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# Manual of Standard Operating Procedures and Policies

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## Standards of Conduct

### Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices

**SOPP 8725**

**Version #1**

**Date: January 13, 2005**

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#### 1. Purpose

The purpose of this document is to describe the procedures for CBER staff to follow when handling inquiries regarding the need for an Investigational Device Exemption application for research involving medical devices.

#### 2. Background

The Center for Devices and Radiologic Health (CDRH) standardizes the review of Investigational Device Exemptions (IDE), Premarket Notification (510(k)), and Premarket Approval (PMA) premarket notifications by issuing review procedures for staff to follow. The Center for Biologics Evaluation and Research (CBER) also reviews and clears premarket notifications under the same authority, FD&C Act.

In an effort to harmonize review principles and procedures between centers, CBER has decided to adopt existing CDRH procedures, also known as Blue Book Memoranda, when feasible. When CBER cannot directly adopt existing CDRH procedures, e.g., because of issues related to a specific CBER regulated device, CBER will prepare an SOPP based on CDRH review principles with adjustments for CBER-regulated devices. In either case, CBER will issue an SOPP for staff to follow.

#### 3. Policy

CBER staff will handle inquiries regarding filing IDEs in accordance with the CDRH Blue Book Memorandum: Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices, issued on October 26, 2001 (#D01-01), with changes limited to CBER-specific administrative procedures.

#### 4. Responsibilities and Procedures

CBER staff will incorporate review procedures contained in the CDRH Blue Book Memorandum: Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices, October 26, 2001 (#D01-01) when handling inquiries regarding filing IDEs.

The attached Blue Book Memoranda (BBM) version has been approved for CBER review purposes by Center management. Revisions to this BBM will need CBER management approval prior to implementation. Thus, reviewers should access this BBM only through this SOPP to ensure CBER review process integrity is maintained.

**5. Appendix**

Appendix 1:

[Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices, October 26, 2001 \(#D01-01\)](#)

**6. Effective Date**

January 13, 2005

**7. History**

<b>Comment / Revision</b>	<b>Approved By</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
Len Wilson	Robert A. Yetter, PhD	1/13/2005	1	Original version Written by RMCC Device Review Subcommittee

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