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 internal process and procedures that CVM employees should use for bringing critical information to the Center Leadership Team related to science or policy decisions that may be controversial or precedent setting and may have the potential for significant adverse impact if all of the information is not considered. When a CVM employee believes that an ongoing issue related to a science or policy decision made by the Center is important because of its potential impact on public or animal health, and that it is either not being addressed or not being given adequate consideration through normal supervisory channels, the employee may request informal internal review by the Center Leadership Team (CLT).

Differences of opinion should be resolved at the lowest organizational level possible. A number of avenues are available to discuss and resolve scientific differences 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 general procedures for resolving scientific/data disagreements within CVM and for resolution of conflicting opinions are outlined in CVM's Program Policy and Procedures Manual (PPM) 1240.2110 "Procedures for Resolving Scientific/Data Disagreements within CVM" (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046328.pdf) and 1240.2120 "Product Manager" (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046330.pdf) respectively. PPM 1240.2110 describes formal procedures for resolving differences of opinion that arise during the pre-approval review process and during the post-approval process due to compliance related enforcement actions. PPM 1240.2110 states that informal methods using good management practices (see PPM 1240.2120) should be attempted prior to implementing the more formal procedures. Disagreements of sufficient immediacy and scale of impact on public health may 'opt-up' to the Center Director in order that she/he may make a decision on the matter within a condensed timeframe.

CVM Culture

In support of CVM's leadership philosophy and guiding principles, Center managers are expected to create an atmosphere in which consultation and open discussion on 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 that follow the dispute resolution process described in this procedure 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 engaging in this process.

The process for making decisions on science and policy allows for differing perspectives and concerns to be

taken into consideration. CVM values a working environment that encourages employees to make known their best professional judgments even though they may differ from a predominately held staff view, disagree with a management decision or policy, 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 record contains the recommendations and decisions of individual employees responsible for handling the matter and includes any significant controversies or differences of opinion and their resolution as per 21 CFR 10.70(b)(2) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.70) .

Background

In any organization there are scientific assumptions, policies and decisions that tend to become institutionalized, i.e., they become part of the structured and well-established system in the organization. Once decisions become institutionalized, organizations often have difficulty scrutinizing them to recognize that they may be flawed, that circumstances have changed, or that new information is available that would necessitate reexamining the decision. Often, other internal or external pressures may drive an organization to push forward in a particular direction, and overlook or discount data that would suggest a more cautious or different approach. When critical information is not factored into the decision making process, unfortunate consequences often result.

CVM routinely makes scientific and science-based policy decisions which can significantly impact its stakeholders. The Center recognizes the importance of being nimble in its decision making to allow for effective reassessment of its thinking as circumstances change or new information becomes available. It is CVM's intention that discussions between the employee and the employee's supervisor be the preferred method of resolution of these issues. However, this new procedure provides a process for employees to raise significant policy or science issues with center leadership, when that input could have a major impact on the ultimate decision the Center will make. The new procedure explicitly encourages employees to raise such issues with their immediate supervisors and if the issue cannot be satisfactorily resolved locally, to appeal for support to the CVM Ombudsman and through the Ombudsman to the Center Leadership Team of the Center for a hearing.

1. Purpose

   This document outlines the procedures to be followed for obtaining informal internal review by CVM's Center Leadership Team (CLT) for science or policy issues related to important issues with far reaching impact.

2. Established Procedures for Resolving Internal Science/Policy Issues

   a. Initial efforts by the employee to bring attention to important science or policy issues that may be precedent setting or controversial are to be handled through the use of informal methods using good management practices as stated in PPM 1240.2120 "Product Manager." (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046330.pdf)

   b. If the informal methods are not successful, the employee may utilize the more formal procedures outlined in PPM 1240.2110 "Procedures for Resolving Scientific/Data Disagreements within

CVM." (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046328.pdf) Formal procedures for resolving disagreements include documentation (relevant reviews, evaluations, memoranda, minutes of meetings, letters etc.) of the bases for significant decisions in the administrative file in accordance with 21 CFR 10.70 (b)(1) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.70 and following the established agency channels of supervision in accordance with 21 CFR 10.75 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.75 for internal agency review of decisions.

c. After the Center-level processes have been properly followed and exhausted (which must include a written opinion by the Center Director) and the employee does not agree with the decision, he/she should be advised of and may consider elevating the dissent to the Agency level as per Staff Manual Guide (SMG) 9010.1 Scientific Dispute Resolution http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm215422.htm at FDA. This process is intended to address serious scientific dissents that could have significant negative impact on public health. The initiator/employee must elevate the scientific dissent issue to the agency appeals process within 10 days of receiving the written opinion rendered by the Center Director.

3. Role of CVM Ombudsman

a. The employee can choose to contact the Ombudsman at any time to discuss the issue(s) and the options that are available for resolving internal science/policy disagreements including the appropriate use of these procedures and the Agency's SMG 9010.1 http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm215422.htm for internal scientific dispute resolution (SDR). 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 Complaints/Dispute Resolution Process Confidentiality (http://www.fda.gov/AboutFDA/CentersOffices/CVM/CVMOmbudsman/ucm079977.htm).

b. After discussion of the science or policy-related issues, the CVM Ombudsman will explore options with the employee as to how to proceed in getting his/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 they have not already done so.

c. If the employee chooses internal review to the level of the Office Director and is not satisfied with the outcome or is unwilling to bring the issue to someone within their chain of command, the employee may discuss, with the Ombudsman, the need for bringing this matter to the attention of the CLT.

d. If the employee requests to have the issue raised with the CLT, and the Ombudsman agrees that it is the appropriate action to take, the CVM Ombudsman will prepare a Statement of Findings Memorandum to briefly inform the CLT about the issue and explain any potential consequences to help the CLT to decide if the issue warrants formal internal review. The CLT will consider the request and convey their decision within 30 days to the CVM Ombudsman

who will communicate this decision to the employee.

e. The employee may be invited by the CLT to discuss the issue during one of the scheduled weekly meetings. It is the employee's responsibility to provide information to support his/her concerns as to why the issue is important and how it may have a significant impact on CVM. The supporting material is provided to the CLT members in advance of the meeting through the Ombudsman. Any discussion between the employee and the CLT members is confidential. The Ombudsman may attend the meeting between the employee and the CLT at the employee's request.

f. While it is preferable for the employee to present the issue(s), if the employee does not wish to meet with the CLT in person but still wants his/her concerns to receive informal internal review, the employee may provide the supporting information to the CVM Ombudsman and request that the Ombudsman bring the issue to the attention of the CLT.

g. After a decision is made, the CLT will inform the employee of its decision the rationale for making that decision in writing within 30 calendar days, either directly or through the CVM Ombudsman.

Center Leadership Team Review Request Scenarios

The following examples are hypothetical scenarios illustrating the types of issues that may be considered as requests for internal informal review by the CLT.

Example 1

Employees in two Divisions within the same or different Offices are working on issues that involve the same product. There is new information on the mechanism of action that was not apparent when originally approved that will impact on the safe and effective use of this product and similar products. An employee in one of the Divisions believes that there is evidence to support official enforcement action which should be initiated by the Center but can't get the other Division to commit and/or support their recommendation. The employee has expressed his concerns to his Team Leader and together they have discussed it with their Division Director. Subsequent meetings between the two Divisions have reached an impasse. The employee contacts the Ombudsman for guidance and is advised to request that the Divisions meet with the Office Director(s) to discuss the issues before making a request for internal review at the Center Management level.

Example 2

A manager or working group writes a new policy document that will determine how the Center will handle issues involving specific types of products [e.g., antibiotics, nonsteroidal anti-inflammatory drugs (NSAIDs)]. An employee with the expertise for reviewing these products was either not consulted or believes that her recommendations have not been considered and that the new policy may result in data requirements that are inadequate and subsequent approvals could have a serious impact on animal or public health. This issue has gone as high as the Office Director and the employee is not satisfied with the outcome. She contacts the Ombudsman to find out how to request internal review by the Center Leadership Team.

Example 3

A Center employee is one of several that have been asked to provide input on complaints from stakeholders on a recent CVM decision that has caused concern from parts of the agency outside the Center. The issue has been given priority status and is therefore under more demanding time constraints, is controversial and has high visibility outside the Center. The employee believes that certain important scientific aspects of the case that the Center should take into consideration before deciding on any future action are being overlooked. He also believes that the CLT should know about these issues but his immediate supervisor and Division Director do not believe the issues are important enough to warrant discussion with the Office Director. He contacts the Ombudsman for guidance and is advised to make a request for discussion of the issues with the Office Director. The Office Director has the same view as the Division Director so the employee decides to have the Ombudsman make the request for internal review by the CLT and, if accepted, for the Ombudsman to present the issues at the meeting for him.

Version History

March 3, 2005 – Original version

December 5, 2005 – minor revisions

January 23, 2009 - Office of the Director revised and updated to comply with the mandatory requirements and to make reference to the new Agency-level process.

June 26, 2011 - added full text to links

July 28, 2011 - The word "calendar" was added to days on page 3, in paragraph 3.d.