

§ 1316.53

(g) Rule on procedural items pending before him.

(h) Take any action permitted to the presiding officer as authorized by this part or by the provisions of the Administrative Procedure Act (5 U.S.C. 551-559).

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 42 FR 57457, Nov. 3, 1977; 62 FR 13970, Mar. 24, 1997]

§ 1316.53 Time and place of hearing.

The hearing will commence at the place and time designated in the notice of hearing published in the FEDERAL REGISTER but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1316.54 Prehearing conference.

The presiding officer on his own motion, or on the motion of any party for good cause shown, may direct all parties to appear at a specified time and place for a conference for:

- (a) The simplification of the issues.
- (b) The possibility of obtaining stipulations, admission of facts, and documents.
- (c) The possibility of limiting the number of expert witnesses.
- (d) The identification and, if practicable, the scheduling of all witnesses to be called.
- (e) The advance submission at the prehearing conference of all documentary evidence and affidavits to be marked for identification.
- (f) Such other matters as may aid in the expeditious disposition of the hearing.

§ 1316.55 Prehearing ruling.

The presiding officer may have the prehearing conference reported verbatim and shall make a ruling reciting the action taken at the conference, the agreements made by the parties, the schedule of witnesses, and a statement of the issues for hearing. Such ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.

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

§ 1316.56 Burden of proof.

At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.

§ 1316.57 Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference.

All documentary evidence and affidavits not submitted and all witnesses not identified at the prehearing conference shall be submitted or identified to the presiding officer as soon as possible, with a showing that the offering party had good cause for failing to so submit or identify at the prehearing conference. If the presiding officer determines that good cause does exist, the documents or affidavits shall be submitted or witnesses identified to all parties sufficiently in advance of the offer of such documents or affidavits or witnesses at the hearing to avoid prejudice or surprise to the other parties. If the presiding officer determines that good cause does not exist, he may refuse to admit as evidence such documents or affidavits or the testimony of such witnesses.

§ 1316.58 Summary of testimony; affidavits.

(a) The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing. Witnesses will not be permitted to read summaries of their testimony into the record and all witnesses shall be available for cross-examination. Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) Affidavits submitted at the prehearing conference or pursuant to § 1316.57 with good cause may be examined by all parties and opposing affidavits may be submitted to the presiding officer within a period of time fixed by him. Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to statements made therein.

[36 FR 7820, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]