Vaccines, Blood & Biologics

SOPP 8007: DCC Binding Procedures for Regulatory Documents

Version #2

Effective Date: November 13, 2009

1. **Purpose**

   The purpose of this document is to provide guidance to CBER staff on the policies and procedures for the binding of regulatory documents submitted to CBER. This guidance will permit CBER staff to provide information to applicants and sponsors planning on submitting documents for regulatory action and will expedite the handling of submissions when received.
2. **Background**
   CBER does not have regulations specifying the size or type of binders and paper to be used for regulatory submissions. However, once received, uniformity of these volumes facilitates their handling, distribution for review, and archiving. This uniformity is achieved by rebinding of submissions as necessary in the Document Control Center (DCC). If regulatory documents arrived in the appropriate binding they could be more rapidly processed and routed for review.

   CBER staff frequently receives inquiries from sponsors, prospective sponsors and applicants about the preparation of regulatory submissions. The physical aspects of the submission have not generally been addressed in their responses, in part because of a lack of information. This SOPP contains information on the type of pressboard report binders used by DCC when submissions are received that are not bound as indicated prior to distribution for review and for subsequent filing.

3. **Policy**

   All regulatory submissions are submitted to CBER through DCC. The information in this SOPP will provide CBER staff with the procedures used for binding of such documents and to enable them to supply information on the preparation of regulatory submissions.

4. **Responsibilities and Procedures**

   It is the responsibility of all CBER personnel who receive a request for information on the preparation of regulatory submissions to provide the following information to sponsors, prospective sponsors and applicants.

   General information

   - all regulatory submissions (applications, supplements, 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.
   - documents submitted in three-hole hard binders (notebooks) are rebound because such binders do not fit on the limited DCC shelving and have been found to open during constant moving.
   - 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.
   - Shipping unbound documents may result in the loss of portions of the submission. This could have an adverse impact on the review of the submission.

   Specific Information

Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)

- New Applications
  - Archive - ACCO Gray Stock Number 25974 or Smead Stock Number 81552 or Oxford Stock Number ESS-129005 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 - Any color pressboard report binder except Gray or Red.
- Amendments
  - If the submission is an amendment and is too large to be held together by a standard office staple (about 15 pages), then the type and color of binders listed above for new applications is used.
- Identification of binders
  - Binders are identified with name of sponsor, name of product, IND number (after assignment), date of submission.

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.

Biologic License Applications (BLA) or Biologic License Supplements (BLS)

- New Application, New Supplement, Annual Report or Post Marketing Submission
  - Archive - ACCO Light Blue Stock Number 25972 or Smead Blue Stock Number 81052 or Universal Stock Number UNV-80572 or similar type
  - Duplicate and all Review Copies - Any ACCO or Smead type binder except Light Blue
- BLA or BLS Amendments
  - If the submission is too large to be held together by a standard office staple (about 15 pages), then the type and color of binders listed above for new applications is used.

Medical Device Applications

- 510(k) Applications and Supplements
  - Archive - ACCO Light Blue Stock Number 25972 or Smead Blue Stock Number 81052 or similar type
  - Duplicate and all Review Copies - Any color pressboard report except Light Blue
- 510(k) Amendments
  - If the submission is too large to be held together by a standard office staple (about 15 pages), then the type and color of binders listed above for new applications is used.
- Pre-Market Approval Applications and Supplements
  - Archive, Duplicate and all Review Copies – Any color pressboard report. If possible a different color for Archive than is used for the other copies.
- Pre-Market Approval Amendments
  - If the submission is too large to be held together by a standard office staple (about 15 pages), then the type and color of binders listed above for new applications is used.

New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA)

- New Application or New Supplement
  - Archive - ACCO Light Blue Stock Number 25972 or Smead Blue Stock Number 81052 or Universal Stock Number UNV-80572 or similar type
  - Duplicate and all Review Copies - Any color pressboard report except Light Blue or type specified by Center for Drug Evaluation and Research (CDER).
- NDA Amendments or ANDA Amendments
  - If the submission is too large to be held together by a standard office staple (about 15

pages), then the type and color of binders listed above for new applications is used.

5. **Effective Date**

   November 13, 2009

6. **History**

Written/Revised	Approved	Approval Date	Version Number	Comment
Jules Meisler	Robert Yetter, PhD	November 13, 2009	2	Revised for updated information
Jules Meisler	Robert Yetter, PhD	November 14, 2000	1	First issuance of this SOPP