
Manual of Standard Operating Procedures and Policies

General Information - Review

Intercenter Consultative/Collaborative Review Process

SOPP 8001.5

Version #1

Date: August 30, 2002

1. Purpose

This document provides the procedures for CBER staff to follow when requesting, receiving, handling, processing, and tracking formal consultative and collaborative reviews of combination products, devices, drugs and biologics.

2. Background

The Commissioner's Office (Ombudsman) requested that CBER, CDER and CDRH develop an intercenter standard operating procedure to increase intercenter review process efficiency. This FDA-level intercenter SOPP is the first Agency-level SOPP among CBER, CDER and CDRH to address intercenter review processes.

Representatives from each of the centers developed this consensus procedure based on CBER's existing SOPP: 8001.1, Interoffice Consultative Review Procedures, and modified it to meet each center's core review process needs. Accordingly, many of the process steps in this new SOPP will already be familiar.

CBER's commitment to continuous process improvement applies to this SOPP and recommendations to increase review process efficiency will be considered

3. Policy

It is CBER policy that:

- CBER personnel will conduct all intercenter (CBER, CDER, CDRH) reviews according to the procedure in the Intercenter Consult/Collaborative Review Process SOPP.
- Process improvement recommendations are welcome from all users and should be forwarded, through supervisory channels, to the Associate Director for Review Management, CBER, for consideration.

4. Responsibilities and Procedures

It is the responsibility of all CBER personnel to conduct intercenter consult/collaborative reviews between CBER and CDER and CDRH in accordance with the policies and procedures documented in the

Intercenter Consult/Collaborative Review Process SOPP (Appendix 1).

Users may use a screen fillable consult request form for convenience. (Appendix 2)

5. Appendices

Appendix 1

[Intercenter Consult/Collaborative Review Process](#)

Appendix 2

[Screen Fillable Consult Request Form \(PDF, 48 KB\)](#)

Note: Documents in PDF format require the [Adobe Acrobat Reader®](#).

6. Effective Date

August 30, 2002

7. History

| Written/Revised | Approved | Approval Date | Version Number | Comment |
|------------------------|------------------------|----------------------|-----------------------|--------------------|
| Leonard Wilson | Robert Yetter, Ph.D | July 30, 2002 | 1 | Original document. |

Updated: September 5, 2002