SOPP 8401.7: Action Package for Posting

Version: 7
Effective Date: December 11, 2020

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for the development and assembly of Action Packages for Posting, pursuant to Section 916 of the Food and Drug Administration Amendments Act (FDAAA) of 2007.

II. Scope

This procedure applies to original Biologics License Applications (BLAs) (including MDUFA BLAs) and New Drug Applications (NDAs) processed within CBER.

III. Background

A. Per FDAAA, action packages for original BLAs or NDAs are required to be posted to the Food and Drug Administration's (FDA) Internet (Web) site within 30 calendar days of approval for new products or within 30 calendar days of the third Freedom of Information Act (FOIA) request for the action package. A summary review [Summary Basis of Regulatory Action

(SBRA)] is required to be posted within 48 hours of approval unless redaction is required.

B. The FDAAA language specifies that the following types of documents be included in the posted action package:

1. Documents generated by the FDA related to review of the application.

2. Documents pertaining to the format and content of the application generated during drug development.

3. Labeling submitted by the applicant.

4. A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team, and how they were resolved; recommendations for action; and an explanation of any non-concurrence with review conclusions.

5. Decision documents of product office Division Directors and Office Directors, including:
- a brief statement of concurrence with the summary review;
- a separate review or addendum to the review if disagreeing with the summary review; and
- a separate review or addendum to the review to add further analysis.

6. Identification by name of each officer or employee of the FDA who:
- participated in the decision to approve the application and
- consented to have his or her name included in the package.

C. There are certain Web-posting policies that must be considered when developing and assembling action packages for posting. These policies are set using legal mandates and technical requirements that must be followed to successfully comply with FDAAA, the Americans with Disabilities Act (ADA) for accessibility under Section 508 of the Rehabilitation Act of 1973 (Section 508), and other federal statutory requirements. Web-posting policies are found under the Policy section of this SOPP.

IV. Definitions

A. Action Package for Posting – consists of those documents that are posted to the Biologics section of the FDA Web site after an approval. Note: Please refer to checklist *C 910.01: Action Package for Posting Document*. Examples of the documents include:

- Approval Letter
- Package Insert
- Summary Basis of Regulatory Action (SBRA)
- Discipline review memos
- Summary minutes for meetings held with applicants
- Telecons with substantive discussions. (Refer to *SOPP 8104: Documentation of Telephone Contacts with Regulated Industry*)
- Emails

B. Administrative Record - The documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action (21 CFR 10.3). Note: Administrative records include sponsor/applicant submissions, CBER/FDA generated documents, and CBER/FDA system records.

C. Administrative File –The file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations (21 CFR 10.3).

D. Substantive Communications – Communications that add new information or change old information in a submission. These communications include discussions involving clarification or resolution of an issue or one that was the basis of a decision. **Note:** FDA requests for information are **always** considered substantive.

V. Policy

A. Web Posting Policies

1. The Agency is required by law to post documents that are compliant with Section 508. The Agency is also required to meet Department of Health and Human Services (DHHS) standards.

2. All CBER generated documents should be provided in Microsoft (MS) Word, MS Excel or, for emails, in Rich Text Format (RTF) or Text (TXT) format. Documents shall not be recreated for this purpose. If a given document exists ***only*** in PDF, and the MS Word file cannot be found, supply the document in PDF.

3. As a result of Section 508 Compliance requirements, all images (including scanned tables/documents and logos) and complex tables included in FDA-generated documents should have alternate (alt) text that is descriptive, in plain language, and conveys all the essential content for the item that is being described.

4. Submission of documents to CBER Web sites including action packages for posting shall follow document formatting requirements

found in regulatory job aids *JA 815.05: How to Create Section 508 Compliant PowerPoint (PPT) Documents*, *JA 815.06: How to Create Section 508 Compliant Word Documents*, and *JA 900.04: Section 508 Compliance Labeling Review*.

B. Action Package for Posting Policies

1. Before posting the Action Package on FDA's Web site, all documents in the Action Package must be reviewed for disclosure according to FOIA and other applicable statutes and implementing regulations. Any information exempt from disclosure, such as confidential commercial, trade secret, personal privacy, etc., will be redacted before posting.

2. CBER product offices must ensure that all appropriate documents are included in the action package for posting. All documents are identified as "Post to Web" in the appropriate regulatory system so the statutory time frames for posting action packages can be met. Immediately upon approval of original BLAs or NDAs, the Approval letter, SBRA, Transmittal Memo and package insert (PI), are sent to the Office of Communication, Outreach, and Development (OCOD) via email to *CBER-OCOD-Action-Packages.*

3. Document security passwords set on PDF and Word documents must be removed before uploading through CBER Connect iinto CBER's Electronic Repository (CER). If the document security password is still in place, OCOD will not be able to access the document for continued processing.

4. Information or data submitted to CBER that is only available in PDF format and used as part of a CBER generated document that will be included in the action package for posting should be identified and **must** adhere to Web-posting requirements. An example of this information type is the inclusion of a table from the applicant's submission that is included in the discipline review memo.

a. If the PDF information or data is included in the CBER generated document, the transmittal memo should clearly indicate that this is the only available form of the document. Refer to regulatory template *T 910.01: Transmittal Memo*.

b. The PDF must meet all the requirements for Section 508 including the accompanying alt text for images, logos, tables, and scanned documents.

5. The Officer/Employee list will contain the names of employees who wrote, co-wrote, and/or signed off on reviews or decisional memos; participated as part of the Review Committee; and who consent to

being identified on the list. Refer to regulatory template *T 910.02: Officer/Employee List Email*.

a. For a review carried out by several Review Committee members, the name of each Review Committee member who consents will be included on the list regardless of who signed the review.

b. Before or at the time of approval of the application, employees (as defined above) will be asked whether they consent to have their names included on the list. Due to the statutory deadlines for posting action packages, employees are asked to respond to this inquiry within seven (7) business days.

c. Only the names of employees who respond in writing that they consent will be included on the list. Note, however, that if the employees chooses not to consent to having his/her name included on the list, it may not prevent disclosure of his/her name as part of the Review Committee under a FOIA request.

d. Employee names will be redacted from FDA records only when it is consistent with FOIA and 21 CFR 20.32. The names of FDA employees may be included in disclosable records, except where such deletion is necessary to prevent disclosure of an informant, or danger to the life or physical safety of the employee, or under other extraordinary circumstances.

e. In most cases, the name of an employee who has written, co-written and/or signed-off on reviews or decisional memos may still be associated with the documents he/she has authored and, thus, will be publicly disclosed, even if the employee's name is excluded from the Officer/Employee List.

VI. Responsibilities

A. Review Committee Members

1. Responsible for Section 508 Compliance for all CBER generated documents related to the submission review and uploading them through CBER Connect before approval.

2. Responsible for ensuring all documents for posting include the PIV locked and signed PDF version with the MS Word (or other acceptable format, i.e. MS Excel, TXT, RTF) version attached.

3. Responsible for ensuring the "Post to Web" check box/ data entry button is selected for the uploaded document.

B. Product Office Regulatory Project Manager (RPM)

1. Responsible for developing and assembling action packages for posting before approval of an original BLA or NDA.

2. Responsible for accurately and completely preparing the transmittal memo.

C. Review Committee Chair

1. Responsible for working with the RPM to ensure the documents identified as “Post to Web” are the correct documents for posting.

D. Division Director (DD) or Office Director (OD) with product responsibility

1. Oversees the development and assembly of the Action Package for Posting **[DD]**

2. Signs the Transmittal Memo to OCOD **[OD]**

E. OCOD/Division of Disclosure and Oversight Management (DDOM)/Electronic Disclosure Team (EDT)

1. Responsible for retrieving the action package documents from the CER as identified by the product offices.

2. Responsible for reviewing for disclosure and redaction of action package for posting documents (including the approval letter, SBRA, transmittal memo and package insert received via email).

3. Responsible for communicating with the OCOD/ Division of Communication and Consumer Affairs (DCCA)/Communication Technology Branch (CTB) upon completion of review and/or redaction of the action package documents that the records are ready for posting.

F. OCOD/Division of Communication and Consumer Affairs (DCCA)/Communication Technology Branch (CTB)

1. Responsible for preparing for posting and posting action package documents on FDA’s Internet Web site once redacted.

2. Responsible for communicating with product office RPMs to inform them that the posting has been completed.

VII. Procedures

A. Before submitting the posting request

1. Send an email to *CBER-OCOD-Action Packages* to get an OCOD Point of Contact (POC) approximately four (4) weeks before approval to coordinate posting of the action package. The product office will inform OCOD of their POC at the same time. **[RPM]**

2. Ensure all appropriate documents are finalized, dated, and uploaded through CBER Connect before routing for approval (signature from Office Director). Refer to *JA 820.02: Dating of CBER Correspondence* for information on which date to use on a document. **[Review Committee Members]**

3. Ensure all PIV signed and locked PDF documents for posting are uploaded through CBER Connect with the MS Word (or other appropriate format) version attached. Refer to *JA 810.02: Automatically Attach the MS Word Document to a PDF* for additional information. **[Review Committee Members]**

4. Ensure documents are consistent with Web-formatting requirements. Refer to *JA 815.06: How to Create Section 508 Compliant Word Documents* for additional information. **[RPM, Review Committee Members]**

5. Confirm the "Post to Web" checkbox is selected for all documents to be posted. The documents indicated with a checkmark will automatically be identified as part of the Action Package for Posting. \

6. Refer to regulatory checklist *C 910.01: Action Package for Posting Document Checklist* for additional information. **[RPM]**

7. Ensure document security passwords have been removed from all PDF and Word documents prior to uploading through CBER Connect. **[RPM, Review Committee Members]**

8. Ensure the transmittal memo (*T 910.01: Transmittal Memo Template*) is signed by the Office Director responsible for the file. **[RPM, OD]**

B. Submitting the Posting Request

1. Ensure the transmittal memo (*T 910.01: Transmittal Memo Template)* the approval letter, the package insert, the SBRA and the REMS document, when applicable, is provided to OCOD in an email to *CBER-OCOD-Action Packages* **on the date of approval** in order to facilitate the 48-hour posting requirement. **[RPM]**

    a. The subject line for this email should contain the STN and the language "new approval."

C. Processing the Posting Request

1. Retrieve all the documents identified as “Post to Web” from the CER. **[OCOD/DDOM/EDT]**

2. Review for disclosure and redact the documents for posting according to Center and Agency policies and procedures. **[OCOD/DDOM/EDT]**

3. Email the approval letter to OCOD/DCCA/CTB once redacted and ready for posting. **[OCOD/DDOM/EDT]**

4. Notify the CTB when the documents have been placed on the Internal OCOD Share Drive and are redacted and ready for posting. **[OCOD/DDOM/EDT]**

D. Posting/After Posting

1. Post the documents on FDA's Internet Web site according to Center and Agency policies and procedures. **[OCOD/DCCA/CTB]**

2. Notify the RPM by email once the posting is completed. **[OCOD/DCCA/CTB]**

3. Ensure the posted information is correct. **[RPM]**

4. Delete the documents on the Internal OCOD Share Drive once the posting is completed and confirmed. **[OCOD/DCCA/CTB]**

E. Additional or corrected documents submitted after the posting request, but before posting

1. **Additional document:** Upload additional documents through CBER Connect or mark additional documents “Post to Web.” **[RPM]**

   a. Send a copy of the additional document via email to *CBER-OCOD-Action Packages*.

   b. The subject line for this email should contain the STN and the language “Additional Action Package Document.”

      NOTE: EDT downloads the documents immediately after receiving the approval email and does not access the CER to retrieve documents again.

2. **Corrected document:** Upload corrected documents through CBER Connect. **[RPM]**

   a. Once the corrected document is uploaded, send a copy of the document with an explanation about which document is being replaced via email to *CBER-OCOD-Action Packages*.

b. Note: The "Post to Web" check box/ data entry button should be unmarked for the originally uploaded erroneous document.

c. The subject line for this email should contain the STN and the language "Replacement Document."

F. Additional or replacement documents submitted after posting

1. Additional document: Mark additional documents "Post to Web." **[RPM]**

a. Send a copy of the additional document via email to '*CBER-OCOD-Action Packages'* as EDT does not access the CER after receiving the approval email.

b. The subject line for this email should contain the STN and the language "New Action Package Document."

2. Replacement Document: If a document is already posted as part of the approval but needs to be replaced on the appropriate Web page: **[RPM]**

a. Documents that need to be replaced on CBER's Web page are those that contain text changes to the document.

b. The notification for replacement document needs to state the reason for the replacement and indicate the changes.

i. Letters: submit the replacement letter with the reason for the replacement. The reason should include the changes made in the letter.

ii. Memos: submit the revised memo with a statement at the top indicating the reason for the replacement and the changes made.

c. Send the revised document with an explanation about the reason for the replacement, and which Web page is affected via email to *CBER-OCOD-Action Packages*.

d. The subject line for this email should contain the STN and the language "Replacement Document."

VIII. Appendices

N/A

IX. References

A. References below are CBER internal:

1. Regulatory Job Aids

a. JA 810.02: Automatically Attach the MS Word Document to a PDF

b. JA 815.05: How to Create Section 508 Compliant PowerPoint (PPT) Documents

c. JA 815.06: How to Create Section 508 Compliant Word Documents

d. JA 820.02: Dating of CBER Correspondence

e. JA 900.04: Section 508 Compliance Labeling Review and Communications

2. Regulatory Checklist

a. C 910.01: Action Package for Posting Document Checklist

3. Regulatory Templates

a. T 910.01: Transmittal Memo Template

b. T 910.02: Officer/Employee List Email

4. CBER's 508 Compliance Intranet Page

B. References below can be found on the Internet:

a. Freedom of Information Act (FOIA)

b. 21 CFR § 20.32

c. Section 916, "Action Package for Approval" of FDAAA

d. Section 508.gov

e. Department of Health and Human Services (DHHS) Section 508 General Information

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Monser	N/A	December 11, 2020	7	Technical Update for retirement of EDR and replacement with CER/CBER Connect.

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Monser	Christopher Joneckis, PhD	August 26, 2019	6	Revised for consistency with Job Aid for Action Packages for Supplements and updates for PIV change and to new CBER font
Monser	Carol Rehkopf, MS	October 17, 2018	5	Technical Changes: Correction to date of Rehabilitation Act and revised references section
Dixon, Burk, Shazor	Chris Joneckis, PhD	September 1, 2017	4	Includes revised procedures
Dixon, Burk	Robert A. Yetter, PhD	November 22, 2011	3	Revised to include information consistent with new CER functionality
Dixon, Burk	Robert A. Yetter, PhD	October 19, 2010	2	Revised to include additional use of RMS-BLA
BPS/RMCC	Robert A. Yetter, PhD	May 6, 2010	1	First issuance of this SOPP