Food and Drug Administration, HHS

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency’s response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HF1–20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301–443–4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Off the record portions of a proceeding may not be videotaped.

(c) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency’s presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency’s interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular
circumstances. The following factors are listed to assist presiding officers in determining whether the agency’s interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the proceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness’ ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness’ testimony, if the witness’ testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer’s responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency’s interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters’ opportunity to record the proceedings.


PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

Subpart A—General Provisions

Sec.
11.1 Scope.
11.2 Implementation.
11.3 Definitions.