comment urged that this language be deleted. FDA disagrees. Under 21 CFR 12.70(m), the presiding officer in formal FDA evidentiary hearings has had this authority for many years, and there have been few, if any, allegations that this authority has been abused.

60. One comment opposed the authorization in § 17.19(b)(5) for issuance of subpoenas by the presiding officer in proceedings under section 303(g)(2)(A) of the act (21 U.S.C. 333(g)(2)(A)). The author of the comment stated that this section of the SMDA authorizes only an investigative subpoena, not a hearing subpoena.

FDA disagrees with the comment's interpretation of the SMDA, which, in pertinent part, reads as follows: ''In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to matters under investigation.'' FDA interprets this to allow the agency to issue subpoenas related to a civil money penalty proceeding at any time, including during the adjudication of the penalty. The legislative history indicates that the agency was given authority to subpoena records and witnesses relevant to the civil penalty proceeding. In addition, the statutory phrase ''attendance and testimony of witnesses and the production of evidence'' reflects an intention that the testimony and documents be useable at the hearing itself.

Section 17.23—Discovery

61. A comment stated that FDA should authorize depositions, written interrogatories, and requests for admissions. The comment argued that, while brevity and economy are worthwhile goals, respondents need fuller discovery. The comment asserts that discovery depositions are necessary tools in the formation of a response to a civil money penalties complaint. Specifically, the comment objects to the presentation of hearing testimony orally without the opportunity to depose witnesses before the hearing.

FDA disagrees, and does not believe that additional forms of discovery are necessary for due process to be accorded to respondents. EPA and HHS adjudicative procedures provide these discovery mechanisms under their regulations enacted pursuant to the Program Fraud Civil Remedies Act (31 U.S.C. 3801, *et. seq.*). However, 31 U.S.C. 3803(g)(3)(B)(ii) requires that discovery be authorized to the extent allowed by the presiding officer. The program statutes that these part 17 provisions implement do not require that discovery be provided and FDA is not required to provide for discovery under the APA, which governs these procedures. (See *Pacific Gas and Electric Co.* v. *F.E.R.C.*, 746 F.2d 1383, 1387 (9th Cir. 1984); *McClelland* v. *Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979).)

FDA has discretion to determine the extent of discovery to which a party is entitled in an administrative hearing. In order to allow the parties to present a witness' testimony in the event that a witness would be unavailable for the hearing, FDA has added § 17.23(e) to provide for depositions in limited circumstances. Specifically, the presiding officer may order depositions upon a showing that the information sought is not available by alternative methods and there is a substantial reason to believe that relevant and probative evidence may not otherwise be preserved for presentation by a witness at the hearing.

In order to provide advance notice of each witness' testimony prior to cross-examination at the hearing, FDA has changed § 17.37(b) to require that direct testimony of witnesses be submitted in written form. Section 17.25(a) requires that parties exchange written testimony at least 30 days before the hearing. This should eliminate any concern that a party may be unfairly surprised by a witness' testimony presented at a hearing. Section 17.19(b)(10) has also been changed to authorize the presiding officer to recall a witness for additional testimony upon a showing of good cause. The failure of a party to provide written direct testimony of a witness before a hearing will result in exclusion of the witness' testimony.

The prehearing production of documents and exchange of exhibits by both parties, coupled with the right to cross-examine witnesses at the hearing and recall witnesses upon a showing of good cause, obviates the need for routine depositions, written interrogatories, and requests for admission. Recent changes to the ''Federal Rules of Civil Procedure'' have significantly reduced the number of depositions available to parties in Federal court litigation because of their expensive and time consuming nature (Fed. R. Civ. Proc. 30(a)(2)). FDA believes that its provision for written direct testimony is more cost effective for all concerned. Additionally, to ensure timely exchange of documents between the parties, § 17.23(a) has been changed to require that requests for production of documents be answered 30 days after the request, and that the request be made no later than 60 days before the hearing, unless otherwise ordered by the presiding officer.

62. Another comment argued that § 17.23 should specifically authorize the presiding officer to grant protective orders for trade secrets and confidential commercial information.

FDA agrees and has added a new paragraph to § 17.19(b)(18) to the final rule authorizing the presiding officer to issue protective orders for the protection of trade secrets and confidential commercial information. In order to reflect this change and to eliminate any confusion that resulted from the proposed rule, FDA has revised §§ 17.28, 17.33, and 17.41 to more clearly state the disclosure rules related to part 17 hearings. Additionally, in § 17.23(d)(3) FDA has added that the burden of showing that a protective order is necessary is on the party seeking the order.

63. A comment argued that § 17.23 should specifically exempt ''privileged'' information from access by FDA, even under a protective order. The comment expressed concern that the subsection authorizing the presiding officer to grant a protective order does not address trade secrets and confidential commercial information.

The agency believes that it would not be appropriate for FDA to be denied access to such information. FDA typically has broad access to confidential documents through its regulatory activities and carefully safeguards the confidentiality of those documents. As discussed in comment 62, the presiding officer is authorized to issue a protective order that will prevent public disclosure of such information.

Section 17.25—Exchange of Witness Lists, Witness Statements, and Exhibits

64. A comment took issue with the harshness of the ''extraordinary circumstances'' test for relief for failure to exchange witness lists, statements, and exhibits. The author argued that this relief should be granted only when a party did not substantially comply or noncompliance was in bad faith.

FDA disagrees with the comment's interpretation of proposed § 17.25(b)(2). However, the agency has clarified that § 17.25 (b)(2) and (b)(3) refer to the timely exchange of witness lists under § 17.25(a). The exclusion of other evidence not exchanged in accordance with § 17.25(a) is within the discretion of the presiding officer as noted in § 17.25(b)(1). The agency believes that it is fair and appropriate to grant relief from sanctions for failure to follow the requirements for the timely exchange of witness lists only if there are ''extraordinary circumstances.''