SMG 9010.5

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

GENERAL OR MULTIDISCIPLINE

DECISION AND DISPUTE RESOLUTION

REQUESTS FOR REVIEW UNDER 21 CFR § 10.75 SUBMITTED TO THE OFFICE OF THE COMMISSIONER BY INTERESTED PERSONS OUTSIDE THE AGENCY

Effective Date: April 20, 2016

1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to provide procedures for FDA staff to follow when an interested person outside the agency asks the Office of the Commissioner, under 21 CFR § 10.75, to provide supervisory review of a decision made within the Office of the Commissioner or at a lower level of the agency.

2. POLICY

- The Office of the Commissioner is committed to resolving submissions under 21 CFR § 10.75 in a timely manner.
- All involved parties should be kept informed throughout the process.
- All timeframe references are to **calendar days**, unless stated otherwise.

3. DEFINITIONS

A. 10.75 appeal or the appeal. Any request submitted to, or within, the Office of the Commissioner by an interested person outside the agency

that seeks review of a decision at a lower level of the agency under 21 CFR § 10.75. The person need not expressly reference 21 CFR § 10.75 for FDA to construe the request as a request for review under that regulation.

B. Center(s). One or more of FDA's Office of Regulatory Affairs, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, Center for Tobacco Products, and National Center for Toxicological Research.

C. Commissioner. The Commissioner of Food and Drugs or, depending on context, an official within the Office of the Commissioner authorized to act on his or her behalf.

D. Deciding Official or the DO. The official in the Office of the Commissioner who has the responsibility to decide, or rule on, the matter elevated to, or within, the Office of the Commissioner under 21 CFR § 10.75, consistent with the delegations of authority in SMG 1410.21 or 1410.37.

E. Initiator. The person who elevates any decision or matter to, or within, the Office of the Commissioner.

F. Office of Appeals or OA. The staff within the Office of Scientific Integrity assigned to processing, and coordinating the agency's response to, decisions or ongoing matters elevated to, or within, the Office of the Commissioner under 21 CFR § 10.75. The Office of Scientific Integrity is part of the Office of the Chief Scientist in the Office of the Commissioner.

G. Office of the Chief Counsel or OCC. The Office of the General Counsel for the Department of Health and Human Services, Food and Drug Division; Office of Chief Counsel, Food and Drug Administration.

H. Office of the Commissioner or OC. The immediate office of the Commissioner of Food and Drugs and all of its subordinate offices, excluding the Centers (as defined in this SMG), the Office of the Chief Counsel, and the Office of the Administrative Law Judges.

I. The Office of the Ombudsman or the OO. The Office within the Office of Scientific Integrity that, among other duties, assists in resolving informal disputes and acts as an intermediary between FDA management and external constituencies.

4. BACKGROUND

A. Under 21 CFR § 10.75(a), "[a] decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor" at the request of an employee or an interested person outside the agency, on the initiative of the supervisor, or as required by delegations of authority.

B. Multiple levels of supervisory review of any agency decision may occur through the chain of command within Centers to the Center Director (or delegee) or within the Office of the Commissioner to the Commissioner (or delegee). Elevating a decision from a Center to the Office of the Commissioner may only occur once a Center Director (or delegee) has rendered a decision for the Center. See 40 Fed. Reg. 40682, 40693 (Sept. 3, 1975).

C. Review under 21 CFR § 10.75 by a Center Director or by OC may occur for any of the following purposes: (1) to resolve an issue that cannot be resolved at lower levels within the agency; (2) to review policy matters requiring the attention of center or agency management; (3) in unusual circumstances requiring immediate review in the public interest; and (4) as required by delegations of authority. 21 CFR § 10.75(c). As made clear in the preamble to the final rule for the predecessor regulation, 21 CFR § 2.17, "[i]t is, of course, entirely within the Commissioner's discretion to grant or deny a request to review any matter." 40 Fed. Reg. 40682, 40693 (Dec. 3, 1975); see also 42 Fed. Reg. 4680, 4692 (Jan 25, 1977) ("[r]eview of the work of subordinates by agency supervisors is . . . a matter of discretion"). The extent of the review is to be determined by the supervisor. 40 Fed. Reg. at 40693.

D. Under 21 CFR § 10.75(b)(1), the supervisory review may include consideration of the administrative file, consultation between the supervisor and the employee, or both. Review of a matter by OC must be based on the information in the administrative file. 21 CFR § 10.75(d). If the interested person submits information that is not in the administrative file, OC will refer the matter back to the appropriate lower level of the agency for reevaluation based on the new information. *Id.*

5. SELECTION OF THE DECIDING OFFICIAL

Where a decision of a Center Director is appealed under 10.75 to the Office of the Commissioner or a decision from within the Office of the Commissioner is appealed under 10.75 to the Commissioner, the Commissioner retains the discretion to assign any official with the proper delegated authority to be a DO. For more significant or controversial matters, the Commissioner or the Counselor to the Commissioner may serve as the DO. For the sake of clarity

and efficiency, the officials identified below will usually function as the DO for the types of matters listed:

A. Associate Commissioner for Special Medical Programs (ACSMP):

appeals of decisions made by staff within the Office of Special Medical Programs, including staff within the Office of Good Clinical Practice, the Office of Combination Products, the Office of Orphan Products Development, and the Office of Pediatric Therapeutics, **unless** those decisions involve directly evaluating the safety and effectiveness of a medical product. If a decision appealed to the ACSMP involves directly evaluating the safety and effectiveness of a medical product, the decision of the ACSMP is subject to further appeal under 21 CFR § 10.75 within the Office of the Commissioner.

B. Chief Scientist:

1. appeals of decisions regarding user fee waivers,[1]

2. appeals of decisions by the ACSMP that involve directly evaluating the safety and effectiveness of a medical product; and

3. appeals of decisions of Center Directors and officials within the Office of the Commissioner (other than the ACSMP) who report directly to the Commissioner.

If the official to whom a particular matter would ordinarily be assigned has been significantly involved in the decision being challenged, he or she should consult with other OC officials to determine whether the matter should be assigned to a different official.

6. RESPONSIBILITIES

A. The Office of the Ombudsman

Among other duties, the OO serves as the agency's focal point for reviewing and addressing informal complaints raised by interested parties outside the agency and assisting in resolving disputes that are not raised under 21 CFR § 10.75. The OO uses informal procedures to work with both interested parties outside the agency and offices throughout the agency to resolve scientific and regulatory disagreements.

Upon receipt of any complaint or inquiry regarding agency decision-making from an interested person outside the agency, the OO will

[1] SMG 1410.21(1)(L) specifically lists the Chief Scientist as the “User Fee Appeals Officer” and states that he or she will hear and decide all “user fee waiver appeals.”

consider whether the issue is more appropriately addressed as a 10.75 appeal and consult with OA and other officials in OC, as appropriate. If the OO is unable to assist in resolving a complaint to the satisfaction of the interested person, the OO may, when appropriate, tell the initiator that the matter may be pursued as a 10.75 appeal. The OO will provide information on appropriate next steps and options.

B. Deciding Official

With the assistance and advice of OCC and, as appropriate, OA and other officials within OC, the Deciding Official will make all substantive decisions on matters pending with him or her as part of a 10.75 appeal. The DO will communicate those decisions pursuant to the procedures and timeframes below. After issuing a decision, the DO will provide all materials constituting the administrative file to OA.

C. Office of Appeals

OA will be the initial recipient of all 10.75 appeals submitted to OC regardless of whether the dispute originated within OC or one of the Centers. OA will track the completion of these appeals and will maintain the administrative files for all decisions.

The DO will ordinarily call upon his or her own staff to assist in communicating with the initiator, analyzing the issues on appeal, arranging expert input from agency scientists, and developing and drafting a decision. OA serves this role in resolving 10.75 appeals where the Chief Scientist is the DO. Other DOs may also call upon OA to provide any or all of these supporting services. A DO may also call upon OA to consult on the 10.75 appeal process or other discrete issues.

D. The Office of the Chief Counsel

OCC is responsible for providing legal advice to OC. OCC will provide timely review of any written decision for issuance by a DO under this SMG to assist in meeting the timeframes described in Section 8 below.

7. PROCEDURES

A. Upon receipt of any 10.75 appeal of a decision from a Center to the Office of the Commissioner or to the Commissioner from within OC, OA will, **within 7 days**,

1. provide a written response to the initiator that (1) acknowledges receipt of the 10.75 appeal; (2) notifies the initiator that, under 21 CFR § 10.35(d), the submission of a 10.75 appeal does not automatically stay

or otherwise delay any administrative action, including any enforcement action; and (3) informs the initiator that OC will decide whether to conduct the review requested within 60 days of the date of receipt (see Appendix A);

2. consult with, as necessary, OC officials and OCC to determine who the DO for the 10.75 appeal will be.

B. Upon being selected as the DO for a 10.75 appeal, the DO will:

1. **within 60 days of the agency's receiving the appeal**, work with OCC to provide written notice to the initiator with respect to whether OC intends to hear the appeal (see Appendices B and C); if the DO has decided to hear the appeal, the notice will also state that he or she will either complete the review and issue a decision within 180 days from the date the agency received the 10.75 appeal or provide an update on the status of the review (see Appendix B);

2. **within 60 days of the agency's receiving the appeal**, notify the initiator and the Center involved whether they will have an opportunity to meet with the DO and, if so, schedule those meetings;

3. **within 180 days of the agency's receiving the appeal**, issue a decision on the 10.75 appeal and provide notice to the initiator or, in the alternative, provide written notice to the initiator of a new date by which the DO expects to rule. The DO will similarly provide notice of any delay at least one day before each subsequent occasion the DO is unable to rule by an expected date.

In rare instances the DO may determine—at some date **after** providing notice to the initiator that OC would hear the 10.75 appeal—that OC substantive review of the matter is not warranted. In that event, in lieu of a decision, the DO will promptly notify the initiator of the determination not to hear the appeal (see Appendix C).

Whenever the DO determines that additional scientific expertise is necessary or appropriate to resolve the issues raised in a 10.75 appeal, he or she will call upon one or more experts to review and assist in evaluating the issues. The expert or experts drawn from throughout the agency will be objective, open-minded, and have the experience and knowledge necessary to provide advice on the issues at stake. The DO's staff or, as needed, OA will coordinate and facilitate meetings between the expert or experts and the DO to discuss the issues involved.

8. EFFECTIVE DATE

The effective date of this guide is April 20, 2016.

9. Document History - SMG 9010.5, Requests for Review under 21 CFR Section 10.75 Submitted to the Office of the Commissioner by Interested Persons Outside the Agency

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/19/2016	N/a	OC/OCS/ OSI	Robert M. Califf, M.D., Commissioner of Food and Drugs

Appendix A

[Date]

By Certified Mail - Return Receipt Requested

[Initiator Name]
[Address]

[Name of Counsel]
[Address]

Re: Receipt of Request for Review under 21 CFR § 10.75

Dear [Initiator] [and Counsel]:

The purpose of this letter is to acknowledge receipt of your request, under 21 CFR § 10.75, that the Office of the Commissioner review a decision made by [Employee, FDA Component] with respect to [matter at issue]. The Office of the Commissioner is processing your request. By [60 days from date of receipt], we will notify you whether the Office of the Commissioner will review the substance of the issues you raise.

Please keep in mind that your request for review does not automatically stay administrative action, including enforcement action of any kind, by FDA based on the decision you are challenging (see 21 CFR § 10.35(d)).

Sincerely,

Director, Office of Appeals

Cc: [Relevant Center]

Appendix B

[Date]

By Certified Mail - Return Receipt Requested

[Initiator Name]
[Address]

[Name of Counsel]
[Address]

Re: Status of Request for Review under 21 CFR § 10.75

Dear [Initiator] [and Counsel]:

The purpose of this letter is to notify you that the Office of the Commissioner intends to review, under 21 CFR § 10.75, a decision made by [Employee, FDA Component] with respect to [matter at issue]. We expect to complete our review of the administrative record and issue a written decision regarding the issues you raise in your request by [180 days after date of receipt]. If we are unable to complete our review and issue a decision by that date, we will update you at that time as to when we expect to do so.

Sincerely,

[Deciding Official]

Appendix C

[Date]

By Certified Mail - Return Receipt Requested

[Initiator Name]
[Address]

[Name of Counsel]
[Address]

Re: Status of Request for Review under 21 CFR § 10.75

Dear [Initiator] [and Counsel]:

The purpose of this letter is to notify you that the Office of the Commissioner is denying your request, under 21 CFR § 10.75, for review of a decision made by [Employee, FDA Component] with respect to [matter at issue]. Having reviewed both the arguments you raise in your request and the administrative file, the Office of the Commissioner has determined, in its discretion, that additional agency review is not warranted.

[Brief explanation may be provided: e.g., the matter was sufficiently considered and resolved by the [FDA component] and does not warrant further review]

Sincerely,

[Deciding Official]