

§ 17.20

determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(18) Issue protective orders pursuant to §17.28; and

(19) Exercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part.

(c) The presiding officer does not have the authority to find Federal statutes or regulations invalid.

§ 17.20 Ex parte contacts.

No party or person (except employees of the presiding officer's office) shall communicate in any way with the presiding officer on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 17.21 Prehearing conferences.

(a) The presiding officer may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The presiding officer may use a prehearing conference to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

21 CFR Ch. I (4-1-03 Edition)

(8) Discovery and scheduling dates for completion of discovery;

(9) The date, time, and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The presiding officer shall issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

§ 17.23 Discovery.

(a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.

(b) For the purpose of this part, the term *documents* includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions, and any forms of discovery, other than those permitted under paragraphs (a) and (e) of this section, are not authorized.

(d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that a protective order is necessary shall be on the party seeking the order.

(4) The burden of showing that documents should be produced is on the party seeking their production.