

Office of the Center Director

**Resolution of Differing Professional Opinions:
Review by Ad Hoc Panel and CDER Director**

CONTENTS

**BACKGROUND
POLICY
RESPONSIBILITIES
PROCEDURES
REFERENCES
DEFINITIONS
EFFECTIVE DATE**

PURPOSE

This MAPP provides the Center for Drug Evaluation and Research (CDER) staff a procedure to express Differing Professional Opinions (DPOs) concerning regulatory actions or policy decisions with significant public health impact in instances when the normal procedures for resolving internal disputes are not sufficient. The DPO procedure provides:

- Short time frames for hearing DPOs so they can be resolved expeditiously
- Review of the DPO by qualified staff not directly involved in the decision under consideration

BACKGROUND

When any scientific or regulatory decision is under consideration, 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 the reviews proceed. It is essential that the views of all persons involved in the review process be respected, that individual reviewers should not feel pressured to change their viewpoints if alignment cannot be achieved, and that the administrative file reflects differences of opinion if they exist. CDER MAPP 4151.1, Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain, 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 in the decision-making process and the resolution of disputes between disciplines, please refer to CDER MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions.

This MAPP should be used if, after exhausting the dispute resolution process outlined in CDER MAPP 4151.1, an employee believes that his or her opinion was not adequately considered. **This MAPP 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.** This MAPP should be used only if an individual expects that an Agency action, or inaction, will have a significant negative impact on public health 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 CDER MAPP 4151.1) or 2) are unlikely to lead to a timely resolution.

POLICY

- 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.
- ***CDER is absolutely committed to the protection of employees from retaliation in any form for expressing differing viewpoints.*** Everyone in the supervisory and management chain is expected to support the DPO process outlined in this MAPP, protecting employees from even the appearance of retaliation for having a differing viewpoint and using the DPO process. The rights of employees should remain intact throughout the entire DPO process, the outcome, and in the resolution of subsequent issues.
- If there are disagreements about a regulatory action or policy decision, the decision-maker must take the differing opinions into consideration and make a final decision. In all cases, the views of all persons involved in the process must be taken into consideration. The administrative file should reflect any differences of opinion.
- When an employee believes a decision will be made, or the Agency is failing to act, and that decision or inaction will have a significant negative impact on public health (e.g., a major increase in the frequency, severity or both of a possible adverse effect or health outcome affecting a large subset of the population), it is CDER's policy to ensure that the employee has the opportunity to express a DPO and to have his or her views heard and carefully considered by CDER management.

- The CDER Ombudsman is the focal point for receiving, managing, and facilitating the DPO process.
 - These DPO procedures are not intended for the resolution of routine disputes that can be addressed through the normal procedures for documenting and responding to different scientific and regulatory viewpoints (see CDER MAPP 4151.1). Rather, the DPO procedures should be reserved for the most serious differences of opinion when an action or inaction by CDER could have a significant negative impact on public health.
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RESPONSIBILITIES

Reviewers/Participants in Decision Making

- File a DPO only when he or she feels an Agency action or inaction is likely to have a significantly negative public health impact and he or she has either exhausted existing mechanisms for resolving disputes, or feels the existing mechanisms are not likely to lead to a timely and satisfactory resolution of his or her concern
- Submit the DPO to the CDER Ombudsman
- If the DPO package is filed, prepare any material in a timely manner that will assist in dispute resolution or panel consideration of the DPO to allow the panel to finish the review in 35 business days
- If the DPO package is not filed, and he or she believes that the criteria for filing were met, he or she may appeal to the Agency level within 10 calendar days of the CDER Ombudsman's filing decision
- Appeal to the Agency level within 10 calendar days of the Center Director's issuance of his or her written decision if the DPO submitter believes there was not adequate opportunity to present concerns and/or believes that Center policies and procedures were not followed

***Ad Hoc* DPO Review Panel Chairperson**

- Appoint *Ad Hoc* DPO review panel members

***Ad Hoc* DPO Review Panel**

- Request technical assistance and additional documentation from appropriate resources, (and notify the CDER Ombudsman) and, review the necessary information. If consensus or alignment cannot be reached, the written recommendation to the Center Director must include documentation of differing panel member opinions
- Review all requested and submitted information in the DPO

- Make a written recommendation to the Center Director within 35 business days, including documentation of any differences of opinion if consensus or alignment cannot be reached

Center Director

- Consult with the CDER Ombudsman to determine whether the potential consequences of a regulatory/scientific action or inaction are serious enough to warrant initiating the DPO process
- Appoint the chairperson of the DPO Ad Hoc panel
- Determine whether or not the issues raised in the DPO warrant a change in review plan (e.g., missing a PDUFA goal date to consider a dispute about a planned action)
- Determine whether or not to shorten the review time allowed for the DPO Ad Hoc panel to conduct its review; if yes, notify the CDER Ombudsman
- Issue a written decision and rationale for that decision on the DPO within 5 business days of receipt of recommendation from the Ad Hoc panel

CDER Ombudsman

- Review the DPO package submitted and work with submitter to ensure that the package is complete
- In consultation with the Center Director, determine whether the potential consequences of a regulatory/scientific action or inaction are serious enough to warrant initiating the DPO process
- If the DPO is not filed, notify (in writing within 5 business days of receipt of the DPO) the DPO submitter, the CDER Director, all individuals within the submitter's supervisory chain, the submitter's team leader, and any Super-Office Directors directly involved in the decision, that the DPO will not be filed and the reasons why the DPO will not be filed; the Ombudsman will maintain a record of the DPO submission and the decision to not file
- If the DPO is filed, notify (in writing within 5 business days of receipt of the DPO) the person submitting the DPO, the CDER Director, all individuals within the submitter's supervisory chain, the submitter's team leader, and any Super-Office Directors directly involved in the decision that the DPO has been filed
- Notify the DPO submitter, the Ad Hoc DPO review panel, and all other parties involved in the review if the Center Director determines that the review time allowed for the *Ad Hoc* DPO review panel to conduct its review must be shortened in the interest of the public health
- Work closely with the Division/Office Project Manager to enter all relevant material into the administrative file if this process concerns a regulatory submission
- Retain all relevant material in a file if this process does not concern a regulatory submission
- Facilitate and coordinate the retrieval of additional documentation requested by the *Ad Hoc* DPO review panel
- Manage and facilitate the DPO process

- Ensure distribution of the written decision
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PROCEDURES

1. Any CDER employee may initiate the formal DPO review process by preparing a written package that includes:
 - i. A summary statement of the position with which the person disagrees, whether it is a prevailing staff view, an existing management decision or stated policy position, or a proposed regulatory action or policy decision
 - ii. A description of the submitter's views and how they differ from the above
 - iii. A description of the nature of the disagreement (e.g., interpretation of data, methodology, judgment)
 - iv. An assessment of the possible significant negative consequences to the public health should the submitter's position not be adopted by CDER
 - v. A list of at least three potential candidates (FDA employees) with appropriate technical expertise for the *Ad Hoc panel* that will be convened (see below)
 - vi. Rationale for bypassing other possible venues for dispute resolution (if applicable)

Note: The package may be brief, but if it does not include the first five elements, it will not be processed as a DPO.
2. The package should be sent to the CDER Ombudsman
3. Within 5 business days of receipt of the DPO, the CDER Ombudsman, in consultation with the Center Director, will consider the merits of the DPO and determine whether the consequences of the decision in question are potentially sufficiently serious to warrant filing the DPO. In most cases, the Ombudsman will ensure that all other avenues for resolution (e.g., dispute resolution process, Advisory Committee discussion, CDER regulatory briefing) have been exhausted before a DPO is filed. However, in some cases, an individual may believe that his or her professional opinion will not be considered by his or her supervisors or that there is not time to exhaust other options for dispute resolution without seriously endangering the public health. In this case, the submitter should include in the DPO package a written request to bypass these other mechanisms and move directly to a DPO
4. If the CDER Ombudsman, in consultation with the Center Director, determines that the potential consequences of the contested decision are not sufficiently significant (i.e., do not have the potential to have a significant impact on public health), the Ombudsman will send notification of the decision in writing (within 5

- business days of receipt of the DPO) to the person submitting the DPO, the CDER Director, all individuals within the submitter's supervisory chain, the submitter's team leader, and any Super-Office Directors directly involved in the decision. The notification will include a statement that the DPO will not be filed and the reasons why the DPO will not be filed. The CDER Ombudsman will retain the DPO in the files for the record. After considering the reasons why the DPO was not filed, the DPO submitter may appeal the filing decision using the Agency appeals process detailed in the Staff Manual Guide 9010.1 "Scientific Dispute Resolution at FDA" within 10 calendar days of the written filing decision
5. If the CDER Ombudsman, in consultation with the Center Director, determines that the DPO should be filed, the CDER Ombudsman will send notification of the decision in writing (within 5 business days of receipt of the DPO) to the person submitting the DPO, the CDER Director, all individuals within the submitter's supervisory chain, the submitter's team leader, and any Super-Office Directors directly involved in the decision that the DPO has been filed
 6. The CDER Director will consider the impact of the DPO review on existing deadlines and will decide whether or not the issues raised in the DPO warrant a change in review plan (e.g., missing a PDUFA goal date to consider a dispute about a planned action)
 7. The Center Director will appoint a chairperson to lead an *Ad Hoc* DPO review panel within two business days of the DPO filing
 8. The chairperson will appoint an *Ad Hoc* DPO review panel within 5 business days of the DPO filing. The panel will be comprised of two to three additional members, including:
 - i. One member who has relevant technical expertise
 - ii. One member chosen from the list proposed by the employee submitting the DPO
 - iii. If time allows, one member with relevant technical expertise external to the Agency chosen by the *Ad Hoc* panel chairperson. Because of the short time frames involved, this member must be a special government employee (SGE). SGE panel members must be screened for conflict of interest (COI) and this can be a lengthy process; therefore, if an expert external to the Agency is needed for a robust review, the final appointment of the panel might be delayed to allow for COI screening
 - iv. To the extent possible, DPO panels should not include individuals who have directly participated in the decision-making process up to the time of the DPO and, when practicable, individuals who participated in the decision-making process should recuse themselves from the panel. However, the panel should include individuals with the *relevant technical expertise and experience* to understand the complex issues at hand

9. The Ombudsman will forward the DPO package to the *Ad Hoc* panel as soon as the panel has been appointed
10. Once the DPO package is received by the *Ad Hoc* panel, the panel should take no more than 35 business days to collect and review the necessary information and to make a written recommendation to the Center Director. The Center Director may decide to shorten the review time in the interest of public health. In this case, the Center Director will notify the Ombudsman, who will then immediately relay the revised timeframe to the DPO submitter, the *Ad Hoc* panel, and all other parties involved in the review
11. The DPO review panel will:
 - i. Determine whether sufficient documentation was provided by the DPO submitter to complete a detailed review and, if not, request additional information
 - ii. Request technical assistance and additional documentation (e.g., reviews, meeting minutes) from appropriate sources within or outside the Center, as necessary. The CDER ombudsman will coordinate these activities
 - iii. Review the DPO and all other relevant materials, and make a written recommendation to the Center Director regarding the appropriate course of action to be taken. If the panel is unable to reach consensus or alignment, the report should reflect the differing opinions of the panel
12. The Center Director must review the panel's recommendation and provide the employee who submitted the DPO and other Center staff included in review chains associated with the DPO with a written decision and rationale for that decision within 5 business days after receipt of the panel's recommendations
13. If the DPO submitter feels that there was not adequate opportunity to present his or her concerns and/or believes that Center policies and procedures were not followed, the DPO submitter may choose to appeal the decision. The DPO submitter must submit the appeal using the Agency appeals process detailed in the Staff Manual Guide 9010.1 "Scientific Dispute Resolution at FDA" within 10 calendar days of the Center Director's written decision
14. All records pertaining to DPOs will be maintained in the pertinent administrative file(s), if applicable. If the DPO is not related to a specific regulatory submission, records will be maintained by the CDER Ombudsman

REFERENCES

- FDA Administrative Practices Regulations, 21 CFR 10.70 and 10.75 and the FDA-NTEU Collective Bargaining Agreement (CBA)
 - CDER MAPP 4151.1 Revision 1. Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain, Effective 9/16/10.
 - CDER MAPP 4150.1, Role and Procedures of the CDER Ombudsman, Effective 10/10/02
 - CDER MAPP 4151.8 Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions, Effective 9/16/10.
 - FDA Staff Manual Guide 9010.1, Scientific Dispute Resolution at FDA, Effective 1/13/09.
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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).

EFFECTIVE DATE

This MAPP is effective upon date of publication.
