
GENERAL PROCEDURAL POLICIES

**PROCEDURES FOR RESOLVING ROUTINE SCIENTIFIC/POLICY
DISAGREEMENTS WITHIN CVM**

Introduction

This document describes the procedures that CVM employees should use for resolving internal disputes (e.g., interpretation of data or the appropriate course of action for the Center to pursue) that arise during routine Center activities such as pre-approval review, guidance and regulations development, and compliance-related activities. For the purposes of this document, “science or policy issues” do not include those related to internal personnel disputes such as administrative employee disputes or work environment situations.

The general procedures for resolving scientific and/or policy issues within CVM¹ and for resolving conflicting opinions are outlined in two CVM Program Policy and Procedures Manual (PPM) documents:

- PPM 1240.2110 “Procedures for Resolving Scientific/Policy Disagreements within CVM” (this document). PPM 1240.2110 describes the procedures for resolving differences of opinion (e.g., interpretation of data or appropriate courses of action) that arise during routine Center activities such as pre-approval review, guidance and regulation development, and compliance-related actions.
- PPM 1240.2115 “Procedures for Internal CVM Review of Science or Policy Issues Related to Significant Decisions of High Impact” (<https://www.fda.gov/media/70002/download>). PPM 1240.2115 describes procedures that should be used to resolve an ongoing issue related to a science or policy decision that could adversely impact public health.²

Background

In support of CVM’s leadership philosophy and guiding principles, Center managers are expected to create an atmosphere in which consultation and open discussion of controversial issues are encouraged. Managers should create an atmosphere of openness, trust, and respect for individuals’ views in resolving issues. Behaviors that are counterproductive to the creation of a desirable work culture are unacceptable. In particular, retribution and/or retaliation against employees who follow this or any other dispute resolution process will not be tolerated. It is the responsibility of all those involved to ensure employees are protected from retaliation by their supervisors, peers, Center leadership, and others when

¹ The process for resolving disputes between the Center and interested persons outside the Center is described in 21 CFR 10.75.

² Public health includes human and/or animal health.

engaging in dispute resolution processes.

CVM values a working environment that encourages employees to make known their best professional judgment even if this differs from a predominately held view, disagree with a scientific or policy decision, or take issue with proposed or current established practices. Employees are strongly encouraged to share their views and resolve any differences through discussion with their supervisors through the established agency channels of supervision or review whenever possible. In all cases, it is essential that the views of all persons involved in the decision-making process be respected and that the official administrative file contain the recommendations and decisions of employees responsible for handling the matter. The official administrative file should also include any significant controversies or differences of opinion and their resolution, as required by 21 CFR 10.70(b)(2)(i)

(https://www.ecfr.gov/cgi-bin/text-idx?SID=52e46f4bce6aeb499942516a3fd262d7&mc=true&node=se21.1.10_170&rgn=div8).

CVM routinely makes important scientific and policy decisions. The Center recognizes the importance of effective reassessment of its thinking as scientific understanding changes or new evidence becomes available. Differences of opinion should be resolved at the lowest organizational level possible. It is CVM's intention that discussions between the employee and the employee's supervisor be the preferred method of resolving these issues. A number of avenues are available to discuss and resolve differences of opinion and enhance decision making by utilizing the channels of supervision or review. These include meetings within the review Team(s) and at the Division level, by established internal groups, and, if necessary, at the level of the Office Director. To ensure prompt resolution of a disagreement, a written response from the supervisor should be issued within thirty (30) calendar days. Copies of the written response will be sent to each principal involved in the disagreement.

Nonetheless, on occasion, there will be disagreements among peers, or among employees and supervisors, where informal methods fail. In such cases, formal procedures to resolve the dispute should be employed and are addressed in this PPM (1240.2110) or in PPM 1240.2115, as appropriate.

The process for making decisions about science and policy issues allows for differing perspectives and concerns to be considered. Normally, there is enough time for these discussions to take place within the established time frames for review. However, there may be differences of opinion that cannot be resolved informally using the processes described in this document or in PPM 1240.2115 within those time frames. Disagreements of sufficient immediacy and scale of impact on public health may "opt-up" to the Center Director that the Director may make a decision on the matter within a condensed time frame. The CVM Ombudsman may advise employees about whether a matter is appropriate to opt-up to the Center Director in lieu of following the procedures in this document (PPM 1240.2110) or PPM 1240.2115.

Role of CVM Ombudsman

An employee can choose to contact the Ombudsman at any time to discuss the issue(s) and the options available for resolving internal science or policy disagreements, including the appropriate use of this process, PPM 1240.2115, and/or the agency's SMG 9010.1

(<https://www.fda.gov/media/79659/download>) for internal scientific dispute resolution. As is consistent with the Ombudsman's role in conflict resolution, any communication between the employee and the CVM Ombudsman is, with few exceptions, confidential at the employee's request (see Ombudsman Principles (<https://www.fda.gov/about-fda/cvm-ombudsman/ombudsman-principles>)).

The CVM Ombudsman is available to explore options with the employee about how to proceed in getting his or her concerns heard. When the issue involves a difference of opinion that arises during

routine Center activities such as pre-approval review, guidance and regulation development, and compliance-related activities, the Ombudsman will likely recommend that, as a first step, the employee try to resolve the issue using the normal channels of internal communication and collaboration prior to considering the procedures described in this document.

Process for Resolving Routine Differences of Opinion about Center Activities

CVM values the opinion of all its employees. During discussions about routine scientific and policy issues, it is common to discuss a number of opinions and approaches. Usually, CVM employees reach agreement on how to approach routine scientific or policy issues. However, on occasion, employees do not reach agreement and an employee may wish to elevate the issue to his or her management chain for further discussion. If the differences of opinion cannot be resolved through discussion between the employee and his or her supervisor, the issue should be elevated through the established agency channels of supervision or review until it is resolved, up to the Center Director level.

In the case where the difference of opinion is between employees in different management chains, the supervisory counterparts in both management chains should meet to attempt to resolve the issue. Although the goal is to resolve the issue at the lowest supervisory level possible, the issue may be elevated to the level of the respective Office Directors for resolution, if necessary. If no resolution can be reached through discussion between the Office Directors, the Office Directors should bring the matter to the Center Executive Board for discussion. If no resolution can be reached through that discussion, the Center Director will make a decision on the matter.

If the CVM employee is not satisfied with the Center Director's decision and would like to elevate the matter to the agency level, he or she should consult the CVM Ombudsman for information about how to use the process described in SMG 9010.1 (Scientific Dispute Resolution (<https://www.fda.gov/media/79659/download>)). Resolution through the agency level is only available for scientific disputes. The process described in SMG 9010.1 is intended to address serious scientific dissents that could have significant negative impact on public health. It is the employee's responsibility to decide whether to continue to pursue the review of a scientific decision. The employee must elevate the scientific issue to the agency appeals process within ten (10) days of receiving the written decision made by the Center Director. Disputes that are not considered to be scientific and therefore ineligible for this process include personnel disputes, administrative disputes, labor and employment disputes, enforcement policy disputes, and disputes related to the rulemaking process.

Documentation of Significant Center Decisions

Documentation of decisions made by employees is addressed in 21 CFR 10.70 (https://www.ecfr.gov/cgi-bin/text-idx?SID=52e46f4bce6aeb499942516a3fd262d7&mc=true&node=se21.1.10_170&rgn=div8). That regulation requires that the agency keep an administrative file (e.g., ANADA, NADA, FAP, INAD, DER) that contains documentation of the bases for recommendations and decisions. This documentation includes signed reviews, memoranda, letters, opinions of consultants, and all other written documents pertinent to the matter. The regulation requires that any significant controversies or differences of opinion and their resolution be noted in the administrative file.

Any decision made by an FDA employee is subject to review by the employee's supervisor. If an employee writes a review or other memorandum containing his or her scientific or regulatory opinion and a supervisor in his or her direct management chain disagrees with the conclusions of that employee, the supervisor and employee should attempt to resolve the disagreement. If the disagreement cannot be resolved, the supervisor should document the disagreement and the reasoning for not accepting the

employee's written opinion. This documentation should be included in the administrative file. The employee may elevate the dispute to the next supervisory level for review.

The review of any decision should be based on information in the administrative file. In a situation where the administrative file is unclear, the reviewing official can request information from the parties to the dispute. To the extent these are verbal communications, the communications should be reduced to writing and included in a memorandum to the administrative file. In addition, the final decision will be reduced to writing and placed in the file. When new information is added to the file, the matter will be returned to the appropriate lower level within the Center for re-evaluation. To ensure the prompt resolution of a disagreement, a written response from the responsible deciding official at each level of management should be issued within thirty (30) calendar days. Copies of the written review(s) will be sent to each principal in the disagreement and included in the administrative file.