SOPP 8005: Formal Dispute Resolution Process

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Table of Contents

I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to describe the policies and procedures for resolving procedural and/or scientific disputes that cannot be resolved at the Divisional level between sponsors and CBER review staff regarding submissions under CBER review. This document also describes the timeframes for a response from CBER to an appeal and for a follow up appeal.

II. Scope

A. This SOPP applies to disputes that arise from unresolved disagreements between sponsors and CBER review staff regarding a sponsor's pre-submission, investigational, marketing, or post-marketing submission.

B. This SOPP does not cover disputes that arise from scientific disagreements between Food and Drug Administration (FDA) review staff regarding the review of sponsor submissions (refer to *SOPP 8006: Resolution of Differences in Scientific Judgment in the Review Process*).

III. Background

A. Regulations (21 CFR 10.75) provide a mechanism for any sponsor, applicant, or manufacturer of a drug, device, or biological product to obtain formal review of an FDA decision by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the primary management (i.e., division) level, the interested person may request that the matter be reviewed at the next higher management level. This process may continue through the FDA's chain of command (i.e., through the Centers to the FDA Commissioner of Food and Drugs).

B. Regulations for dispute resolution during the investigational new drug application (IND) process (21 CFR 312.48) and the new drug application (NDA)/abbreviated new drug application (ANDA) process (21 CFR 314.103) specifically establish procedures for the resolution of scientific and procedural matters at the division level and subsequent formal review of decisions through center management.

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

IV. Definitions

A. **Dispute Resolution Project Manager (DRPM) –** The individual or group charged with coordinating and tracking the receipt, review, and resolution of disputes. Note: In CBER, the DRPM function is performed by the CBER Ombudsman.

B. **CBER Ombudsman** - The individual in the Office of the Center Director (OD) who investigates complaints and assists in dispute resolution.

C. **Deciding Official -** The individual charged with reviewing the request and determining the action to be taken. Note: The Deciding Official may be a Deputy Office Director, Office Director, Associate CBER Director, Deputy CBER Director, or CBER Director.

D. **Sponsor –** For the purposes of this SOPP, the party, e.g. submitter, applicant, manufacturer, who submits a pre-submission, investigational, marketing, or post-marketing submission to CBER. Note: The sponsor makes the decision after CBER action or inaction to request formal dispute resolution in accordance with the *Guidance for Industry and Review Staff: Formal Dispute Resolution: Sponsor Appeals Above the Division Level.*

V. Policy

A. 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 sponsor or until resolution is achieved.

B. It is CBER's policy that issue(s) that cannot be resolved at one level can 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 formal dispute resolution requests (FDRR) will be coordinated by the CBER Ombudsman, Immediate Office of the Center Director, CBER, so that they can be triaged, tracked and included in the necessary reports.

C. Further it is CBER's policy that for products covered by PDUFA, GDUFA and BSUFA, the procedures and timeframes set forth in this document will be used when the requirements for formal dispute resolution are met. For non-PDUFA product disputes and products covered under MDUFA, CBER will make every effort to resolve them as expeditiously as possible using the applicable user fee timeline as a general guide.

D. If a meeting or teleconference must take place to discuss the formal review of any FDA decisions or actions taken on a CBER medical device submission, the meetings will be scheduled as a Submission Issue Meeting as described in the *Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Q-Submission Program*.

E. After any type of response letter regarding the FDRR has been issued by CBER, the clock is stopped. Upon official receipt of a complete response submitted by the sponsor, the review clock is reset to day zero (0) and restarted.

F. The sponsor should be notified of the decision within 30 days from the date of receipt of the FDRR in CBER or, if presented to an Advisory Committee, within 30 days of the meeting. Initial notification may be by a rapid means of communication (e.g., telephone, email). Written confirmation of the decision should be sent to the sponsor within 14 days of the rapid communication.

G. If the decision is to disagree with the FDRR, in other words to agree with the FDA staff that made the decision initially, the response should include reasons for disagreement and any additional action the sponsor may take in order to continue pursuit of the appeal (where applicable).

VI. Responsibilities

A. **CBER Ombudsman –** coordinates the routing, review, system entry, and response letter signoff of all Office and Center FDRRs; makes all contacts with the sponsor.

B. **Office of Regulatory Operations (ORO)/ Division of Informatics and Information Technology (DITT)/Regulatory Information Branch (RIB)** - prepares a monthly status report on all FDRRs for review by the Center Director, Deputy Center Director, Associate Center Directors, and Office Directors; prepares the year end and status reports for inclusion in the Report to Congress.

C. **Deciding Official –** performs the review and signs the written response to the sponsor. Note: The Deciding Official at each level of appeal has the same responsibilities and follows the same procedures as at the previous level.

VII. Procedures

A. Receive the FDRR from the CBER Document Control Center (DCC). **[CBER Ombudsman]**

B. Check the FDRR immediately against Section IV of the *Guidance for Industry and Review Staff: Formal Dispute Resolution: Sponsor Appeals Above the Division Level* to make sure all required elements are contained in the request. **[CBER Ombudsman]**

1. If all required elements are present, begin the 30-day review clock (from date of CBER's receipt). **[CBER Ombudsman]**

2. If all required elements are not present, contact the sponsor to obtain any of the information missing from the FDRR. After the information requested by CBER is received by CBER, and the submission is deemed administratively complete, then begin the 30-day review clock (from date of CBER's receipt of information requested).

C. Log the complete FDRR into the appropriate system, and the SharePoint Dispute Resolution site. **[CBER Ombudsman]**

D. Determine the appropriate person to review and respond to the FDRR, usually the highest management level in the reviewing office, or if the office director has already had substantial involvement in the decision being appealed by the sponsor, the next level of management in CBER OD, or their designee). **[CBER Ombudsman]**

E. Send the FDRR to the Deciding Official by emailing a link to the FDRR in SharePoint. **[CBER Ombudsman]**

F. Confirm receipt of the FDRR with the CBER Ombudsman by emailing a statement that the FDRR has been read and that all requests in the FDRR are understood (or not). **[Deciding Official]**

G. Send a letter or email acknowledging CBER's receipt of the FDRR to the sponsor within 3 calendar days of the FDRR receipt. This communication should include the date the Center's response is due and to whom the document was sent for review (i.e., the Deciding Official). **[CBER Ombudsman]**

H. Determine whether additional information is needed (i.e., interim response):
[Deciding Official]

1. Discuss additional information needed with the sponsor by telephone within 30 days of FDRR receipt date in CBER (review clock stopped).

2. Send written confirmation of the additional information needed to the sponsor within 14 days of the telephone discussion.

3. Once the additional information and/or data have been obtained by the Deciding Official (review clock started), continue with review.

I. Arrange consultative review by other segments of the Agency (e.g., Office of Chief Counsel) as appropriate: **[Deciding Official]**

1. Call the appropriate segment of the Agency to arrange consultative review.

2. Send the FDRR to the appropriate official by emailing a link to the FDRR in SharePoint, together with a list of the specific questions or issues to be addressed and the due date for receipt of comments.

3. Include consultative review comments in the documentation for the FDRR.

J. If a meeting with the sponsor is required to address the issue(s), For biological products, schedule it as a Type A Meeting. Refer to *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* for additional information. For medical device products, schedule it as a Submission Issue Meeting. Refer to *Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Q-Submission Program* for additional information. **[Deciding Official]**

K. Decide whether any request for FDA Advisory Committee review in the FDRR is appropriate for review by an FDA Advisory Committee: **[Deciding Official]**

1. If yes:

a. Arrange for consideration of the issue by the appropriate FDA Advisory Committee. **[Deciding Official]**

b. Notify the sponsor that the issue has been placed on the Advisory Committee agenda within 30 days of receipt in the Center of the complete FDRR. Date of the meeting to be determined by availability. **[CBER Ombudsman]**

c. Present the issue to the Advisory Committee. **[Deciding Official or their designee]**

d. Decide on whether to agree or disagree with the appeal and notify the sponsor of the decision within 30 calendar days of the presentation at the Advisory Committee meeting. **[Deciding Official]**

2. If no:

a. Draft a letter to the sponsor explaining why their request for an Advisory Committee review was not granted. **[Deciding Official]**

b. Provide the signed response letter to the CBER Ombudsman **[Deciding Official]**

c. Issue letter to the sponsor **[CBER Ombudsman]**

L. Review appeal and decide whether to agree or disagree. **[Deciding Official]**

M. Provide the decision in memorandum form or draft response letter to the CBER Ombudsman within 20 calendar days of CBER receipt of the original FDRR, or within 20 calendar days of CBER receipt of any requested additional information or data. **[Deciding Official]**

N. Contact the Deciding Official one week prior to the 30-day due date to remind him/her that a response to the FDRR is coming due, if memorandum decision or draft letter has not been received. **[CBER Ombudsman]**

O. Send the decision letter to the sponsor within 30 calendar days of CBER receipt of the original FDRR or within 30 calendar days of CBER receipt of any requested additional information or data. **[CBER Ombudsman]**

P. Notify the Deciding Official, Division Directors, Office Director, Deputy Center Directors or Center Director, and others that have been involved (as deemed appropriate) regarding the decision conveyed to the sponsor. **[CBER Ombudsman]**

Q. Ensure that review and resolution of the dispute are appropriately documented. **[Deciding Official]**

R. Upload all communications and correspondence through CBER Connect into the appropriate regulatory system. **[Deciding Official]**

S. Obtain all documentation pertaining to the FDRR from the Deciding Official. **[CBER Ombudsman]**

T. Enter the final documentation into the appropriate system, and the SharePoint Dispute Resolution site, and close-out the FDRR in both locations. **[CBER Ombudsman]**

U. Provide an update every 6 months on all active FDRRs to CBER's RIB. **[CBER Ombudsman]**

V. Prepare a monthly status report on all FDRRs for review by the Center Director, Deputy Center Directors and Office Directors. **[RIB]**

W. Prepare the year end and status reports for inclusion in the Report to Congress. **[RIB]**

VIII. Appendix

N/A

IX. References

A. References below are CBER internal:

1. SOPP 8001.5: Inter-Center Consultative Review Process

B. References below can be found on the Internet:

1. Guidance for Industry and Review Staff: Formal Dispute Resolution: Sponsor Appeals Above the Division Level

2. SOPP 8006: Resolution of Differences in Scientific Judgment in the Review Process

3. SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products

4. Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Q-Submission Program

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Monser	N/A	February 27, 2022	5	Technical Revision for changes due to 2022 CBER reorganization
Monser	N/A	December 11, 2020	4	Technical Update for EDR retirement and replacement with CBER Connect and replace database with system.
Sherry Lard	Darlene Martin, MS, PMP	March 25, 2020	3	Updated to current procedures, format/font and updated references
Howard Balick	Christopher Joneckis, ADRM	January 18, 2018	2	Update to be consistent with revised companion CBER/CDER Guidance Document on Formal Dispute Resolution; device information added
RMCC	Rebecca Devine	February 11, 1999	1	Original Document