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# Manual of Standard Operating Procedures and Policies

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## License Applications

### Resolution of Differences in Scientific Judgement in the Review Process

**SOPP 8006**

**Version #1**

**January 25, 1999**

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#### 1. Purpose

The purpose of this document is to describe the policies and procedures for addressing scientific issues identified during the review of Investigational New Drug Applications, license applications, New Drug Applications, and supplements.

#### 2. Background

Differences in scientific judgement on the interpretation of information contained in submissions to the Agency sometimes occur. Review timelines have been established for many of these submissions either by regulation or in a letter from the Secretary, Health and Human Services, Donna Shalala, to Senator James M. Jeffords, dated November 12, 1997. In order to meet these timelines it is necessary that such differences be resolved in a timely manner. However, it is important to assure that the process leading to resolution of these differences is scientifically sound, well documented, and consistent with CBER's mission.

#### 3. Policy

CBER is committed to addressing scientific issues identified during the review process through discussion of the issues, data and the scientific principles involved. Differences in judgement regarding these issues will be addressed at successively higher levels of the chain of command until resolution is achieved.

It is CBER's policy that issue(s) that cannot be resolved at one level, be referred to the next level in the chain of command, and that the discussions and decisions reached will be appropriately documented for the file.

#### 4. Procedures

##### **Resolution of differences in scientific judgement**

Differences of judgement on scientific issues occurring during the course of review of a submission (e.g., disagreement on interpretation of data) should be discussed and resolved by the Review Team. This discussion and its outcome should be documented in the file.

If the Review Team is unable to resolve the difference in judgement, the issue should be taken to the appropriate Division Director. The discussion of the issue and outcome of the discussion should be documented in the file.

If the Review Team and Division Director are unable to come to a mutually agreeable resolution of the

difference in judgement, the issue should be taken to the Director of the Office with product responsibility. The discussion of the issue and the Office Director's resolution of it must be documented in the file.

### **Supervisory concurrence**

A reviewer's or review team's recommendations on an issue or submission are subject to supervisory concurrence. If the Division Director responsible for the review does not concur with the recommendations of the reviewer or the review team, the reasons for the lack of concurrence must be clearly documented and placed in the file.

If the Division Director does not concur with the recommendations of a reviewer or review team, the reviewer or review team may appeal that decision to the Office Director.

- The request for review of the supervisory non-concurrence should be in the form of a written memo outlining the concerns of the reviewer or review team.
- The Office Director will review the decision, the reasons for non-concurrence, and the request for appeal.
- The Office Director's decision on the issue and the reasons for that decision must be clearly documented in the file.

If the Office Director supports the non-concurrence and the reviewer or review team feels that their concerns have not been adequately addressed, a request may be made to the CBER Ombudsman to review the decision. The request should clearly explain the issue and the reviewer's or review team's concerns. Copies of the documentation of the the supervisory non-concurrence and the Office Director's support of the non-concurrence should be attached to the request.

The Ombudsman should review the decision, the reasons for non-concurrence, and the request for appeal. The Ombudsman may:

- facilitate a discussion of the issue with all concerned parties
- refer the issue to the appropriate Medical Policy Coordinating Committee or Chemistry, Manufacturing and Controls Coordinating Committee (as appropriate), or
- refer the issue to the Center Director or Deputy Director.

The final decision on the issue and the reasons for that decision must be clearly documented in the file.

### **5. Effective Date**

January 25, 1999

### **6. History**

<b>Written/Revised</b>	<b>Approved</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
		January 25, 1999	1	Original document.

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