GENERAL PROCEDURAL POLICIES

PROCEDURES FOR INTERNAL CVM REVIEW OF SCIENCE OR POLICY ISSUES RELATED TO SIGNIFICANT DECISIONS OF HIGH IMPACT

Introduction

This document describes the procedures that CVM employees should use for resolving internal disputes with respect to CVM review of science or policy issues related to significant decisions of high impact. These are issues related to science or policy decisions that may be controversial or precedent setting and may have the potential for significant adverse impact on public health if all relevant information is not considered. 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 CVM[1] 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" (https://www.fda.gov/media/69995/download). 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 activity.
- PPM 1240.2115 "Procedures for Internal CVM Review of Science or Policy Issues Related to Significant Decisions of High Impact" (this document). 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 differences. Behaviors that are counter-productive 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

[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.

others when 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 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 scientific and policy decisions that can significantly impact its stakeholders and public health. 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, review by established internal groups, and, if necessary, at the level of the Office Director.

The procedure described in this PPM provides a process for employees to raise policy or science issues related to significant decisions of high impact with Center leadership if the issue cannot be satisfactorily resolved using the normal channels of supervision or review.

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 PPM 1240.2110 or in this PPM (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 PPM 1240.2110 or this document (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 and 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. The Ombudsman will likely recommend that the employee take the issue to the next level in the chain of command and, if necessary, to the level of the employee's Office

Director. If the employee chooses internal review to the level of the Office Director and is not satisfied with the outcome, or if the employee is unwilling to bring the issue forward through their chain of command, the employee and Ombudsman should discuss the need for bringing this matter to an Ad Hoc Internal Review Committee (IRC).

In addition, the Ombudsman will consider the potential impact on public health and the urgency for the need for a scientific or policy decision in determining when scientific or policy disagreements warrant more immediate review or review at a higher organizational level.

CVM Ad Hoc Internal Review Committee

When a CVM employee believes that an ongoing issue related to a science or policy decision is important because of its potential impact on public or animal health, and that the issue is either not being addressed or not being given adequate consideration through normal supervisory channels, the employee may request internal review by the Center's Ad Hoc Internal Review Committee (IRC).

If the employee requests to have the issue resolved by an Ad Hoc IRC, the employee should provide information to the CVM Ombudsman to support his or her concerns about why the issue is important and how it may have a significant impact on CVM. The CVM Ombudsman will prepare a request for review by an Ad Hoc IRC to resolve the issue in question. The request for review will contain the following documents:

- A Statement of Findings (SOF) Memorandum
- A table of contents of attached material
- All material provided by the employee, and any other information relevant to the issue in dispute (e.g., the results of all efforts that have been made to resolve the dispute, memoranda, letters, reviews, and any written decisions to date)

The Ombudsman should provide this material to the CVM Deputy Center Director for Science Policy, with a copy to the employee, within five (5) calendar days of the decision to forward the matter to an Ad Hoc IRC.

The CVM Deputy Center Director for Science Policy will consider the request, determine whether internal review by an Ad Hoc IRC is appropriate, or, depending on the scientific or policy issue(s) involved, whether the procedures in CVM's Policy and Procedures Manual (PPM) 1240.2110 "Procedures for Resolving Scientific/Policy Disagreements within CVM" might provide a more efficient means of resolving the issue(s). The CVM Deputy Center Director for Science Policy should make this determination and notify the Ombudsman and the employee within five (5) calendar days of receiving the request for review by an Ad Hoc IRC from the Ombudsman.

For each matter brought forward for an Ad Hoc IRC review, the CVM Deputy Center Director for Science Policy will appoint CVM staff/managers to be part of an Ad Hoc IRC to resolve the dispute. The CVM Deputy Center Director for Science Policy should assign members of the Ad Hoc IRC within three (3) calendar days of making the decision to use the process in this PPM to resolve the dispute and will provide the Ad Hoc IRC members with the Ombudsman's request for review by an Ad Hoc IRC, including all documents contained in the Ombudsman's request.

The Ad Hoc IRC will consist of a Chair (the CVM Deputy Center Director for Science Policy or another member of the Office of the Director, as assigned by the CVM Deputy Center Director for Science Policy) and a minimum of three (3) members who have scientific or regulatory expertise

relevant to the issue in dispute. The Ad Hoc IRC members should be determined by the issue(s) involved in the dispute. The Ad Hoc IRC may also seek expert advice by consulting on an as-needed basis with others inside the agency. To the extent possible, the Ad Hoc IRC members should not include anyone who has directly participated in the specific issue in dispute, or who reports directly to a manager within the same Office as the person seeking resolution of the issue in dispute.[3]

The Ad Hoc IRC should be convened no later than seven (7) calendar days after the members have been provided the Ombudsman's request for review by an Ad Hoc IRC and attached material. The employee and any other CVM employee who has participated in the matter may be invited to meet with the Ad Hoc IRC in person to discuss the issue(s). The Ombudsman may attend the meeting between the employee and the Ad Hoc IRC at the employee's request. All discussions and other fact-finding activities should be conducted within a time frame that allows for a final written decision by the Ad Hoc IRC no later than twenty-one (21) calendar days after the Ad Hoc IRC's initial meeting.

If the employee is not satisfied with the decision rendered by the Ad Hoc IRC, he or she may request review of the issue(s) by the Center Director. The CVM Ombudsman will provide all of the relevant documentation (including the original memoranda, letters, reviews, etc.) and any written decision(s) on the issue(s) to the Center Director. The employee may request a meeting with the Center Director to discuss his or her concerns. The Ombudsman may attend the meeting between the employee and the Center Director, at the employee's request. The Center Director should provide a written decision within twenty-one (21) calendar days of being provided the relevant documentation or the meeting with the employee bringing forward the dispute for resolution, whichever is later.

If the Center-level processes have been properly followed and exhausted (which includes a written decision by the Center Director), and the employee does not agree with the decision, he or she should be advised by the Ombudsman of the possibility of elevating the issue to the agency level as described in Staff Manual Guide (SMG) 9010.1, Scientific Dispute Resolution at FDA (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, 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.

The Ombudsman's request for review by an Ad Hoc IRC and all information considered by the Ad Hoc

[3] It is anticipated that this may occur in very limited circumstances with the permission of the parties in dispute.

IRC is part of the administrative file. The Ad Hoc IRC review will be based on information in the administrative file. In a situation where the administrative file is unclear, the Ad Hoc IRC 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. Copies of the written decision of the Ad Hoc IRC will be sent to each principal in the disagreement and included in the administrative file.

If the employee requests review of the issue(s) by the Center Director and if she/he subsequently elevates it to the agency level (when applicable as per SMG 9010.1), copies of each of those written decisions should also be included in the administrative file.