that the presiding officer may order a party to pay expenses. This remedy, the author argued, is unenforceable and outside the authority of the Government to provide.

FDA does not agree that it lacks the authority or that such an order of the presiding officer is unenforceable. However, because of the wide range of other sanctions available to the presiding officer for regulating the conduct of the hearing, FDA has made the change requested by the comment and eliminated § 17.35(g) as proposed.

Section 17.37—Witnesses

76. One comment took issue with what was viewed as a requirement that a cross-examining party pay a witness' travel expenses in a situation where direct testimony was submitted in writing. This was not FDA's intention in drafting § 17.37. FDA advises that it intends that a party submitting a witness' testimony in writing is responsible for paying the travel and other expenses of that witness on cross-examination at the hearing. FDA has added § 17.37(g) to clarify its intention.

77. A comment objected to § 17.37 because it could be interpreted to permit rebuttal witnesses and evidence to be submitted without any provision for discovery or identification, as provided for in connection with a party's presentation of its case in chief. FDA advises that, because rebuttal testimony and other rebuttal evidence are limited in scope and in quantity, requirements for notice and discovery are not necessary. Thus, FDA is not specifically providing for discovery or notice of a rebuttal witness' appearance. However, § 17.39(g) allows the presiding officer to permit the parties to introduce rebuttal witnesses and evidence. Implicit in this authority is the authority to set the terms of rebuttal testimony, as justice may require.

78. Yet another comment argued that § 17.37(e) is unduly broad in permitting cross-examination of witnesses on matters other than those within the scope of his or her direct examination. The comment recommended that the rules for cross-examination be predicated upon the ''Federal Rules of Evidence.''

FDA disagrees. In the interest of truth seeking in general and in the interest of procedural economy, FDA prefers § 17.37(e) as proposed. This provision is similar to what EPA and HHS provide in their Program Fraud Civil Remedies of regulations, which give the presiding officer discretion to allow cross-examination of witnesses beyond the scope of their direct examination, rather than limiting cross-examination to only those matters within the scope of direct examination. Otherwise, the opposing party would have to request that a subpoena be issued to a witness by the presiding officer, making the witness its own in a manner that unnecessarily wastes time.

Section 17.39—Evidence

79. One comment objected to § 17.39 to the extent that it renders privileged information nondiscoverable. Section 17.39 is similar to Rule 45 of the ''Federal Rules of Civil Procedure,'' which allows privileged information to be withheld by a person responding to a subpoena. FDA rejects the comment.

80. Another comment objected to language in § 17.39(b), which allows the presiding officer discretion to apply the ''Federal Rules of Evidence.'' According to the comment, the presiding officer is given authority to invoke the ''Federal Rules of Evidence'' in an arbitrary and capricious fashion, which, the comment alleges, abridges the due process rights of both parties. The comment does not, however, provide any details to support its assertion.

FDA disagrees with the comment. To the contrary, under § 17.39(b) the presiding officer is allowed to apply the ''Federal Rules of Evidence'' *when appropriate* which is similar to what EPA and HHS provide in their Program Fraud Civil Remedies regulations. Section 17.39(f) has been changed to substitute the relevant language of Rule 408 of the ''Federal Rules of Evidence'' in place of the reference to Rule 408 in the proposed rule.

Section 17.41—The Administrative Record

81. A comment suggested that § 17.41 should include an explicit exemption to the ''open record'' provision, not subject to the discretion of the presiding officer, if the officer has determined that a portion of the record contains trade secrets or confidential commercial information.

FDA believes this to be a good suggestion, and has so provided. Trade secrets, confidential commercial information, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20 are to be protected from disclosure by order of the presiding officer. Additionally, FDA is amending 21 CFR 20.86, concerning disclosure of information in administrative proceedings, to include part 17.

82. Another comment was concerned that the proposal does not contain a provision authorizing the correction of the hearing transcript and recommended that a provision similar to that contained in 21 CFR 12.98(d) be included in § 17.41. FDA has made the requested change in § 17.41(a).

Section 17.43—Posthearing Briefs

83. A comment objected to the requirement that briefs be filed simultaneously and be limited to 30 pages. According to the comment, these restrictions may prejudice respondents, however, the comment does not state how respondents may be prejudiced.

Under § 17.43, a party may file a longer brief if the presiding officer has found that the issues in the proceeding are so complex or the administrative record is so voluminous as to justify longer briefs. In the absence of a showing that simultaneous briefs will prejudice a party unfairly, FDA sees no reason to change this requirement. Additionally, parties may file proposed findings of fact and conclusions of law. FDA has added to § 17.43 that proposed findings of fact and conclusions of law are also limited to 30 pages unless the presiding officer orders otherwise.

84. Another comment requested that § 17.43 be clarified to state whether the 30-page limitation includes exhibits and attachments. FDA advises that the 30-page limitation does not include exhibits and attachments unless some material is made part of an exhibit or attachment to avoid the 30-page limitation when the material should reasonably have been included in the main portion of the brief itself.

Section 17.45—Initial Decision

85. One comment complained that requiring the presiding officer to decide the case within 90 days will inherently increase the risk of an incorrect result, thereby allegedly denying due process. FDA disagrees. Ninety days should be an ample amount of time for a presiding officer to decide most part 17 hearings. If the presiding officer needs more time, he or she may request that the entity deciding the appeal set a new deadline under § 17.45(c). As stated in the preamble, the DAB will be deciding, at least initially, appeals to the Commissioner for presiding officer decisions under this part, including a presiding officer's request for extending deadlines.

86. Another comment urged FDA to include timeframes for extensions of deadlines for rendering an initial decision. This would assure a speedier process, according to the comment. FDA disagrees. It is difficult if not impossible to set forth in a regulation the criteria for extending timeframes in issuing