

# SOPP 8795: Posting and Announcement of Premarket Approval Application and Humanitarian Device Exemption Approvals and Denials

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### I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide to Center for Biologics Evaluation and Research (CBER) staff for providing the public with notice of an order approving or denying a Premarket Approval Application (PMA) or Humanitarian Device Exemption (HDE) application.

### II. Scope

This SOPP applies to all **original PMAs and panel track** PMA supplements and HDEs that have not been withdrawn.

### III. Background

**A.** Offices in CBER responsible for approving or denying applications must follow 21 CFR 814.44 and 814.45 for PMAs and 21 CFR 814.116 and 814.118 for HDEs.

- B.** Under these regulations, CBER is required to post on the Internet a notice of the order approving (21 CFR 814.44(d)(1)) or denying approval (21 CFR 814.45(d)(1)) of a PMA along with a detailed Summary of the Safety and Effectiveness (SSE) data, including information about any adverse effects of the device on health.

Likewise, CBER is required to post on the Internet a notice of the order approving (21 CFR 814.116(b)) or denying approval (21 CFR 814.118(b)) of an HDE along with a detailed Summary of the Safety and Probable Benefit (SSPB) data, including information about any adverse effects of the device on health.

- C.** This information must also be filed with the Dockets Management Staff (DMS), Division of Information Governance (DIG) Office of Enterprise Management Services (OEMS), Office of Operations (OO), Office of the Commissioner (OC) and be placed on public display in the Federal Document Management System (FDMS).
- D.** There are certain web-posting policies that must be considered when developing and assembling a public notice of an order approving or denying a Premarket Approval Application (PMA) or Humanitarian Device Exemption (HDE) application. 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. Approval or Denial Order** - The signed and dated letter sent by FDA to the applicant approving or denying a PMA or HDE.
- B. Humanitarian Device Exemption (HDE)** – A marketing application for a HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the **effectiveness** requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.
- C. Premarket Approval Application (PMA)** - Any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein (see 21 CFR 814.3(e)).
- D. Summary of Safety and Effectiveness Data (SSED)** – The Summary of Safety and Effectiveness Data (SSED) is a document mandated by 520(h)(1)(A) of the Federal Food, Drug and Cosmetic Act. It is to be

publicly available upon issuance of an order approving or denying approval of a PMA (see 21 CFR 814.20(b)(3)).

- E. Summary of Safety and Probable Benefit (SSPB)** – The Summary of Safety and Probable Benefit (SSPB) is a document mandated by 520(m) of the Federal Food, Drug and Cosmetic Act. This document is intended to present a reasoned, objective, and balanced critique of the scientific evidence which served as the basis for the approval of the HDE. It provides a reasonable assurance of safety and probable benefit for the device as labeled based on the nonclinical and clinical information described in the HDE. The SSPB is a publicly releasable document that the applicant is required to submit under 21 CFR 814.104(b)(4).

## **V. Policy**

- A.** It is CBER policy to comply with the regulations found in 21 CFR 814.44 and 814.45 for PMAs and 21 CFR 814.116 and 814.118 for HDEs, and to complete in a timely manner (usually within 30 days) the redaction, posting, and filing of the PMA or HDE documents, and issuance of the FR notice, as provided below in Sections VI (Responsibilities) and VII (Procedures).

- B.** PMA or HDE documents for posting should be written to ensure little or no redaction is necessary prior to posting.

### **C. 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, the PDF document should be supplied.
- 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.*

## **VI. Responsibilities**

### **A. Review Committee Members**

1. Responsible for Section 508 Compliance for all CBER-generated documents related to the submission review and importing them into CBER's Electronic Repository (CER) before approval.
2. Responsible for ensuring that all documents for posting imported into CER include the PIV locked and signed PDF version with the MS Word (or other acceptable format, i.e., MS Excel, TXT, RTF) version attached.

### **B. Review Committee Chair**

1. Responsible for working with the RPM to ensure the documents identified are the correct documents and the documents (e.g., package inserts) are 508 compliant for posting.

### **C. Product Office's Regulatory Project Manager (RPM):**

1. Assuring compliance with all applicable SOPPs for clearing documents, including obtaining supervisory concurrence
2. Completing the *T930.01 Transmittal Memo* and submitting it via email to *CBER-OCOD-Action Packages*
3. Working with the Communication Technology Branch (CTB) as requested to address accessibility, security, and other issues
4. Reviewing the document or external link periodically for timeliness, appropriateness, and reliability of information, and informing the CTB of any necessary changes
5. Notifying CBER's Regulations and Policy Staff (RPS) of the establishment of the docket

### **D. Office of Communication, Outreach, and Development (OCOD)/Division of Communication and Consumer Affairs (DCCA)/Communication Technology Branch (CTB):**

1. Reviewing policy, content, and maintenance of the internal and external Web sites, assuring that all Center, FDA, and Department guidelines are met

2. Submitting documents to Office of Communication, Outreach, and Development/ Division of Disclosure and Oversight Management/ Electronic Disclosure Branch (OCOD/DDOM/EDB) for disclosure review, when appropriate
  3. Posting disclosure reviewed and redacted information or documents, while giving priority to time sensitive material
  4. Informing the Point of Contact (POC) when the information or document is posted
- E. OCOD/Division of Disclosure and Oversight Management (DDOM)/ Electronic Disclosure Branch (EDB):**
1. Performing disclosure review and redaction, if needed
  2. Providing disclosure reviewed and redacted documents to OCOD/DCCA/CTB for posting
- F. Dockets Management Staff (DMS)/ Division of Information Governance (DIG)/ Office of Enterprise Management Services (OEMS)/ Office of Operations (OO)/ Office of the Commissions (OC):**
1. Assigning a docket number
  2. Placing documents on public display

## **VII. Procedures**

### **A. Before submitting the request for posting:**

1. Send an email to CBER-OCOD-Action Packages to get an OCOD Point of Contact (POC) approximately two (2) weeks prior to approval or denial. This email will include the product office's POC for OCOD. **[RPM]**

**Note:** An OCOD POC is provided for the product office to direct any specific questions regarding the posting of documents. Please follow step VII.B.1 below for providing documents to OCOD.

2. Ensure that all appropriate documents are finalized, dated, and imported into CER 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 that all PIV signed and locked PDF documents for posting are imported into CER 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 that 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]**

## **B. Submitting the Posting Request**

1. Provide OCOD POC the completed *T930.01 Transmittal Memo* and the appropriate approval or denial documents in an email to CBER-OCOD-Action Packages and request review for disclosure in accordance with 21 CFR 814.9 and other applicable regulations and posting on the internet. **[RPM]**
  - a. Ensure all appropriate documents for posting are finalized and are the most up-to-date electronic version at the time of approval or denial in accordance with *T930.01 Transmittal Memo*. The Decision Package may include, but is not limited to:
    - i. The signed approval or denial order,
    - ii. SSED or SSPB data including information about any adverse effects of the device on health,
    - iii. Other supporting documents, e.g., package inserts.
  - b. Ensure Transmittal Memo is signed by the assigned RPM and included in the Web Posting Request email:
    - i. The subject line for this email should contain the STN “BP/BH#####\_Approval/Denial Order”
    - ii. The Transmittal Memo will indicate all the appropriate documents for posting and the appropriate FDA Internet website(s) that require(s) the posting of these documents.
2. Send a request for assignment of a Docket Number to the DMS. **[RPM]**

**Note:** Please refer to *T930.01: Transmittal Memo* for additional information.

- a. The request should include, as appropriate:

- i. The PMA/HDE number
- ii. Name of the applicant
- iii. Trade name of the product
- iv. Date of approval or denial of the PMA or HDE

**C. Processing the Posting Request**

1. Review for disclosure and redact (if needed) the Decision Package documents according to Center and Agency policies and procedures. **[OCOD/DDOM/EDB]**
2. Notify the Communication Technology Branch when the documents have been redacted and are ready for posting. **[OCOD/DDOM/EDB]**

**D. Posting/After Posting**

1. Post the Decision Package on FDA's Internet web site according to 21 CFR 814.44 and 814.45 and Center and Agency policies and procedures. **[OCOD/DCCA/CTB]**
2. Notify the requesting product office POC that the documents have been posted. **[OCOD/DCCA/CTB]**
3. Review all the documents posted and the content on the website. **[RPM]**

**E. Correcting documents submitted after the posting request**

1. If a document already posted as part of the Decision Package for posting needs to be replaced on FDA's Internet web site: **[RPM]**
  - a. Send a copy of the document with an explanation about which document is being replaced, and the reason for the replacement as this will be included under the link of the document on the FDA Internet website via email to CBER-OCOD-Action Packages for redaction. The explanation provided cannot exceed 255 characters.
  - b. The subject line for this email should contain the PMA/HDE number and "replacement document."

**F. Submitting posted documents to Dockets Management Staff (DMS)**

1. Ensure that a single PDF document compiled from the documents posted on the FDA Internet website is sent to DMS for public display under the docket number established for the PMA or HDE. **[RPM]**

**Note:** Please refer to *T930.01: Transmittal Memo* for additional information.

- a. The PDF document should include the following documents:
  - i. A cover page listing the PMA/HDE number, assigned Docket number, trade name of the product, and a list of the documents attached to the package.
  - ii. Dated and signed approval or denial order without concurrence page
  - iii. Final SSED or SSPB
  - iv. Other supporting documents, e.g., package insert.

## VIII. Appendix

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 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: 508 Compliance Labeling Review and Communications
2. Regulatory Templates
  - a. T930.01: Transmittal Memo

B. References below can be found on the Internet:

1. [21 CFR](#) (Relevant Section: Part 814)
2. [FDA Internet domain](#)
3. [Section508.gov](#)



4. [Department of Health and Human Services \(DHHS\) Section 508 General Information](#)
5. [Federal Docket Management System](#)
6. [Federal Register](#)

## X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
M. Monser	N/A	February 27, 2022	7	Technical update for the 2022 CBER Reorganization
C. Ward- Peralta	N/A	February 14, 2022	6	Technical update for the revised rule on posting of PMA and HDE announcements & new docket management staff office title
M. Monser	N/A	December 11, 2020	5	Technical update for the retirement of the EDR and replacement with CER
DRS	Christopher Joneckis, PhD	August 19, 2020	4	Updated the process to current web posting procedures, SOPP format/font, 508 Compliance requirements for labels, and correct typos
DRS/OCOD	Christopher Joneckis, PhD	January 17, 2018	3	Revised the Web Posting Procedures
RPS/DRS/OCOD	Christopher Joneckis, PhD	June 13, 2016	2	Updated for new procedures
RPS, DRS	R. Yetter	Sept 7, 2007	1	First issuance of this SOPP