Office of the Center Director

Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions

CONTENTS

BACKGROUND

This MAPP provides the framework and principles for the implementation of Equal Voice (EV) in the Center for Drug Evaluation and Research (CDER). It provides general guidance for incorporating the philosophy and practices of EV into CDER decision-making processes. This MAPP should be referenced in all CDER MAPPs relevant to decision-making, and the principles and practices should be incorporated into those MAPPs directly, when appropriate.

CDER staff are involved in making a wide variety of decisions every day. These decisions may be scientific and/or regulatory in nature, or they may relate to the administration and management of the Center. 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. After all appropriate input is obtained, CDER must reach an institutional decision and may need to do so efficiently within legislative, regulatory and/or practical time limits.

For each of the many regulatory decisions that CDER makes, someone must be designated as the decision-maker, i.e., the individual with the delegated responsibility and authority to make the decision. In many cases, this is the signatory authority. The EV initiative was developed to ensure that, regardless of where the signatory authority resides, decisions are made only after all appropriate expertise is brought to bear.

CDER has instituted a number of policies and procedures to foster quality and timely decision-making. Examples include numerous MAPPs defining drug review and

approval processes, MAPPs regarding dispute resolution (including the Differing Professional Opinion process), and a Memorandum of Agreement between the Office of New Drugs (OND) and the Office of Surveillance and Epidemiology (OSE) that describes the roles and responsibilities of these Offices in the management of significant safety issues associated with pending drug applications and approved drug products.

EV expands on existing policies and procedures and requires a collaborative environment for decision-making. Such an environment requires open communication and exchange of ideas in a mutually respectful professional environment, and the full and open participation of all relevant disciplines and organizational components in the decision-making process. It is expected that the EV process will increase engagement and transparency and allow early identification of concerns that could disrupt the decision-making process. EV provides a foundation to achieve the "5 Cs" (Communication, Collaboration, Community, Conflict management, and Consumer focus) in the way CDER conducts its business. EV is designed to help the Center make high-quality decisions.

EV is intended to apply to pending decisions with potential outcomes that could have a substantive impact on the overall integrity, function, responsibilities, or mission of CDER, or on the public health. EV is not intended to include administrative disputes.

POLICY

- All appropriate expertise should be brought to bear for decisions made in CDER. Disciplines with expertise relevant to the decisions being made should be represented in the decision-making process. The designated decision-maker is expected to carefully consider the input of all relevant disciplines before reaching what he or she considers to be the best decision based on law, regulations, science, precedents, and public health concerns.

- CDER operates in a collaborative team-based environment that encourages the full and open participation of all relevant staff and disciplines, seeks and engages the professional input of all parties during the decision-making process, and strives to create alignment among the disciplines and organizational components involved in decision-making through discussion and scientific exchange.

- Each individual who contributes to the decision-making process is also responsible for fully representing the views of his or her discipline. To do this effectively, it is critical that each individual works within his or her management chain to be sure the position represented is consistent with the scientific, regulatory, and/or administrative policies of that discipline and organizational

component. If an individual disagrees with the position of his or her management chain, he or she should refer to guidelines set out in CDER MAPP 4151.1, Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain.

- While the decision-maker may not have considered each discipline's perspective to carry equal importance when reaching a conclusion, EV gives all disciplines and organizational components the opportunity to voice their concerns. Discipline and office representatives should provide an understanding of their discipline's role in the decision being made to all participants in the Equal Voice process, after considering how central their discipline expertise and policy is to the specific decision to be made. For example, if a decision to be made is central to regulation of pharmaceutical quality, then quality staff have a key role in the decision-making process and may plan to raise the matter to higher level staff if the decision is in conflict with existing policy. On the other hand, if there is a quality issue that toxicology and clinical staff need to be made aware of, but that is not crucial to policy in the quality area, then quality discipline representatives simply need to ensure that their analysis has been considered in making the decision. The delegated decision-maker should document how the differing opinions were taken into consideration and fully discuss with the team how the input of each discipline and organizational component was considered in making the final decision.

- Opinions of staff should be documented and supported by data in a manner commensurate with the magnitude of the decision being made. Each staff member in CDER is expected to produce high-quality reviews or other documents that provide the rationale for his or her position. These documents should reflect good scientific practices as well as be consistent with applicable laws, regulations, and policies.

- If an individual representing the views of his or her discipline cannot align with a decision to be made, the decision should be promptly escalated and resolved through the management chain (see MAPP 4151.1).

- Once all relevant disciplines and organizational components have had a chance to provide input, in most cases, the group will achieve alignment around the decision to be made. It is essential that the views of all persons involved in the review process be respected and that individual reviewers should not be pressured to change their viewpoints if alignment cannot be achieved. If alignment among disciplines and/or organizational components cannot be reached on a decision, 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. When alignment cannot be achieved by the interdisciplinary team,

decisions should be elevated up through the management chain of the relevant disciplines.

- Critical to the implementation of EV are 1) exercising good judgment in determining which issues are of sufficient magnitude to be elevated to increasingly senior management levels and 2) accountability and responsibility for raising such concerns and citing the data, policies, and regulatory authorities relevant to the concerns during the decision-making process in a timely manner. Concerns raised late in the EV process, and/or close to the deadline, by any party, are difficult to incorporate in timely decision-making. Therefore, all participants in the decision-making process are responsible for raising concerns as early as possible in the process to allow adequate time for resolution of differences of opinion. However, it is understood that some concerns may not emerge until later in the review process, or that emerging concerns may subsequently impact a participant's or participants' opinions about the decision-making process or the decision to be made.

- All staff are expected to express their views and the rationale for them in a respectful manner.

RESPONSIBILITIES

Lead Office

- Invites the input of all relevant disciplines and/or organizational components.

- Solicits and fully considers the input of each discipline and organizational component represented in the decision-making process.

- Strives to create alignment, clearly identifies important areas of disagreement, and engages in constructive dialogue during the process as early as possible.

- Encourages individuals on the decision-making team to elevate areas of disagreement through their management team to clarify discipline-specific positions.

- Arranges to include more senior management in decision-making when it becomes clear that alignment cannot be reached among the disciplines involved.

- Provides feedback and documentation to all participants about the decision that is made, and the rationale for the decision, including how the input of participating disciplines and Offices was considered.

Individual Reviewer/Participant

- Fully participates in the decision-making process

- Represents the position of his or her specific discipline and ensures the position is understood and considered. If an individual reviewer or participant has views that differ from those of his or her specific discipline, the individual should feel free to discuss those views with the team, but must clearly specify when the views differ from those of his or her discipline. The individual should document his or her views, e.g., in a review, and discipline management should document the rationale for choosing an alternate position

- Evaluates the need for additional disciplines and organizational components to be included in the decision-making process. Informs the lead office when needed

- Discusses any contentious points with his or her supervisor and documents his or her point of view to include the rationale for his or her position

- Strives to achieve alignment and clearly identifies and communicates areas of disagreement throughout the process as early as possible

Office Director

- Each Office is responsible for developing and ensuring staff awareness of policies and processes for:

    - Early and continued involvement within the management chain regarding upcoming decisions to be sure each individual is representing the views of the discipline/Office
    - Escalating decisions within the management chain

PROCEDURES

- When a decision is to be made, the lead office/decision-maker should invite the input of relevant disciplines and organizational components to determine the appropriate action. This is described in other CDER processes, such as the *21st Century Review Desk Guide* (Section 3 – Plan for the Review of the Application) and Interim MAPP

6700.8 *Establishing and Operating Safety Issue Teams in the Center for Drug Evaluation and Research*).

- All relevant disciplines identify individual(s) who are able to fully represent such disciplines to participate in the decision-making process.

- Each individual who contributes to the decision-making process works within his or her management chain to be sure the position he or she represents is consistent with the scientific, regulatory, and/or administrative policies of that discipline.

- If an individual cannot align with a decision, he or she may appeal through the management chain under CDER's existing dispute resolution process (see MAPP 4151.1).

- If, after following the dispute resolution process, an individual is not aligned with the decision-maker and believes a decision has the potential to result in an action (or inaction) with very serious negative public health consequence, that individual should invoke the Differing Professional Opinion (DPO) process (see MAPP 4151.2).

- Once all disciplines have had a chance to provide input, in most cases, the group will achieve alignment on a decision. Specific disciplines participating in the decision-making process are responsible for ensuring that their opinions and positions are understood.

- **If one of the disciplines or organizational components cannot align with a pending interdisciplinary decision because the proposed action is believed to be counter to law, regulation, interpretation of data, or existing precedent without adequate justification for deviation, or will result in a significant adverse impact on public health and safety, the decision should be escalated.** Escalation widens the circle of discussion and input to include more senior staff from each discipline or organizational component. Each Office and discipline should have clear policies and procedures for including more senior staff in decision-making when important differences cannot be resolved.

- Escalation should continue up the management chain, engaging more senior staff/representatives of each discipline until Office Directors or Super-Office Directors are involved.

- If alignment cannot be achieved at this level, the decision should be raised to the Center Director or his or her designee.

REFERENCES

- FDA Administrative Practices Regulations, 21 CFR 10.70 and 10.75 and the FDA-NTEU Collective Bargaining Agreement (CBA).

- Memorandum of Agreement (MOA) Between the Office of New Drugs (OND) and the Office of Surveillance and Epidemiology (OSE) in the Center for Drug Evaluation and Research, effective date June 16, 2008

- CDER MAPP 4151.1 Revision 1, Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain, Effective 09/16/10

- CDER MAPP 4151.2 Revision 1, Resolution of Differing Professional Opinions: Review by *Ad Hoc* Panel and CDER Director, Effective 09/16/10

- CDER Interim MAPP 6700.8, Establishing and Operating Safety Issue Teams in the Center for Drug Evaluation and Research, Effective 05/08/09

- 21st Century Review Desk Reference Guide for New Drug Application and Biologic License Application Reviews (NDA/BLA Review Process), version 12/3/09.http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM218757.pdf

DEFINITIONS

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).

Discipline: An area of particular expertise that lends a relevant perspective to a decision to be made. For example, multidisciplinary review teams include a number of disciplines (e.g., medicine, biostatistics, clinical pharmacology). For the purpose of Equal Voice, some types of decisions, most notably those related to administrative or management issues, benefit from the perspectives of relevant organizational components, rather than disciplines. For example, a decision about how to manage advisory

committees would require input from different Offices, such as the Offices of Executive Programs, New Drugs, Surveillance and Epidemiology, Translational Science, and Pharmaceutical Science.

Lead Office: The office (or other CDER organizational component) that is coordinating and leading the process relating to the decision being made. Often this will be the office (or other CDER organizational component) that will be the signatory authority on documentation regarding the decision.

EFFECTIVE DATE

This MAPP is effective upon date of publication.