

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding is a part of the administrative record of the hearing, and will be promptly placed on public display in the office of the Division of Dockets Management, except as provided in § 12.105.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i) (a) and (b). Such closed proceedings will be conducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on.

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Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i)(a) and (b), except as specifically authorized in a protective order issued under § 10.20(j)(3).

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commissioner if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commissioner, a participant may file a brief with the Commissioner only if specifically authorized by the presiding officer or the Commissioner, and if such authorization is granted, within the period the Commissioner directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commissioner directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commissioner. The oral argument will be transcribed. If briefs are authorized, oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the office of

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the Division of Dockets Management upon receipt.

(c) Except as provided in § 12.105, copies of the transcript may be obtained by application to the official reporter and payment of costs thereof or under part 20.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 12.99 Motions.

(a) A motion on any matter relating to the proceeding is to be filed under § 12.80, and must include a draft order, except one made in the course of an oral hearing before the presiding officer.

(b) A response may be filed within 10 days of service of a motion. The time may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The order or regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed by the Division of Dockets Management under §§ 12.20 through 12.22;

(3) The notice of hearing published under § 12.35;

(4) All notices of participation filed under § 12.45;

(5) All FEDERAL REGISTER notices pertinent to the proceeding;

(6) All submissions filed under § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and