SMG 9010.2

FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM DIRECTIVES

GENERAL OR MULTIDISCIPLINE

DISPUTE RESOLUTION

CROSS-CENTER DISPUTE RESOLUTION AT THE FDA

Effective Date: January 6, 2014
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1. PURPOSE

The purpose of this document is to describe the policies and procedures for addressing differences in scientific or regulatory opinion among staff from different FDA centers[1] pertinent to decision-making. The goal of this process is to resolve disputes at the center level through mutual agreement or, at a minimum, to reach alignment of the affected parties.[2]

[1] 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.

[2] For the purpose of this document the term alignment represents 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 a group or an individual's recommendation(s).

The dispute resolution process may proceed through either an informal or formal path. The agency strongly encourages staff to make every effort to address disagreements informally at the lowest possible organizational level. The formal process should be reserved for circumstances where informal efforts to address differences among staff in different centers have failed. The formal process may also be used when an expedited decision is required due to serious public health concerns.

2. SCOPE

This process is intended to cover intercenter differences of opinion regarding scientific or regulatory issues, i.e., differences between personnel in different centers within the Agency. This includes but is not limited to teams engaged in coordinated or joint reviews of combination products or related co-development projects (e.g., companion diagnostic and related therapeutic drug or biologic, development of guidance, or development or adoption of standards). Disagreements regarding jurisdictional decisions ordinarily made by the Office of Combination Products, e.g., medical product classification or center assignment, should be referred to the center product jurisdiction officers or designated center equivalent for resolution. Issues regarding research misconduct or the ability of an employee to publish FDA-related work should be directed to the FDA Office of Chief Scientist, Office of Scientific Integrity.

This process is for internal FDA use and is only intended to address differences in scientific opinion or interpretation of regulatory policy in the regulatory review process that involve more than one center or agency level organizational component. It is not intended to address other issues such as those related to personnel or work environment situations or employee disputes of agency policies or scientific positions that have no significant implications for the employee's center or the agency as a whole.

This cross-center procedure to address differences of opinion between staff at FDA provides:

- o informal and formal routes to address scientific and/or regulatory differences of opinion that involve FDA staff from more than one center;

- o review of the cross-center dispute resolution request by equivalent levels of management in the affected centers that were not directly involved in the original decision-making process, with an option to elevate the request through the chain of command up to and including Center Directors[3]

[3] In this dispute resolution process the term "Center Director" is intended to mean the highest level management official in a Center or an FDA organizational unit, or their specified designee.

- a path for cross-center disputes not resolved in the course of elevating the dispute to the Center Directors to be resolved by the FDA Commissioner or his/her designee;

- specified time frames for hearing formal cross-center dispute resolution requests so they can be addressed in a timely manner; and

- guidance for documentation of scientific and regulatory review findings, perspectives, and opinions for individuals who initiate or are involved in the dispute resolution process.

3. BACKGROUND

Differences in scientific opinion can occur regarding the interpretation and/or application of information pertinent to the regulatory process. Public health considerations, legislative mandates, regulations and commitments made under the user fee acts underscore the importance of addressing such differences in a timely manner. It is equally important that the process leading to resolution of these differences be scientifically sound, well documented, transparent to internal stakeholders, and consistent with FDA's mission.

Center staff are routinely engaged in the decision-making process related to the review and regulation of products under their purview. These decisions may be scientific and/or regulatory in nature, and in some instances may directly impact the review and regulation of associated products regulated by other centers within the agency. In some cases, these products are linked through co-packaging and/or cross-labeling of distinct components of a combination product, with a review process that includes formal consultation or collaboration between centers. In others, the link is less formal but nonetheless important. Examples may include a drug that references the use of a diagnostic test that is not approved or cleared for use in that manner, or a regulatory policy or pathway decision made for a human medical product that inadvertently impacts the regulation of a cosmetic, dietary supplement or veterinary product. The decision-making process for such linked products is complex and may involve multiple staff (primary reviewers, team leaders, supervisors, and managers) in different organizational components.

Each center utilizes a set of internal policies and procedures to foster quality and timely decision-making adapted to address the specific needs of the products under their purview. Examples include procedures like Manual of Policies and Procedures, Standard Operating Procedures and Policies, Policy and Procedures Manual that define review and approval processes, roles and responsibilities of different review components, communication strategies and expectations, and internal and external dispute resolution. Because there are differences in organizational structure, operational policies, and the type of products the centers regulate, it can be challenging to reconcile differing perspectives. This cross-center dispute resolution process was developed to ensure that decisions affecting more than one center are

made only after all appropriate expertise is brought to bear and cross-center impact is given due consideration by the appropriate level of management.

The process described here is designed to complement existing center level policies and procedures to promote a collaborative environment for decision-making. Such an environment requires open communication and exchange of ideas as well as the full and open participation of all relevant disciplines in the decision-making process.

4. POLICY

It is FDA policy that all issues should be deliberated in a scientifically sound, collegial, open and objective fashion based on unbiased, accurate fact(s), and without retaliation against any employee. There is an expectation that agency employees will follow an orderly progression in the process of addressing a difference of opinion. Reasonable, good-faith efforts should be made to consider and resolve scientific or regulatory disagreements between centers informally at the lowest operational level possible during the review process. Cross-center disagreements that cannot be resolved at the review team[4] level may be pursued either through an informal or a formal scientific or regulatory dispute resolution (SDR) process. This process moves the issue through sequential levels of management (i.e., chain of command) for the affected teams, up to and including the Center Director, as needed. Any individual or group directly involved in the cross-center disagreement may initiate the SDR process at any point during the conduct of a cross-center review or collaboration, up to and including final review at the Center Director level. Appeals above the center level can only be initiated through this SMG by the affected Center Directors.

A sequential review of a cross-center scientific or regulatory disagreement by the chain of command in the affected centers may proceed as part of an informal process, with or without the assistance of the Center Ombudsmen, at the discretion of the review teams and their management. If at any time the informal process is deemed to be insufficient to address the difference of opinion, a formal dispute resolution process may be initiated. Center Ombudsmen will be engaged in any formal dispute resolution process initiated through the procedures in this SMG. To initiate a formal SDR, the disputant notifies his/her Center Ombudsman[5] in writing of the decision to pursue formal SDR. The Center Ombudsman will notify his/her counterpart(s) in other affected centers.

Formal dispute resolution differs from the informal process primarily with respect to documentation and adherence to specified timelines at each step. While a center documents the scientific opinions and regulatory perspectives of significant decisions in an administrative file (see 21 CFR 10.70), formal dispute resolution is accompanied by additional documentation that addresses the areas of

[4] The term “review team” denotes any working unit or team comprised of primary staff level employees.
[5] Not all Centers within the FDA have an Ombudsman. Those that do not may choose to designate an individual to provide support for the dispute resolution process.

disagreement, is cross-cutting with regard to product-related issues and is consistent across centers. Written documentation (as described below) representing both sides of the disagreement is received by the Center Ombudsmen and used to create the administrative record for the formal dispute. The documentation will be placed in the administrative file for each proposed agency decision or action that is directly affected by the disagreement. Scientific disputes addressed by this SMG should be presented in an accurate, concise and clear manner. In order to accomplish a timely and effective review, disputes and responses must be documented in such a way that successive levels of managerial review can be conducted efficiently.

Whether pursuing a formal or informal resolution of scientific or regulatory differences, centers should follow their normal process for consultation with the Office of the Chief Counsel and the Office of Policy when dealing with complicated policy issues or issues of regulatory or statutory interpretation.

Note regarding timing: because resolution cannot be predicted at any given management level, it is important to move as quickly as possible throughout the process, regardless of whether an informal or formal process is invoked. This is particularly important for a scientific dispute that involves a pending product approval or clearance action. To the extent possible, staff should be mindful of any relevant regulatory review time frames. In the event that a disagreement involves more than one application, the timeline for the dispute resolution process should take into account the application with the shortest timeline for completion to ensure that targets and milestones are met.

As noted above, the goal of the SDR process is to address differences of opinion at the lowest operational level possible. However, in some instances it may be necessary to notify or potentially engage center management when an SDR request is initiated or at a point during the proceedings earlier than a normal chain of command review would require. For example, when a dispute has the potential to impact the outcome or timeliness of an approval or clearance action, the highest management level engaged in the SDR process may want to notify his/her center management of the situation. Similarly, in the event that a cross-center SDR request challenges an existing policy or process defined by another center, the center whose policy is under discussion will determine the initial level of management to be engaged in the review of the request.

While the scientific dispute resolution process is pending, work on the submission and a final regulatory decision will continue unless the affected Center Directors decide that:

1. the appeal raises substantial questions involving a significant risk to the public health; and

2. postponing the decision would not result in a negative impact on the public health.

Center personnel are not expected to postpone regulatory decisions on time-sensitive regulatory actions, e.g., pending investigational or marketing submissions. If an accelerated timeline is required for dispute resolution because of a significant action due date or imminent public health concern, Center Ombudsmen should be contacted and the formal process initiated.

If a situation arises where the disputant believes that the immediacy and scale of public health impact warrants immediate action, the disputant may ask the Ombudsmen to request an expedited time frame for the review. If an expedited process is followed and the disputant is not satisfied with the lower management level response, the disputant may request an appeal directly to the Center Directors after receiving the response. The request should be submitted to the Center Ombudsmen, who will, after consultation with the Center Directors, determine whether or not the appeal will be reviewed by the Center Directors or at a lower level. As with all formal appeals, the appeal documentation should clearly describe the issue and opinions (i.e., disputant perspective and supervisory response), on the Scientific/Regulatory Differences Summary Form (See Attachment C). The appeal must be accompanied by clear and persuasive evidence of a serious and imminent public health risk.

In the event that the dispute reaches the Center Director level and the Center Directors cannot come to an agreement or reach alignment, the matter may be raised either formally or informally to the Commissioner or his or her designee(s) to render a final agency decision.

The SDR process has the potential to involve a wide range of disciplines within the Agency with differing concerns, policies and procedures. The goal of this procedure is to provide a collegial, inclusive process to help a divergent group reach alignment while ensuring that all perspectives are heard and duly considered. If an individual or group in one of the centers disagrees with the agreement or alignment reached through the cross-center dispute resolution process, they may dispute the issue through their center management structure according to the center's scientific dispute resolution process.

5. RESPONSIBILITIES

Disputant:

1. Exhaust attempts to resolve the issue(s) at the review team level or other appropriate operational level whenever possible, prior to initiating the SDR process.

2. Complete and submit the Scientific/Regulatory Differences Summary Form (Attachment C), and other appropriate documentation to the disputant's

Center Ombudsman, where applicable (e.g., for a formal dispute resolution request).

3. Present or coordinate the presentation of their center's perspectives on the disputed issues at the cross-center dispute resolution meeting.

4. Decide whether to continue the SDR process at the next level of management in the affected centers if alignment is not reached.

Center Ombudsman, or Center Designee:

1. Upon request from the affected staff or their supervisors, assist with the informal dispute resolution process to resolve differences of opinion between staff in different centers or agency-level work units.

2. Determine which centers are affected by a formal dispute resolution request and distribute the associated documentation accordingly.

3. Manage the administrative component of the formal dispute resolution process, including receipt of the SDR Form (Attachment C) from the disputant when the request originates in the ombudsman's center, and conduct a preliminary assessment of the incoming request to verify that it is complete and eligible for the cross-center process prior to disseminating the request to the other affected centers.

4. Work with other affected Center Ombudsmen, or center designee, to confirm that all affected centers agree that the documentation is complete and eligible for the cross-center dispute resolution process.

5. Obtain the counterpoint document (see Definitions in section 7. of this document) from other affected center(s), and ensure that it is complete.

6. Identify appropriate Reviewing Official(s) in the Ombudsman's own center, then work with the Ombudsmen from the other affected centers to ensure that reviewing officials for all centers are at an equivalent level of management.

7. Schedule and attend the dispute resolution meeting[6] with affected centers' representatives.

8. Review written responses from affected centers and facilitate further discussions as needed.

[6] This meeting may take a variety of different forms including, but not limited to an in-person discussion, conference call or video conference, depending upon the circumstances.

9. When alignment or agreement is reached, confirm that all documentation is complete and filed in the administrative record for each of the affected products and in the SDR electronic file and inform appropriate staff.

10. Consolidate documentation and present to the next level of management if alignment or agreement is not reached and a decision is made to continue the dispute resolution process.

11. Determine whether or not a direct appeal to the Center Director should be reviewed at that level or below.

Reviewing Official:

1. Review documentation of dispute and participate in the dispute resolution meeting.

2. Provide a written response on the disputed issues to the involved Center Ombudsmen.

3. Request review at next higher management level in affected centers if alignment not reached.

Center Director:

1. Review documentation of a dispute which has been unresolved at lower management levels and provide written response to Center Ombudsmen.

2. If Center Directors cannot reach agreement or alignment, the affected Center Director, at his or her discretion, will request review by the Commissioner or his or her designee(s), to render a final agency decision. If this process is necessary the FDA Office of the Ombudsman will serve in place of the Center Ombudsmen to assure assignment and management of any associated paperwork.

FDA Commissioner or his or her designee(s):

1. At the request of one or more Center Director(s), review and consider relevant information and documentation related to a dispute which has been unresolved at center level to render a final agency decision.

6. PROCEDURES

A. General Principles for Cross-Center Interactions

Each center within the FDA has its own unique culture and responsibilities. All FDA components share the overarching goals of protecting and promoting the

public health. However, each center's mission and vision, operational regulatory frameworks, product characteristics and work level business practices differ. As a consequence, participants in cross-center teams and working groups need to be sensitive to these potential differences and take precautions to ensure effective communication both among their own center representatives and between centers. General principles to keep in mind when working with cross-center teams or groups include:

- When a regulatory decision is to be made, the lead office/center should invite the input of relevant disciplines in all affected centers regarding the appropriate course of action. The administrative process as well as roles and responsibilities for the conduct of cross-center reviews are described in other documents and should be employed where applicable, including SMG 4101 (*Combination Products: Intercenter Consultative/Collaborative Review Process*[7]).

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

- When differences of opinion develop regarding scientific or regulatory issues affecting more than one center (e.g., the joint review of a combination product or linked therapeutic and diagnostic products), the affected review staff should attempt to discuss informally and resolve the issue at the review team level during the review process, whenever possible. This discussion and its outcome should be appropriately documented in the administrative file for each of the affected product(s), where applicable.

B. Informal Dispute Resolution

In the event that a difference of opinion between staff from different centers cannot be resolved informally within the immediate review or project team(s), the matter should be brought to the attention of the next highest successive level of management in each center, engaging as necessary more senior staff/representatives of the affected centers until Office Directors or other center designees are involved. The level of management involved in the discussion should be equivalent across the affected centers. If it is not clear how different management structures relate, Ombudsmen or center designees from the affected centers can be consulted to ensure that equivalent levels of management are engaged.

For informal dispute resolution, participants involved in the process are not obligated to engage their respective Ombudsmen. However, the disputant is free

[7] https://www.fda.gov/media/81927/download

to request such assistance as needed, including but not limited to administrative assistance or mediation.

If alignment cannot be achieved through the direct management chains in the affected centers, the matter may be raised to the Center Directors. In the unlikely event that the affected Center Directors cannot reach alignment and continued discussion is desired, these discussions may, at the discretion of the affected Center Directors, engage the Commissioner or his/her designee, through either the informal or formal process.

C. The Formal Dispute Resolution Process

Formal dispute resolution may be invoked at any time during the process if agreement or alignment cannot be achieved informally. In order to pursue formal dispute resolution, the SDR Form (Attachment C) must be completed by the disputant and the completed forms (including management responses to each issue raised) must be documented in the administrative file for the dispute as well as in each of the product file(s).

Requests for formal dispute resolution will follow the timelines provided below unless a specific request is made to conduct an expedited process. The Center Ombudsmen, in conjunction with their center management, will consider such a request based on the presence of an imminent public health risk, review deadlines or other extenuating circumstances.

- Upon receipt of the formal SDR request the individual Center Ombudsman will work with the Ombudsmen in the other affected center(s), to verify that the SDR request is complete and eligible for the cross-center process. If it is not, the Center Ombudsman will notify the disputant in writing no later than ten (10) business days after receipt of the package.

- If the incoming request is complete and eligible for the formal SDR process, the Ombudsmen will share the incoming SDR request with appropriate center staff and solicit the perspective of the other affected center's review teams (in the form of a counterpoint document). The perspective of the other group(s) will be recorded on the same dispute resolution form and in the same format as the incoming request and returned to the respective Center Ombudsman within ten (10) business days of receipt of the request.

- The formal SDR process officially begins when the written documentation of all affected center review teams' perspectives are compiled and determined to be complete and eligible for the formal process by the Center Ombudsmen.

- When the SDR request is complete, the Center Ombudsmen will work together to identify the appropriate management level within the affected centers to address the disagreement. When equivalent levels of management

are confirmed, the Ombudsmen will notify them of the disagreement and provide the documentation to be reviewed. The process of identifying and assigning the review to the next level of center management will generally take approximately three (3) business days but should be no more than seven (7) business days.

- A meeting will be scheduled so that representatives from all of the affected centers can discuss the issues no later than twenty-one (21) business days after receipt of the complete package (or sooner depending on review timelines). For the purpose of the formal dispute resolution process this meeting is referred to as the “21-day meeting”. A written response from each affected center’s management engaged in the SDR process should be forwarded to the Center Ombudsmen within seven (7) business days following the cross-center meeting addressing that center’s decision or perspective on the request.

- When written responses are received from all affected centers the Ombudsmen will review the documentation and facilitate further discussion as needed.

- If agreement or alignment cannot be reached at this management level, the disputant (or respective management) has six (6) business days in which to request a review at the next higher level of management in the affected centers.

- Upon receipt of a written request to move the discussion to the next higher level of management, the Ombudsmen will consolidate the input received from all affected centers in the previous round of discussion to prepare a single package for review at the next management level. Documentation that is provided or referenced in support of a given position may be included in the dispute resolution file. However, no additional topics or issues for discussion may be added to the dispute resolution request after it has been filed. If new issues or topics arise, a new request is required, and the process must start over at the first level of management. The same process for a 21-day meeting will be followed.

- At the conclusion of each round of the formal SDR process, the administrative file for the formal dispute (e.g., the completed SDR form, supervisory responses and relevant associated documentation), will be reviewed for completeness and compliance with this SMG by the affected Center Ombudsmen to ensure that all affected Centers have the same documentation. If the dispute is resolved at that level of review, the completed file will be provided to the affected Centers for inclusion in the administrative file for each decision (e.g., IND, IDE, etc.) directly impacted by the dispute resolution. If the dispute is not resolved and the disputant wishes to carry the case forward, the dispute file will be submitted by the affected Center

Ombudsmen for review by the next highest level of management in each affected center. For a scientific disagreement that is not associated with a specific product or file, the Center Ombudsmen will maintain the file of the formal dispute resolution documentation. Each successive response cycle should follow the same timeframe as described above for the meeting and submission of the written management response. If the next level of management across the affected centers cannot reach alignment, the cycle repeats up to and including review by the affected Center Directors.

- Disputes that rise to the level of the Office of the Center Director(s) will be addressed by the Center Director, with assistance from other senior staff as needed, within twenty-one (21) business days of receipt of the complete SDR package.

    - If the outcome is an agreement or alignment, the SDR request and associated documentation are reviewed for completeness by the affected Center Ombudsmen and filed with the administrative record for each of the affected products and in the SDR database maintained by the Center Ombudsmen, as described above.

    - In the event that the affected Center Directors cannot reach agreement or alignment, the matter may be taken to the FDA Commissioner or his or her designee, to render a final agency decision. If the Center Directors elect to pursue formal dispute resolution, the additional documentation will be managed by the Office of the FDA Ombudsman.

    - If agreement or alignment is reached between the affected Center Directors (or at any level of management below that), but an individual or group involved in the SDR does not agree with the intercenter resolution of the dispute, subsequent appeals will be addressed through their center-specific dispute resolution process.

    - A disputant may appeal the result of the center-specific dispute resolution process to the Office of the Commissioner in accordance with SMG 9010.1 Scientific Dispute Resolution at FDA (see references).

The time frames discussed above may be accelerated when a regulatory action is due to take place within twenty (20) business days of the initiation of the dispute resolution request.

A flowchart illustrating the basic steps involved in formal cross-center dispute resolution is provided in Attachment B.

7. DEFINITIONS

Affected Centers: The centers directly involved in a given dispute or disagreement.

Agreement: A harmony of opinion, concord or a negotiated meeting of the minds.

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 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 a group or an individual's recommendation(s).

Counterpoint document: Document that explains the perspective of the individual or group(s) involved in a cross-center dispute that is generated in response to the initial dispute resolution request submitted by a disputant from another center or agency component.

Disputant: In the cross-center dispute resolution process, the individual or group who believes that a significant scientific or regulatory issue that affects more than one center or agency organizational unit has not been adequately addressed at the working group or review team level. The disputant may be an individual, group, or organizational unit (division, office, etc.).

Formal path: A dispute resolution process or pathway managed by the Center Ombudsmen which has specified timelines and written documentation requirements for each. This path is typically invoked only after attempts to use an informal process have failed.

Informal path: A dispute resolution process or pathway which has no formal time lines, and which does not require that formal written documentation be generated at each step of the process.

Lead Office/Center: In instances where a joint (cross-center) review is taking place, there may be a designated “lead” center that has primary responsibility for the management of the regulatory process. The degree to which the other participating centers or offices may influence the decisions made in the course of that process varies.

Next level of management or next highest management official (also referred to as the ‘reviewing official’ for that round of review): The management official one level above the management official who made the most recent decision being disputed.

Reviewing Official: The individual (or team) from each center (or designated official from the Office of the Commissioner for appeals that rise above the center level), involved in the dispute who is responsible for reviewing the arguments presenting by the opposing sides, engaging in discussion of the issues with all affected parties, then rendering a decision on behalf of their center or the agency.

8. REFERENCES

FDA Administrative Practices Regulations, 21 CFR 10.70 and 10.75

Center for Biologics Evaluation and Research (CBER) SOPP 8006, Version 2, Resolution of Differences in Scientific Judgment in the Review Process.

Center for Devices and Radiological Health (CDRH) – Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision-Making.

Center for Drug Evaluation and Research (CDER) MAPP 4151.1, Scientific/Regulatory Dispute Resolution For Individuals Within a Management Chain

CDER MAPP 4151.2, Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director.

CDER MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions.

Center for Tobacco Products (CTP) Tobacco Policy and Procedure (ToPP) DR001: Internal Scientific Dispute Resolution (SDR) in Regulatory Decision Making (http://inside.fda.gov:9003/downloads/policyprocedures/sopsbyprogram/tobaccoproducts/ucm270816.pdf)

Center for Veterinary Medicine (CVM) Program Policy and Procedures Manual 1240.2110, Procedures for Resolving Scientific/Data Disagreements within CVM.

CVM Policy and Procedures Manual 1240.2115, Procedures for Internal CVM Review of Science or Policy Issues Related to Significant Decisions of High Impact.

CVM Program Policy Procedures Manual 1240.2120, Product Manager.

NCTR Operational Summary #28—Procedures for Resolving Scientific Disputes at the National Center for Toxicological Research. (On FDA Intranet see: Inside FDA – Home > Policies & Procedures > SOPs by Program : Research)

FDA Compliance Manuals

FDA Regulatory Procedures Manual

FDA Staff Manual Guide 9010.1, Scientific Dispute Resolution at FDA

FDA Staff Manual Guide 4101, Combination Products: Intercenter Consultative/ Collaborative Review Process

FDA Staff Manual Guide 9001.1, Scientific Integrity at FDA

9. FORMS AND DOCUMENTATION

To begin the formal dispute resolution process the disputant will complete a summary of the Scientific/Regulatory differences on the Scientific/Regulatory Dispute Resolution (SDR) Form (Attachment C), describing the position, concept, opinion, or recommendations with which the individual or group disagrees, the nature of and reasons for the difference in opinion, as well as the proposed changes and rationale for changes in recommendations and/or conclusions. This statement will be provided to the next highest management official for his/her consideration and resolution. This statement will be provided to the individual(s) with whom the disputant disagrees, to other relevant employees, and entered in the administrative file.

The SDR form as well as all other supporting documents must:

1. relate only and specifically to the factual, scientific issues under consideration;

2. be dated and signed by the disputant(s);

3. be included in the administrative file for each affected product, with copies directed to supervisory and all other relevant personnel;

4. indicate to whom documents are sent (distribution);

5. not be changed, altered or removed by any party after completion, signing and inclusion in the administrative file; and

6. avoid defamatory remarks, undocumented charges or irrelevant matters (e.g., personnel issues).

10. EFFECTIVE DATE.

The effective date of this guide is January 6, 2014.

11. Document History - SMG 9010.2, Cross-Center Dispute Resolution at FDA

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/18/2013	N/a	CBER/OD/RPS	Jessie Goodman, Chief Scientist, OC
Change	06/21/2019	Sect. 8: NCTR and CTP references	OC/OCS/OSI	Matthew Warren, Director, OC/OCS/OSI

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