OFFICE OF THE CENTER DIRECTOR

Scientific / Regulatory Dispute Resolution for Individuals Within a Management Chain

CONTENTS

PURPOSE

This MAPP provides:

- Guidelines for documentation of scientific and regulatory review findings, perspectives, and opinions for individuals initiating or involved in the dispute resolution process.
- A procedure for resolution of scientific or regulatory differences of opinion within a management chain.

BACKGROUND

When any scientific or regulatory decision is under consideration, the Center for Drug Evaluation and Research (CDER) must reach an institutional position after all appropriate scientific and regulatory recommendations are obtained and considered. The decision-making process is complex and may involve multiple staff members (primary reviewers, team leaders, supervisors, and managers) within one or more organizational components.

In most cases, alignment on a decision is achieved through discussion as reviews proceed. It is essential that the views of all persons involved in the review process be respected and that the official administrative file reflects differences of opinion if they exist. **This MAPP describes how individual differences of opinion within a management chain are to be managed and documented.**

For CDER's policy on the participation of various disciplines and organizational components in the decision-making process and the resolution of disputes, please refer to

CDER MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions.

REFERENCES

- FDA Administrative Practices Regulations: 21 CFR 10.70 and 10.75 and the FDA-NTEU Collective Bargaining Agreement (CBA).
- CDER MAPP 4151.2, Revision 1, Resolution of Differing Professional Opinions: Review by *Ad Hoc* Panel and CDER Director, Effective 09/16/10.
- CDER MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions, Effective 09/16/10.
- 21st Century Review Desk Reference Guide for New Drug Application and Biologic License Application Reviews (NDA/BLA Review Process), version 12/03/09. http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM218757.pdf

DEFINITIONS

Administrative File. Under 21 CFR Part 10, Administrative Practices and Procedures, 21 CFR 10.70 states "FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents." The file must also contain "recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter" and "reveal significant controversies or differences of opinion and their resolution." An employee who "has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file." For a full description of the administrative file, see 21 CFR 10.75.

Alignment. A state of general support for a position to be taken or a decision to be made. Alignment does not necessarily mean full agreement by all disciplines and organizational components involved in a decision. Rather, alignment indicates that all involved individuals agree to support the action to be taken. This alignment should be based on the knowledge that all perspectives (including alternative opinions) and a range of potential options were considered and informed and justified the final action. Therefore, the action to be taken can be considered reasonable, even if the action differs from an individual's recommendation(s).

First Level Supervisor/Team Leader. A supervisor, team leader, or any other person who manages a reviewer's day to day work, directly oversees the work product of a reviewer, and sometimes writes secondary reviews. Cross-Discipline Team Leaders (CDTL) are not included in this definition; for an explanation of the CDTL, see the 21st Century Review Desk Reference Guide for New Drug Application and Biologic License Application Reviews (NDA/BLA Review Process).

Next Highest Management Official. The management official one level above the management official who made the decision being disputed. Ultimately, this could be the CDER Director.

POLICY AND PROCEDURES

1. It is the policy of CDER to maintain a working environment that encourages employees to make known their best professional judgments even when they may differ from a prevailing staff view, disagree with a management decision or policy position, or take issue with proposed or established practices.

2. If alignment is not achieved, unresolved scientific or regulatory issues may be brought to the Next Highest Management Official, as appropriate, for resolution. In all cases, the individual who disagrees with a decision (disputant) is responsible for presenting the dispute to the Next Highest Management Official, if they choose to do so. If the individual decides to initiate a dispute resolution process, prompt action is recommended so that the issues can be fully evaluated and resolved in a timely manner.

3. The disputant may initiate a dispute resolution process by writing a statement (called a dispute statement) describing the position, concept, opinion, or recommendations with which the disputant disagrees, the nature of and reasons for the difference in opinion, as well as the proposed changes and rationale for changes in recommendations and/or conclusions. This statement will be provided to the Next Highest Management Official for his or her consideration and resolution. This statement should also be distributed to the individual(s) with whom the disputant disagrees, to other relevant employees, and entered in the administrative file.

4. The dispute statement as well as all other supporting documents must:
    i. Relate only and specifically to the factual, scientific issues under consideration
    ii. Be dated and signed by the author

iii. Be directed to the administrative file with copies directed to supervisory and all other relevant personnel
iv. Indicate to whom documents are sent (distribution)
v. Not be changed, altered, or removed by any party after completion, signing, and inclusion in the administrative file
vi. Avoid defamatory remarks, undocumented charges, or irrelevant matters (e.g., personnel issues)

5. A disputant, in developing and drafting an initial statement of disagreement, may develop successive drafts or alter a primary draft with the intent of clarification or improvement of the statement. Such early drafts are not considered part of the administrative file and can be discarded once a final draft of the statement has been submitted to the administrative file. Once a final draft of the statement of disagreement or any other supporting document is part of an administrative file, no changes can be made in those documents. Any subsequent revisions or amendments must be made as new documents.

6. After review, discussion, and consideration of all relevant points of view, the Next Highest Management Official will make a decision on the matter, write a memorandum stating and supporting his or her decision, provide a copy to the individuals involved in the dispute, and place the memorandum in the administrative file. The decision-maker must take differing opinions into consideration and the views of all persons involved in the process will be respected and included in documenting the disagreement.

7. If a disputant cannot align with the decision made, a disputant may choose to continue the dispute resolution process by presenting his or her disagreement with the decision up the management chain to the Next Highest Management Official, following the same dispute resolution process outlined above. This appeals process can be repeated until the dispute ultimately reaches the CDER Director for consideration and resolution.

8. If a dispute arises between two individuals within a discipline and neither one is the final decision-maker, the dispute should still be documented in the administrative file. For example, if a primary reviewer and his or her First Level Supervisor/Team Leader disagree, the First Level Supervisor/Team Leader should write a brief summary memorandum describing the precise nature of his or her disagreement with the primary review or recommended regulatory action. This memorandum should address and describe any differences in opinion or recommendations, should be shared with the primary reviewer, should be entered into the administrative file, and should serve as the initial tool to facilitate discussions with the decision-maker towards achieving alignment. This process is more fully described in the 21st Century Review Desk Reference Guide for New Drug Application and Biologic License Application Reviews (NDA/BLA Review

Process).

9. If a decision-maker reaches a decision that is inconsistent with the conclusions or recommendations made by any individual on his or her staff, that decision-maker must write a memorandum documenting his or her rationale for the decision, including a discussion of how differing opinions were taken into consideration, enter the memorandum into the administrative file, and provide the memorandum to relevant staff. This will apply even if an individual has not initiated the dispute resolution process.

10. If, after exhausting the dispute resolution process outlined in this MAPP, an employee believes that his or her opinion was not adequately considered, and, as a result, an Agency action or inaction will have a significantly negative public health impact, CDER MAPP 4151.2, Resolution of Differing Professional Opinions: Review by *Ad Hoc* Panel and CDER Director, can be used. CDER MAPP 4151.2 describes a formal process by which individuals in this situation can ensure that their views are heard; these individuals are given an opportunity to request a review of the dispute by the Center Director and an *Ad Hoc* panel. CDER MAPP 4151.2 should be used only if an individual expects that an Agency action, or inaction, will have a significantly negative public health impact and 1) the mechanisms detailed in CDER MAPP 4151.1 have been utilized to their full extent, i.e., up to the highest management official (see Definitions in this MAPP) or 2) are unlikely to lead to a timely resolution.

11. The CDER Ombudsman can respond to questions and concerns regarding this dispute resolution process.

12. CDER is committed to the protection of employees from retaliation in any form for expressing different professional viewpoints or opinions. Everyone in the supervisory and management chain is expected to respect the process of dispute resolution and to protect employees from retaliation or even the appearance of retaliation for expressing a difference of professional opinion.

EFFECTIVE DATE

This MAPP is effective upon date of publication.