

§ 12.97

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

21 CFR Ch. I (4–1–04 Edition)

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

written testimony, pleadings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 12.92;

(8) All documents relating to any motion for summary decision under § 12.93;

(9) All documents of which official notice is taken under § 12.95;

(10) All pleadings filed under § 12.96;

(11) All documents relating to any interlocutory appeal under § 12.97;

(12) All transcripts prepared under § 12.98; and

(13) Any other document relating to the hearing and filed with the Division of Dockets Management by the presiding officer or any participant;

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with § 10.20(j). Documents available for examination or copying will be placed on public display in the office of the Division of Dockets Management promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.120 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.

(b) The initial decision must contain—

(1) Findings of fact based upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a

discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and

(6) An effective date for the regulation or order.

(c) The initial decision must refrain from disclosing specific details of matters specified in § 10.20(j)(2)(i) (a) and (b), except as specifically authorized in a protective order issued pursuant to § 10.20(j)(3).

(d) The initial decision is to be filed with the Division of Dockets Management and served upon all participants. Once the initial decision is filed with the Division of Dockets Management, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Division of Dockets Management will be decided by the Commissioner.

(e) The initial decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Division of Dockets Management under § 12.125(a) or the Commissioner files a notice of review under § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Division of Dockets Management, and serving them on the other participants, within 60 days of the date of the initial decision.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.