POLICY AND PROCEDURES

OFFICE OF EXECUTIVE PROGRAMS

EQUAL VOICE: COLLABORATION AND REGULATORY AND POLICY DECISION-MAKING IN CDER

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PURPOSE

Equal Voice: Description, Purpose, Scope

Equal Voice is a process and set of principles aimed at ensuring input from all levels of staff is heard and valued to create a mutually respectful and professional environment. This MAPP describes the principles behind Equal Voice and how the process is used for collaborative review and regulatory and policy decision-making in the FDA Center for Drug Evaluation and Research (CDER). CDER uses Equal Voice to:

- Seek and engage all relevant expertise into the regulatory and policy decision-making process
- Enable professional opinions to be fully expressed, understood, considered, and documented
- Strive to achieve ***alignment*** (support for a decision, not necessarily the same as agreement)[1]
- Provide informal and formal means to resolve differences of professional opinion
- Ensure decisions are shared with relevant staff and documented

[1] Alignment is a state of general support for a decision. It does not always mean full agreement or consensus. Rather, it indicates that all involved individuals agree to support the decision or action to be taken based on the knowledge that the decision-maker considered all applicable perspectives and weighed all potential options and that the decision is evidence-based, is in the best interests of patients and consumers, practicable, and consistent with CDER's mission. Therefore, an individual may align on a decision, even if it differs from their recommendation.

Following Equal Voice creates an inclusive, team-based environment for robust discussions that lead to more fully informed decision-making and enhance CDER's ability to carry out its mission to protect and promote public health. Equal Voice principles combined with CDER's regulatory/statutory requirements, policy, precedents, and scientific evidence form the basis for CDER's regulatory and policy decisions and actions. This MAPP also contains the formal appeal procedures to be followed when alignment cannot be reached informally. All procedures outlined in this MAPP apply to pending regulatory and policy decisions or actions and not to matters pertaining to human resources or labor and employee relations.[2]

POLICY

- The Equal Voice principles and process outlined in this MAPP apply to all CDER staff when making pending regulatory or policy decisions and resolving differences of opinion. This MAPP does not apply to matters pertaining to human resources or labor and employee relations.

- All staff, including CDER supervisors, managers, and senior managers, are expected to adhere to and support the Equal Voice principles and process. Staff support Equal Voice by creating an inclusive and safe environment that encourages participants to voice their professional opinions even when they differ from prevailing views, pending decisions, or proposed or established practices.

PROCEDURES

Implementing Equal Voice

For each of the many regulatory and policy decisions that CDER makes, the Center must designate an individual with the delegated responsibility and authority to make the decision. Often, a decision-maker is designated according to established regulatory authorities or Center hierarchies. For some types of decisions, the decision-maker is the signatory authority. When it is not clear who the decision-maker will be, it is helpful to pinpoint the regulatory or policy decision by defining and articulating the question that needs to be answered or the problem that needs to be solved. In situations where the decision-maker is not the signatory authority (e.g., in a cross-office policy decision), it may be necessary to align on who makes the decision.[3] It is important that all staff involved have the same understanding of the decision that needs to be made and who will make it. In some cases, the decision-maker may change as the Equal Voice process unfolds.

[2] For matters pertaining to authorship disputes, refer to Staff Manual Guide 9010.3, Authorship Dispute Resolution at FDA.

[3] For certain regulatory decisions, the designation of decisionmaker may be determined by the relevant delegation of authority. Consult the Office of Regulatory Policy for questions about who can be the designated decisionmaker for a particular action under CDER's delegations.

The Equal Voice principles apply throughout the collaborative process within and across management chains. Multiple factors, listed and diagrammed below, contribute to the collaborative approach that is central to Equal Voice (Figure 1). These factors are dynamic and interconnected. Although some must be initiated by the decision-maker, it is also incumbent upon all participants to engage fully in the Equal Voice process. The Equal Voice principles and process apply to all CDER staff when making regulatory or policy decisions and resolving differences of opinion.

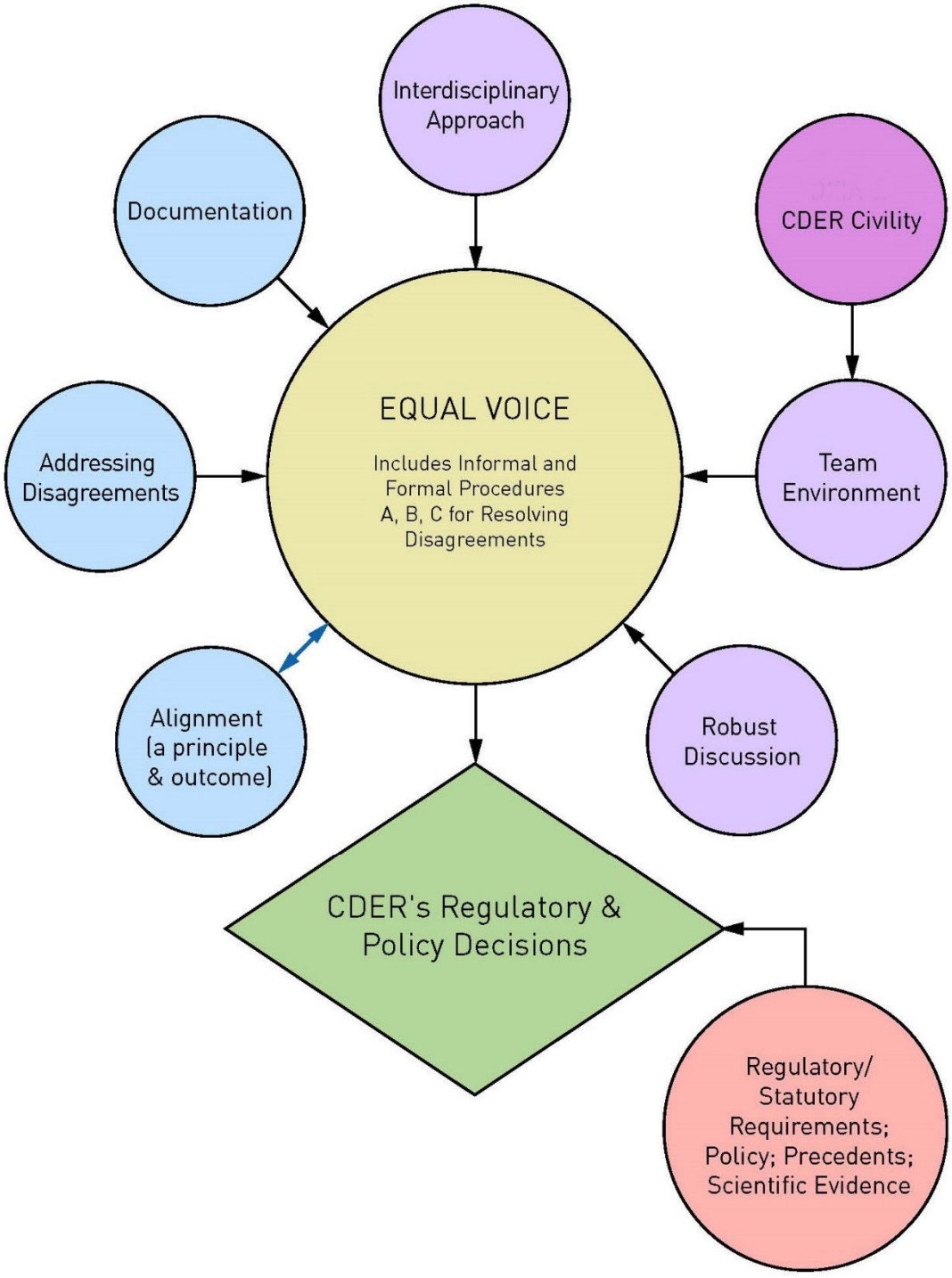
Interdisciplinary Approach
Documentation
CDER Civility
EQUAL VOICE
Includes Informal and Formal Procedures A, B, C for Resolving Disagreements
Addressing Disagreements
Team Environment
Alignment (a principle & outcome)
Robust Discussion
CDER's Regulatory & Policy Decisions
Regulatory/ Statutory Requirements; Policy; Precedents; Scientific Evidence

Figure 1. Equal Voice Principles Contribute to CDER's Regulatory and Policy Decisions. CDER's regulatory and policy decisions are based on the Equal Voice principles and process as well as regulatory and statutory requirements, policy, precedents, and scientific evidence. Multiple factors support the collaborative approach that is central to Equal Voice. An interdisciplinary approach and respectful, robust discussion enrich the exchange of ideas. Engaging leadership within and across management chains can help achieve alignment. Documentation requirements support transparency and accountability. The Equal Voice principles and process apply to informal and formal ways to resolve differences of opinion. Following Equal Voice leads to more fully informed decision-making and enhances CDER's ability to carry out its mission to protect and promote public health.

Principles of Equal Voice

Ensuring an interdisciplinary approach encourages the full and open participation of all relevant disciplines[4] in the collaborative process and enables the decision-maker to make the best-informed decision. Equal Voice was developed to ensure that, regardless of where the final decision-making authority resides, decisions are made only after all appropriate expertise is brought to bear. The designated decision-maker is expected to seek and carefully consider the input of all relevant disciplines before reaching the best decision based on law, regulations, science, public health concerns, and precedents, and within required time frames.

Each discipline should identify individuals who can fully represent their views. It is critical that each discipline's representatives work within their management chain to ensure the views they put forward are consistent with the scientific, regulatory, and/or administrative policies of that discipline. Each discipline should consider how central their expertise and policy are to the specific decision to be made. The decision-maker may consider the perspectives of some disciplines to be weighted more heavily than others based on their relevance to the issue in question. Participants from the relevant disciplines should also evaluate whether additional expertise is needed and, if so, inform the decision-maker.

Creating a team environment fosters meaningful interactions, robust discussion, and problem-solving in a mutually respectful and professional manner. The decision-maker and discussants can apply CDER's Civility Code to help create a welcoming team environment. Those serving as subject matter experts (from CDER or other parts of FDA) should be treated as part of the team.

Fostering robust discussion enriches the exchange of ideas and encourages innovative thinking and novel solutions. It can also facilitate early identification of concerns that could affect the decision-making process. CDER supervisors, managers, and senior managers should be aware that staff members may be reluctant to express views that differ from leadership. As such, they should create an inclusive and safe environment that encourages participants to voice their professional opinions, including rationale and recommendations, even when they differ from prevailing views, pending decisions, or proposed or established practices. It is incumbent on those leading or participating in robust discussions to express their views respectfully, consistent with CDER's Civility Code, and be mindful of the impact of their words, actions, and reactions on colleagues.

Those participating in discussions should practice active listening by giving full attention to the ideas being expressed, carefully considering each perspective, asking clarifying questions when needed, and responding respectfully even when disagreeing. Staff are encouraged to raise concerns early to allow time for issues to be resolved before a

[4] In this MAPP, "disciplines" refers to CDER's organizational components, which may include super-offices, offices, divisions, or particular areas of expertise.

decision must be made. Staff should be mindful of regulatory or statutory timeframes, applicable laws and regulations, and imminent public health concerns.

Protection from Retaliation. ***CDER is absolutely committed to the protection of employees from retaliation in any form for expressing differing professional opinions.*** Everyone in the supervisory and management chain is expected to support and respect the Equal Voice process and protect employees from retaliation or the appearance of retaliation for expressing a difference of opinion.

Achieving Alignment

Once all relevant disciplines have provided input the team will often achieve alignment around a pending decision. Alignment is a state of general support for a decision. It does not always mean full agreement or consensus. Rather, it indicates that all involved individuals agree to support the decision or action to be taken based on the knowledge that the decision-maker considered all applicable perspectives and weighed all potential options, and that the decision is evidence-based, is in the best interests of patients and consumers, practicable, and consistent with CDER's mission.

There are multiple points in the collaborative process that present opportunities to achieve alignment. When striving for alignment, it is essential that the views of all persons involved be respected and that CDER staff are not pressured to change their viewpoints if alignment cannot be achieved. If the decision-maker disagrees with the views of a particular discipline, they must articulate – and, where appropriate, document – why they disagree and provide sufficient notice to enable opportunities to resolve the disagreement, including elevation.

Addressing Disagreements

If disagreements arise and alignment cannot be reached, CDER strongly encourages staff to make every effort to address disagreements informally at the lowest possible organizational level. When striving to reach alignment, those involved should meet to consider one another's positions, find areas of common agreement, identify specific areas of disagreement, and work to resolve them. Some options for facilitating informal resolution include one-on-one discussions, consulting with additional subject matter experts, holding meetings to hear all perspectives, and bringing issues to committees. Throughout the process, staff members should keep each other informed (Figure 2).

If the above efforts do not result in alignment, the matter may be elevated and the circle of discussion widened by engaging the next level of management from relevant disciplines. When working across management chains, elevation should be to equivalent levels. Those who disagree with the decision are responsible for presenting the disagreement to the next level of management; the informal options mentioned above for reaching resolution still apply. The most senior management official in any organizational component may elect to seek input from the Center Director or designee on the disagreement. Staff should exercise professional judgement in determining

whether the issue is of sufficient magnitude to be elevated to increasingly senior management levels.

Decision-Making

After carefully considering input from staff, the designated decision-maker must make a timely decision based on law, regulations, science, precedents, and public health concerns. The decision-maker must share the planned decision with relevant staff, including how input from each discipline was considered.

Documentation

Staff should enter their views and supporting information into the administrative file and provide evidence-based rationales for their stated opinions and conclusions, regardless of whether a disagreement arose. Positions and recommendations should reflect good regulatory and scientific practices, be supported by relevant data, and be consistent with applicable laws, regulations, and policies. The Equal Voice principles do not dictate documentation above and beyond established records management requirements and policies.[5]

After review, discussion, and consideration of all relevant points of view, the decision-maker will decide on the matter and write a memorandum explaining the rationale for their decision. Because the administrative file should reflect how the decision was reached, the memorandum should capture the key issues discussed, the critical thinking that went into the decision, and how differences of opinion, if any, were considered. The decision-maker then provides copies to those involved in the process and places the memorandum in the administrative file in accordance with 21 CFR 10.70.

[5] If a dispute relevant to the decision arises between two individuals and neither one is the final decision-maker, the dispute should still be documented in the administrative file.

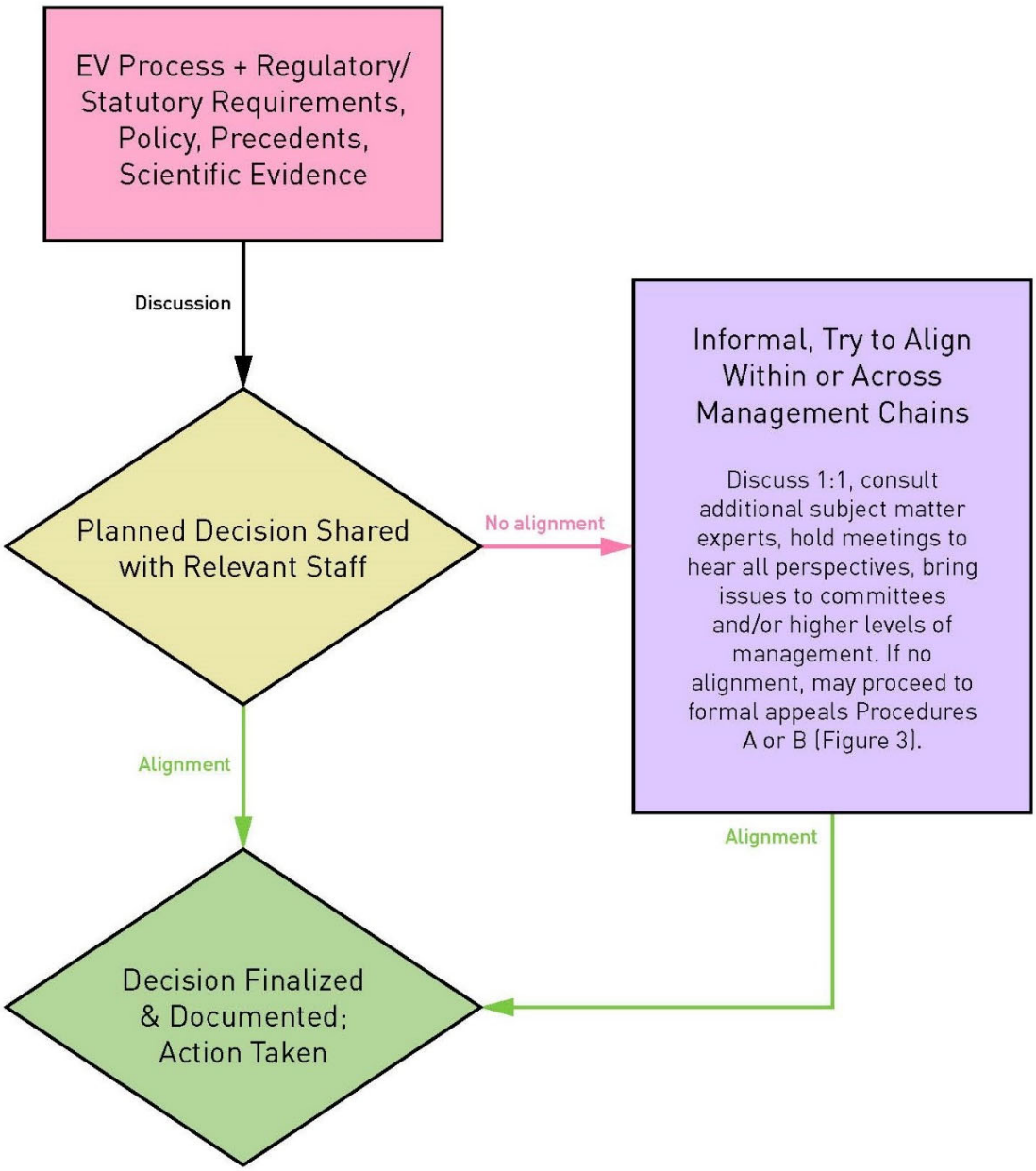

Figure 2. CDER's Informal Process for Resolving Disagreements Within or Across Management Chains. After receiving reviews, memorandums, and/or input from relevant staff contributing to a pending decision, the designated decision-maker shares their proposed decision. If others within or across the disciplines align, the decision is finalized and acted upon. If others do not align, the group uses Equal Voice principles and informal efforts to try to achieve alignment. If unsuccessful, the matter may be raised to the next level of management informally or via formal appeal Procedure A for within a management chain or formal appeal Procedure B for across management chains (Figure 3).

Formal Appeals Procedures for Regulatory and Policy Decisions When Alignment Cannot Be Achieved

Alignment on a decision is often achieved through discussion. CDER strongly encourages staff to make every effort to address disagreements informally at the lowest possible organizational level and to be judicious in deciding whether to elevate to higher levels of management. If a CDER employee believes a pending regulatory or policy decision, action, or inaction will have a negative impact on the Agency's mission to protect public health, they have the opportunity to express differences of opinion and to have their views heard and carefully considered by management.[6] At any time, staff may initiate formal appeals procedures, outlined below, which are also based on Equal Voice principles.[7,8] If staff decide to appeal, prompt action is recommended for all involved so the issues can be fully evaluated and resolved in a timely manner. Formal appeals differ from informal dispute resolution (see Section II) primarily with respect to documentation (formal appeals require a dispute statement) and, in some cases, adherence to specified timelines.

This section outlines three formal appeals procedures for resolving disputes:

- **Procedure A** is used for resolving regulatory or policy disputes ***within*** a management chain
- **Procedure B** is used for resolving regulatory or policy disputes ***across*** management chains
- **Procedure C** is used for resolving disputes by directly elevating them to the CDER Director and an ad hoc review panel

At the culmination of any of the formal appeals processes, the management official making the decision on the appeal should also become the signatory authority on the pending regulatory or policy decision itself.

Procedure A. Formal Appeals Within a Management Chain

When alignment cannot be reached within a management chain, the regulatory or policy decision can be promptly elevated to the Next Highest Management Official (NHMO)[9] within that chain (Figure 3).

Initiating the Process; Writing and Submitting a Dispute Statement

One or more staff members may initiate a formal dispute resolution process (appeal) by writing a statement (called a dispute statement) describing the position, concept, opinion,

[6] Management may include divisional, office, or super-office leaders, and when appropriate, Center leaders.
[7] When possible, appeals should be submitted when a decision is pending and before it is rendered. However, under 21 CFR 10.75, Internal Agency Review of Decisions, a decision can also be appealed after it is rendered.
[8] If formal appeals processes exist for specific situations in the Center, those may supersede formal processes outlined in this MAPP but should still adhere to Equal Voice principles.
[9] Next Highest Management Official: The management official one level above the management official authorized to make the decision currently under dispute. Ultimately, this could be the CDER Director.

and/or recommendations with which the staff member disagrees as well as the proposed changes and rationale for changes in recommendations and/or conclusions. The statement may also include a description of informal efforts to resolve the disagreement. The staff member (disputant) provides this statement to the NHMO and other relevant staff and enters it in the administrative file.

The dispute statement must:

i. Relate only and specifically to the factual, regulatory and policy issues under consideration
ii. Avoid defamatory remarks, undocumented charges, or irrelevant matters (e.g., personnel issues)
iii. Verify (or confirm) that no new information has been submitted in support of the appeal and that the designated decision-maker had the opportunity to review all the material now being relied upon for appeal. If the disputant wants consideration of the new information that may affect the original decision on a matter, they should submit the new information to the original decision-maker. CDER considers new analyses of previously reviewed data to be new information.[10]
iv. Indicate to whom documents are sent (distribution)
v. Be dated and signed by the author
vi. Be directed to the administrative file with copies directed to supervisory and all other relevant personnel
vii. Not be changed, altered, or removed by any party after completion, signing, and inclusion in the administrative file

Considering Viewpoints and Rendering a Decision

After review, discussion, and consideration of all relevant points of view, the NHMO will decide on the matter, write a memorandum stating and supporting their decision, provide a copy to the individuals involved in the dispute and other relevant staff, and place the memorandum in the administrative file. The decision-maker must take differing opinions into consideration, respect the views of all persons involved in the process, and document the differing opinions in the administrative file.

Further Appeals

If a disputant cannot align with the decision made by the NHMO, they may choose to continue the appeals process by presenting the disagreement to the NHMO next in the management hierarchy, following the same process outlined above. This appeals process can be repeated until the dispute ultimately reaches the CDER Director. Once the CDER Director or designee renders a decision, any further appeal should be submitted to the Commissioner's Office as outlined in FDA Staff Manual Guide (SMG) 9010.1.

[10] The Code of Federal Regulations (21 CFR 10.75(d)) states, "Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information."

Procedure B. Formal Appeals Across Management Chains.

When alignment cannot be reached across disciplines, the decision can be elevated to the NHMO (i.e., one level above the designated decision-maker) (Figure 3). Because the dispute is across disciplines, the circle of discussion should be widened to engage equivalent levels of management from the relevant disciplines.

Initiating the Process: Writing and Submitting a Dispute Statement

A staff member may initiate an appeal by writing a dispute statement describing the position, concept, opinion, and/or recommendations with which the staff member disagrees as well as the proposed changes and rationale for changes in recommendations and/or conclusions. The dispute statement as well as all other supporting documents must meet criteria i-vii outlined in Procedure A (pages 9-10). The statement may also include a description of informal efforts to resolve the disagreement. The disputant provides the statement to the NHMO and other relevant staff and enters it in the administrative file.

Widening the Circle Across Disciplines

To inform their decision and widen the circle of discussion, the NHMO should invite the input of relevant disciplines including their counterparts at equivalent levels in other management chains (e.g., to the office level or the super-office level for each discipline involved). Each person contributing to the decision-making process works within their management chain to be sure the position represented is consistent with the regulatory and scientific policies of that discipline. Specific disciplines participating in the decision-making process are responsible for ensuring that their opinions and positions are understood.[11]

Considering Viewpoints and Rendering a Decision

As in Procedure A, after review, discussion, and consideration of all relevant points of view, the NHMO will decide on the matter, write a memorandum stating and supporting their decision, provide a copy to the individuals involved in the dispute and other relevant staff, and place the memorandum in the administrative file. The decision-maker must take differing opinions into consideration, respect the views of all persons involved in the process, and document the differing opinions in the administrative file.

Further Appeals

If a disputant cannot align with the decision made by the NHMO, they may choose to continue the appeals process by presenting the disagreement to the NHMO next in the management hierarchy, following the same process outlined above. This process can be repeated until the dispute ultimately reaches the CDER Director. Once the CDER Director or designee renders a decision, any further appeal should be submitted to the Commissioner's Office as outlined in FDA SMG 9010.1.[12]

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[11] While using Procedure B, if an individual cannot align with a position within their discipline, Procedure A may be used to resolve the disagreement.

[12] If a disagreement between FDA centers (involving CDER) exists, staff can use the EV process by informally elevating the matter through the center's management chains. If the issue is still not resolved at

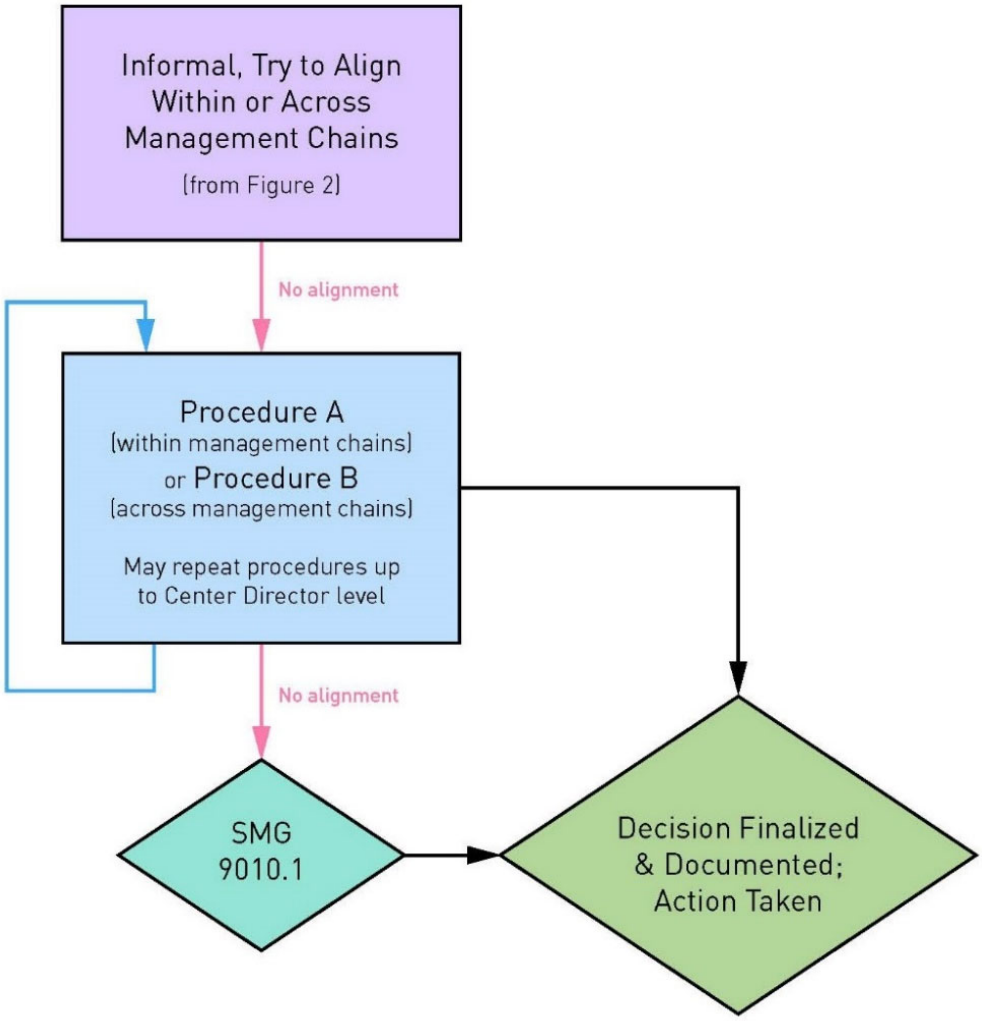

Figure 3. CDER Formal Appeal Procedures A or B for Resolving Disagreements Within or Across Management Chains. If CDER's informal process does not lead to alignment, the matter may be raised to the next level of management via formal appeal Procedures A or B to strive for alignment within or across management chains, respectively. If those who disagree with the pending decision cannot align with the next level of management, they may choose to continue the dispute resolution process through the Center's chain of command until it ultimately reaches the CDER Director for a final Center-level decision. If those who disagree exhaust the Center's management levels and remain unsatisfied with CDER's

the Center Director level, an appeal may be submitted to the Commissioner's Office as per FDA SMG 9010.2, Cross-Center Dispute Resolution at FDA. Note: In this document the term "centers" is intended to encompass all discrete operational units within the Agency including the product review centers (CDRH, CDER, CBER, CFSAN, CVM, and CTP) and organizational components such as ORA and NCTR.

decision, they may request review by the Commissioner of Food and Drugs as per FDA SMG 9010.1.

Procedure C. Direct Appeals to the Center Director and Ad Hoc Review Panel

When alignment cannot be reached and there is an urgent need for a decision, elevation via a direct appeal to the CDER Director or designee and an ad hoc review panel may be appropriate (Figure 4). This formal process should be reserved for the most serious circumstances when a staff member believes an Agency action, or inaction, will have a significant negative impact on the Agency's mission to protect public health,[13] **and** neither formal procedure A nor B is likely to lead to timely resolution. Procedure C may only be used if the Center Director or designee has not previously rendered a decision.

Initiating Procedure C

A CDER staff member may initiate Procedure C by submitting a written package to the CDER Ombuds. In order to be processed, the package must meet the criteria outlined in Procedure A (pages 9-10) and also must include:

i. A summary statement of the position with which the person disagrees (including supporting documentation if available), 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 disputant's views (including supporting documentation if available) 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 impact on the Agency's mission to protect public health should the disputant's position not be adopted by CDER
v. Rationale for bypassing other possible venues for dispute resolution (informal dispute resolution as described in Section II; formal Procedures A or B). If an avenue for dispute resolution was initiated but not completed, the written package should include a description of the process followed and a rationale for why it was not exhausted.
vi. Optional: At the discretion of the disputant, the package may also include a list of at least three potential candidates (FDA staff) with appropriate technical expertise for the ad hoc review panel that will be convened (see below).

Role of the CDER Ombuds and the Center Director

Within 5 business days of receipt of the written package, the CDER Ombuds, in consultation with the Center Director, will consider the merits of the request and determine whether the consequences of the decision in question are sufficiently serious to

[13] A significant negative impact on the Agency's mission to protect public health may include a decision or action that is counter to law, regulation, interpretation of data, or existing precedent without adequate justification for deviation; or establishes a precedent that could have a significant negative impact in the future.

warrant a decision by the Center Director or designee and an ad hoc review panel. The Ombuds will make every attempt to ensure that all other avenues for resolution (informal dispute resolution as described in Section II; formal Procedures A or B) were considered before a request for Procedure C is accepted for filing.

If the CDER Ombuds, in consultation with the Center Director, determines that the potential consequences of the contested decision are not sufficiently significant (i.e., is unlikely to have a significant impact on the Agency's mission to protect public health), the Ombuds will send notification of the decision in writing (within 5 business days of receipt of the package). The Ombuds will send notification to the staff member who initiated the appeal (the disputant), the CDER Director, all individuals within the disputant's management chain, the disputant's team leader (if applicable), and any super-office directors directly involved in the decision (if not already included in the disputant's management chain). The notification will include a statement that the request will not be filed and the reasons why. After considering the reasons why the package was not filed, the disputant may proceed with formal appeals Procedures A or B or appeal the filing decision using the Agency appeals process detailed in SMG 9010.1 within 10 calendar days of the written filing decision.

If the CDER Ombuds, in consultation with the Center Director, determines that the request should be filed, the CDER Ombuds will send notification of the decision in writing (within 5 business days of receipt of the package) to the disputant, the CDER Director or designee, all individuals within the disputant's management chain, the disputant's team leader (if applicable), and any super-office directors directly involved in the decision (if not already included in the disputant's management chain).

The Center Director or designee will consider the impact of the request on existing deadlines and will decide whether the issues raised warrant a change in review plan (e.g., missing a PDUFA goal date to consider a dispute about a planned action).

All records pertaining to the appeal will be maintained in the pertinent administrative file(s). If the decision under consideration is not related to a specific regulatory submission, the CDER Ombuds ensures that the documents are entered into the CDER archival record.

Ad Hoc Review Panel

The Center Director or designee will appoint a chairperson to lead an ad hoc review panel within 2 business days of the appeal being filed. The chairperson will appoint panel members – typically at least two to three individuals -- within 5 business days of the filing. The panel will include:

i. One member who has relevant technical expertise
ii. One member chosen from the list provided by the employee submitting the dispute statement
iii. If time permits, one member with relevant technical expertise internal or external to the Agency chosen by the ad hoc review panel chairperson. Because of the short time frames involved, if external, 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. The panel should include individuals with the relevant technical expertise and experience to understand the complex issues at hand. To the extent possible, ad hoc review panels should not include individuals who previously made a decision about the matter.

The Ombuds will forward the package to the ad hoc review panel as soon as the panel is appointed. Once the ad hoc review panel receives the package, the panel should take no more than 35 business days to collect and review the necessary information and make a written recommendation to the Center Director or designee. If the Center Director or designee decides to shorten the review time in the interest of the Agency's mission to protect public health, they will notify the Ombuds, who will then immediately relay the revised timeframe to the disputant, the ad hoc review panel, and all other parties involved in the review. The ad hoc review panel will:

i. Review the submission and all other relevant materials. Determine whether sufficient documentation was provided by the disputant to complete a detailed review.
ii. If needed, request additional documentation or clarification (e.g., reviews, meeting minutes) from appropriate sources within or outside the Center, as necessary. The panel may want to consider a meeting with relevant staff and possibly the Center Director or designee. The CDER Ombuds will coordinate these activities.
iii. Make a written recommendation to the Center Director or designee 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.

Within 5 business days of receiving the panel's recommendations, the Center Director or designee must:

- Review the panel's recommendation
- Make a decision
- Write a memorandum stating and supporting their decision
- Provide a copy of the memorandum to the individuals involved in the dispute and other relevant staff, and
- Place the memorandum in the administrative file.

Appeals

If the disputant believes there was not adequate opportunity to present their concerns and/or believes that Center policies and procedures were not followed, the disputant may choose to appeal the decision. The disputant must submit the appeal using the Agency appeals process detailed in SMG 9010.1 within 10 calendar days of the Center-level written decision.

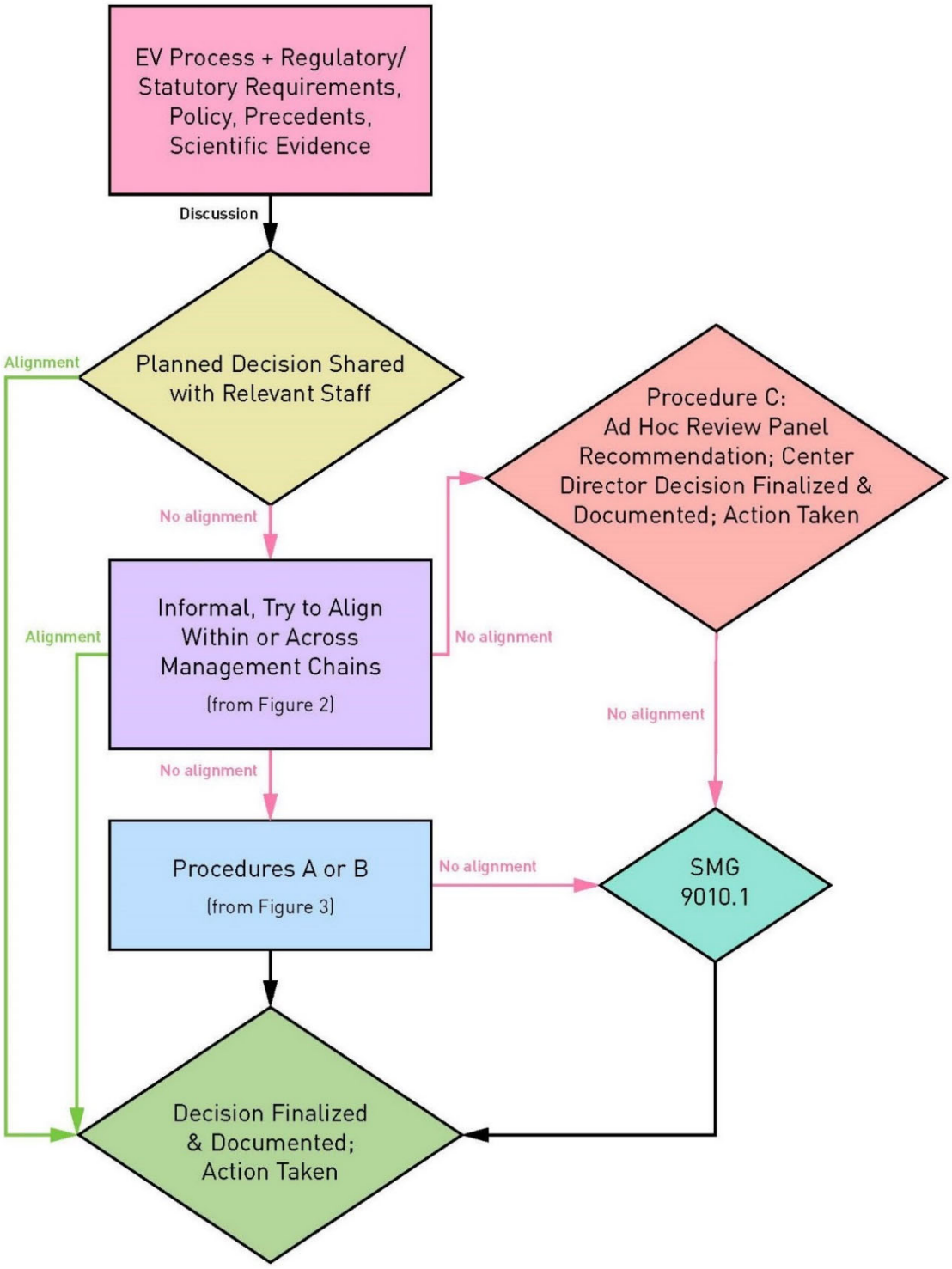

Figure 4. Procedure C. Direct Appeal to the Center Director and Ad Hoc Review Panel. When alignment cannot be reached and there is an urgent need for a decision, elevation via a direct appeal to the CDER Director or designee and an ad hoc review panel may be appropriate. This formal process should be reserved for the most serious circumstances.

REFERENCES

FDA, 2021, SMG 9010.1 Scientific Dispute Resolution at FDA.
FDA, 2019, SMG 9010.2 Cross Center Dispute Resolution at the FDA.
FDA, 2021, SMG 9010.3Authorship Dispute Resolution at FDA.
21 CFR 10.70, Documentation of significant decisions in administration files.
21 CFR 10.75, Internal agency review of decisions.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
9/16/10	n/a	
4/12/22	1	• Supersedes and cancels MAPP 4151.1, Rev. 1, Scientific / Regulatory Dispute Resolution for Individuals Within a Management Chain. (Effective 9/16/10.) • Supersedes and cancels MAPP 4151.2, Rev. 1, Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director. (Effective 9/16/10.) • Significant edits to all sections, to reflect updates.
8/12/25	2	• Revised to comply with Executive Order 14151