
Manual of Standard Operating Procedures and Policies

License Applications

Major Dispute Resolution Process

SOPP 8005

Version #1

February 11, 1999

1. Purpose

The purpose of this document is to describe the policies and procedures for resolving procedural and/or scientific issues involving the review of Investigational New Drug Applications (INDs) license applications, New Drug Applications (NDAs), and supplements that cannot be resolved at the Divisional level. It also describes the timeframes for a response from the Center to an appeal and for a follow up appeal.

2. Definitions

Dispute Resolution Project Manager (DRPM)

The individual or group charged with coordinating and tracking the receipt, review, and resolution of disputes.

Reviewing Official

The individual charged with reviewing the request and determining the action to be taken. This may be an Office Director, Deputy Center Director, or Center Director.

3. Background

Title 21 of the Code of Federal Regulations Section 10.75 establishes the right of an interested individual to request internal agency review of an agency decision. The enclosure in a letter from the Secretary, Health and Human Services, Donna Shalala, to Senator James M. Jeffords, dated November 12, 1997, identified performance goals for resolving procedural and/or scientific issues involving the review of INDs, License Applications, NDAs, and supplements for products covered by PDUFA2.

The Dispute Resolution Goals, as defined by PDUFA2, are as follows:

FY 1999	70% acted on within 30 calendar days
FY 2000	80% acted on within 30 calendar days
FY 2001+	90% acted on within 30 calendar days

Actions may include, but are not limited to, requesting additional information, scheduling a meeting with the requester, presenting the issue(s) to an advisory committee, requesting an opinion from Office of Chief Counsel, agreeing with the appeal or disagreeing with the appeal.

4. Policy

CBER is committed to resolving scientific and procedural differences with sponsors as quickly and amicably as

possible through the cooperative exchange of information. Differences with sponsors will be addressed at successively higher levels of the chain of command at the request of the applicant or until resolution is achieved.

It is CBER's policy that issue(s) that cannot be resolved at one level, be appealed, in writing, to the next level in the chain of command (with a copy to the appropriate individual at the prior level). All major dispute resolution requests (DRR) will be coordinated by the Dispute Resolution Project Manager (DRPM), Immediate Office of the Center Director, HFM-7 CBER, so that they can be triaged, tracked and included in the necessary reports.

Further it is CBER's policy that for products covered by PDUFA2 the performance goals established in the previously cited letter will be met. For products not covered by PDUFA2 the procedures set forth in this document will be used, however the performance goals will not apply. CBER will make every effort to resolve non-PDUFA product disputes as expeditiously as possible.

5. Responsibilities and Procedures

CENTER DRPM:

- Receive all Office and Center DRRs and log them into the DRR Tracking System (DRRTS).
- Forward the DRR to the appropriate person within 3 calendar days of receipt
- Send a letter acknowledging the request to the requester, including the date the Center's response is due and where the document was sent for review (see [Appendix 1](#))
- Track the progress of, and the actions taken for, each outstanding DRR
- Coordinate the appropriate filing of the review and resolution of each DRR
- Enter the final information into the DRRTS
- Prepare a monthly status report on all DRRs for review by the Center Director, Deputy Center Directors and Office Directors
- Prepare the year end and status reports for inclusion in the Report to Congress

OFFICE DRPM (see [Appendix 2](#))

- Receive the DRR from the Center's DRPM.
- Confirm the receipt of DRR with the Center's DRPM.
- Enter receipt of the DRR into the DRRTS.
- Within 2 calendar days of receipt from Center's DRPM, give the DRR to the reviewing official, alerting them to the due date.
- Contact the reviewing official one week prior to the 30 day due date to ensure that the action is completed on time
- Obtain all documentation pertaining to the DRR from the reviewing official.
- Enter the necessary information into the DRRTS.
- Send the decision or action plan letter to the requester. Send copies of the letter sent to the requester to the Center DRPM, Division Directors, Office Director, Deputy Center Directors or Center Director, as deemed appropriate.
- Contact the Center's DRPM to convey the final action and then send copies of documentation.
- Send copies of the documentation to the appropriate file (e.g., IND, BLA, NDA product correspondence).

REVIEWING OFFICIAL:

The Reviewing Official at each level of appeal has the same responsibilities and follows the same procedures as at the previous level:

- Review the document to ensure that all information necessary to resolve the dispute is included
- If additional information is needed, develop a plan to obtain the information:
 - This plan should be discussed with the requester by telephone within 30 days of DRR receipt date in CBER.
 - Written confirmation of the plan must be sent to the requester within 14 days of the telephone discussion.
 - Once the additional information or data has been obtained by the Reviewing Official a decision must

be made and conveyed to the sponsor within 30 calendar days of the date of receipt of such information.

- Arrange consultative review by other segments of the Agency (e.g., Office of Chief Counsel) as appropriate:
 - Call the appropriate segment of the Agency to arrange consultative review
 - Forward the document to the appropriate office together with a list of the specific questions or issues to be addressed and the due date for receipt of comments
 - Include consultative review comments in the documentation for the DRR.
- If a meeting with the requester is required to resolve the issue(s), schedule it as a Type A Meeting (see [SOPP 8101.1](#)).
- If a request for review by an FDA Advisory Committee is made decide whether such review is appropriate:
 - If review by the Advisory Committee is appropriate, place the issue on the schedule (see below)
 - If review by an Advisory Committee is not granted, the reason that it is not granted must be explained in the letter to the requester.
- Arrange consideration of the issue by a FDA Advisory Committee as appropriate.
 - Place the issue on the agenda at the next scheduled Advisory Committee meeting for which there is time available on the agenda.
 - Notify the requester that the issue has been placed on the Advisory Committee agenda within 30 days of receipt in the Center of the DRR.
 - Present the issue to the Advisory Committee
 - Decide on whether to agree or disagree with the appeal and notify the requester of the decision within 30 calendar days of the presentation at the Advisory Committee meeting.
- Decide whether to agree or disagree with the appeal:
 - The requester should be notified of the decision within 30 days from the date of receipt of the DRR in CBER. Notification may be by telephone or other rapid means of communication.
 - Written confirmation of the decision should be sent to the requester within 14 days of a telephone contact.
 - If the decision is to disagree with the appeal, the response should include reasons for disagreement and any action the sponsor may take in order to persuade the Center to reverse the decision.
- Alert other levels that have been involved as to the decision that has been conveyed to the requester
- Ensure that review and resolution of the dispute are appropriately documented

6. Effective Date

February 11, 1999

7. Appendices

Appendix 1: [Acknowledgement Letter for Request for Formal Dispute Resolution \(PDF, 6KB\)](#)

Appendix 2: [Locations Office Level Dispute Resolution Project Managers](#)

8. History

Written/Revised	Approved	Approval Date	Version Number	Comment
RMCC	Rebecca Devine	February 11, 1999	1	Original Document

Updated: Month Day Year