§ 10.55 Separation of functions; ex parte communications.

(a) This section applies to any matter subject by statute to an opportunity for a formal evidentiary public hearing, as listed in §10.50(c), and any matter subject to a hearing before a Public Board of Inquiry under part 13.

(b) In the case of a matter listed in §10.50(c) (1) through (10) and (12) through (15):

(1) An interested person may meet or correspond with any FDA representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry on the matter; the provisions of §10.65 apply to the meetings and correspondence; and

(2) Upon publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry, the following separation of functions apply:

(i) The center responsible for the matter is, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the center at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the center may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the center and representatives of the office of the Commissioner concerning the matter before the decision of the Commissioner. The Commissioner may, however, designate representatives of a center to advise the office of the Commissioner, or designate members of that office to advise a center. The designation will be in writing and filed with the Division of Dockets Management and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the Commissioner and any other persons in the office of General Counsel or in the involved center with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either
§ 10.60 Referral by court.

(a) This section applies when a Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination under §10.25(c) or §10.45(b).

(b) The Commissioner shall promptly agree or decline to accept a court referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept a referral and shall proceed to determine the matter referred.

(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) A written communication contrary to this section must be immediately served on all other participants and filed with the Division of Dockets Management by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Division of Dockets Management. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Division of Dockets Management.

(2) The prohibitions specified in paragraph (d) of this section apply to a person who knows of a notice of hearing in advance of its publication from the time the knowledge is acquired.

(3) The making of a communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.


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(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) A written communication contrary to this section must be immediately served on all other participants and filed with the Division of Dockets Management by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Division of Dockets Management. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Division of Dockets Management.