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, what documents are needed to comply with the federal mandates, and how to post the documents to CBER's website.

II. Scope

This SOPP applies to all original PMAs, panel track PMA supplements, and HDEs that have not been withdrawn.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 FDA's website (http://www.fda.gov) 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 FDA's website 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. PMAs and HDEs approved by CBER may be found at: Premarket Approvals and Humanitarian Device Exemptions with Supporting Documents | FDA.

C. There are certain web-posting policies that must be considered when developing and assembling a public notice of an order approving or denying a PMA or 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. CBER will 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 complete in a timely manner (usually within 30 days) the redaction and posting of the PMA or HDE documents on CBER's webpage, 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 websites follow document formatting requirements found in regulatory job aids: *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. Ensures Section 508 Compliance for all CBER-generated documents related to the submission review and imports them into CBER's Electronic Repository (CER) before approval.

2. Ensures that all documents for posting are imported into CER are PIV locked and signed PDF with the MS Word (or other acceptable format, i.e., MS Excel, TXT, RTF) version attached.

B. Review Committee Chair

1. Works 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. Assures compliance with all applicable SOPPs for clearing documents, including obtaining supervisory concurrence
2. Completes *T930.01 Transmittal Memo Template – PMA/HDE/510(k)/De Novo Device Submissions* and submits via email to *CBER-OCOD-Action Packages*
3. Works with the Communication Technology Branch (CTB) as requested to address accessibility, security, and other issues
4. Reviews the document or external link periodically for timeliness, appropriateness, and reliability of information, and informs the CTB of any necessary changes
5. Adds the assigned docket number to the appropriate regulatory system.

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

1. Reviews policy, content, and maintenance of the internal and external websites, assuring that all Center, FDA, and Department guidelines are met
2. Submits 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. Posts disclosure reviewed and redacted information or documents, while giving priority to time sensitive material
4. Informs 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. Performs disclosure review and redaction, if needed
2. Provides 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. Assigns a docket number

VII. Procedures

A. Before submitting the request for posting

1. Email CBER-OCOD-Action Packages to get an OCOD Point of Contact (POC) approximately 2 weeks before 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* and *JA 900.04: Section 508 Compliance Labeling Review* for additional information. **[RPM, Review Committee Members]**

B. Submitting the Posting Request

1. Provide OCOD POC the completed *T930.01 Transmittal Memo Template – PMA/HDE/510(k)/De Novo Device Submissions* 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 that all appropriate documents for posting are finalized and are the most up-to-date electronic versions at the time of approval or denial in accordance with *T930.01 Transmittal Memo Template – PMA/HDE/510(k)/De Novo Device Submissions*. The Decision Package may include, but is not limited to:

      i. The signed approval or denial order.

      ii. If approved,

         a. the SSED or SSPB data including information about any adverse effects of the device on health, and

b. any other supporting documents, e.g., package inserts.

b. Include the signed Transmittal Memo 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. If approved, send a request for assignment of a docket number to the DMS and ensure that the docket number is included in the appropriate regulatory system for tracking purposes. **[RPM]**

Note: Please refer to *JA 940.01: Administrative Processing of Premarket Approval (PMA) and Humanitarian Device Exemption (HDE) Applications* and *T930.01: Transmittal Memo Template – PMA/HDE/510(k)/De Novo Device Submissions* for additional information.

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 CBER's website: **[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 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."

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 815.06: How to Create Section 508 Compliant Word Documents
   - **c.** JA 820.02: Dating of CBER Correspondence
   - **d.** JA 900.04: 508 Compliance Labeling Review and Communications
   - **e.** JA 940.01: Administrative Processing of Premarket Approval (PMA) and Humanitarian Device Exemption (HDE) Applications
2. Regulatory Templates
   - **a.** T 930.01: Transmittal Memo Template – PMA/HDE/510(k)/De Novo Device Submissions

B. References below can be found on the Internet:

1. 21 CFR Part 814
2. Premarket Approvals and Humanitarian Device Exemptions with Supporting Documents | FDA.
3. Section508.gov
4. Department of Health and Human Services (DHHS) Section 508 General Information

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Heba Degheidy	Sonday Kelly, MS, PMP, RAC Director, DROP/ORO	June 3, 2024	8	Removed Docket posting requirement
M. Monser	N/A	February 27, 2022	7	Technical update for the 2022 CBER Reorganization
Cherie Ward-Peralta	Regulatory Programs Branch (RPB) Chief	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