissions within each section.
    - Initial IND submissions should have items 1-10 numbered using 2 sets of 5-tab dividers.
    - Create labels for dividers.
    - For subsequent submissions: Create “attachment” cover sheets for accompanying attachments to be inserted in submission (i.e., clean /tracked version of protocol, 1572, etc.).
2. Create a cover memo (addressed to the Regulatory Project Manager (if known); have signed and save a scanned copy in IND file.
3. Complete a 1571 inserting the serial number next in sequence from the last submission (0000 if original IND); have signed and save a scanned copy in IND file.
4. Complete 1572 if a new protocol being submitted to an IND or a change in Principal Investigator, Laboratory information, IRB information, etc.; have signed and save a scanned copy in IND file.
   Note: *Only the initial 1572 needs to be submitted to the FDA. Revisions to the 1572 should be kept in the IND files*.
5. Review previous submissions to be sure that form 3674 has been sent in a separate submission. If not, complete form 3674; have signed and save a scanned copy in the IND file.
6. Create (or update) binder labels:

- Click to View Sample Label of FDA Form 2675

- Click to View Sample Label of FDA Form 3316 for DMF Submissions

STEP 2: Shipping

1. Make one original plus 3 copies of your complete submission packet. The original should be single-sided and the copies may be double-sided. The original and 2 copies will be sent to the FDA at the address below. File 3rd copy in IND files OR, eliminate 3rd copy if maintaining electronic IND files.
2. For DMF submissions – the FDA requires the original plus one (1) copy of the cover letter and amendment information.
3. When shipping documents of less than 15 pages, documents may be stapled. Documents too large to fit in a standard staple should be bound in binders with ACCO-type hidden spine fasteners.
4. FedEx package to the FDA requesting signature receipt.
5. For IND submissions – the original and 2 copies of the information will be shipped via FedEx to the FDA at the appropriate address listed on the cover letter.
6. For DMF submissions – the original and 1 copy of this information will be shipped via FedEx to the FDA at the appropriate address listed on the cover letter.
7. Save a PDF copy of the FedEx delivery confirmation at the FDA in the IND file for that submission.
8. Shipping address information (address to the attention of the regulatory project manager for all submissions after the first):

CBER:
FDA/CBER
Document Control Center, HFM-99, Suite 200N
1401 Rockville Pike
Rockville, MD 20852-1448
301-827-5386

CDER:
For a DRUG:
FDA/CDER
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266
301-210-2880

For a Therapeutic Biological Product:
FDA/CDER
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266
301-210-2880

STEP 3: Supplies

General:
Order supplies through your Administrative Officer (AO) or Purchasing Officer:

- Avery 2x4 labels, item 8163
- Avery 5-tab dividers, item 11446
- ACCO prong fasteners, 3 ½ inch, item 70724
- 3-hole paper
- Binders as outlined below
- FedEx medium and large boxes, envelopes, and plastic label envelopes

CBER:
Binders for IND submissions:

- Archive – ACCO Gray Stock Number 25074 or Smead Stock Number 81552 or similar type
- Duplicate (or First Review Copy) – ACCO Executive Red Stock Number 25079 or Smead Red Stock Number 81752 or similar type
- Second and additional review copies – ACCO Tangerine Stock Number 25977 or Smead Orange Stock Number 81652 or similar type or any color except Gray or Red.

Master Files (MF):
Master File submissions are in the same type of binders outlined above for Investigational New Drugs, except only two copies (Archive and Duplicate) are required.

CDER:
Binders for IND submissions:

- For more information refer to: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094966.html

Call the following number to order FDA IND, NDA, ANDA and Drug Master File binders:
U.S. Government Printing Office (GPO)
Washington, DC 20404-0001
(202) 512-1800

- FDA Form 2575 – IND Archival Binder - ACCO RED or similar type
- FDA Form 2675a – IND Chemistry Binder - ACCO Green or similar type
- FDA Form 2675b – IND Microbiology Binder - ACCO Orange or similar type

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Master File submissions are in the same type of binders outlined above for Investigational New Drugs, except only two copies (Archive and Duplicate) are required.

- FDA Form 3316 – Red - DRUG MASTER FILE ARCHIVAL BINDER
- FDA Form 3316a – Blue - DRUG MASTER FILE BINDER