

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

Version: 3

Effective Date: January 22, 2018

I. Purpose

- A.** 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

- A.** This SOPP applies to all **original** PMAs and HDEs that have not been withdrawn.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 Division of Dockets Management (DDM), Office of Executive Secretariat (OES), Office of the Commissioner (OC) and be placed on public display in the Federal Document Management System (FDMS).

- D. At the end of each quarter, CBER is required to publish a list of such approvals and denials in the Federal Register (FR) (21 CFR 814.44(d)/814.116(b) and 21 CFR 814.45(d)/814.118(b), respectively).

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 premarket approval application for a class III medical device seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the Federal Food Drug and Cosmetic Act as authorized by section 520(m)(2) of the FDCA (see 21 CFR 814.3(m)). Note: an HDE is a type of PMA.
- 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.

VI. Responsibilities

A. CBER Product Office's Regulatory Project Manager (RPM):

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

B. 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 Team (OCOD/DDOM/EDT) 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

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

1. Performing disclosure review and redaction, if needed

2. Providing disclosure reviewed and redacted documents to OCOD/DCCA/CTB for posting

D. Division of Dockets Management (DDM)/Office of Executive Secretariat (OES)/Office of the Commissions (OC):

1. Assigning a docket number
2. Placing documents on public display

E. CBER's Regulations and Policy Staff (RPS):

1. Conducting periodic reviews of the PMA and HDE action orders posted
2. Preparing quarterly FR notices of PMA and HDE approvals and denials

VII. Procedures

- A.** 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. The product office will inform OCOD of their POC in reply. **[RPM]**
- B.** 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]**
 1. Ensure all appropriate documents 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.
 2. The Decision Package may include, but is not limited to:
 - a. The signed approval or denial order
 - b. SSE data including information about any adverse effects of the device on health
 - c. Other supporting documents, e.g., labeling
 3. Ensure Transmittal Memo is signed by the assigned RPM and included in the Web Posting Request email:
 - a. The subject line for this email should contain the STN "BP/BH#####_Approval/Denial Order"

- 1.** The PDF document should include the following documents:
 - a.** A cover page listing the PMA/HDE number, assigned Docket number, name of the device, and a list of the documents attached to the package.
 - b.** Dated and signed approval or denial order without concurrence page
 - c.** Final SSED or SSPB
 - d.** Other supporting documents, e.g., labeling.
- K.** Notify CBER RPS or designee of the docket number established for the PMA/HDE, the PMA/HDE number, trade name of the product, and date of the PMA/HDE approval or denial order. **[RPM]**
- L.** Conduct a quarterly review (i.e., January to March; April to June, etc.) of the PMA and HDE decision orders (approved or denied), and confirm with the Regulatory Information Management Staff (RIMS), Review Management, and/or appropriate CBER Offices, that the PMAs and HDEs that were approved or denied during that quarter were posted on the Internet and in the Docket. **[RPS]**
- M.** Prepare and publish, at the end of each quarterly review, an FR notice listing the PMA and HDE approvals and denials announced in that quarter. **[RPS]**

VIII. Appendix

N/A

IX. References

- A.** References below are located on CBER's Intranet Web Page
 - 1.** 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.** [Federal Docket Management System](#)
 - 4.** [Federal Register](#)

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
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