

(paragraph 62). Proposed § 17.23(d)(3) has been renumbered (d)(4). Section 17.23(e) has been added to provide for oral depositions under limited circumstances (paragraph 61).

15. Section 17.25(a) has been revised to change the deadline for the exchange of witness lists, prior written statements, and exhibits from 15 days to 30 days before the hearing (paragraph 64). For clarification, § 17.25(b)(2) and (b)(3) have been changed to specifically clarify that the paragraphs concern the admission of testimony by any witness whose name does not appear on the witness lists exchanged under § 17.25(a). Section 17.25(c) now imposes a deadline of "5 days" prior to the hearing for objection to authenticity of documents (paragraph 64).

16. Section 17.27(a) now explicitly limits the issuance of subpoenas to when such issuance is "authorized by law" (paragraph 65). For ease of proving service, § 17.27(e) has been changed to delete the provision on service of subpoenas by first class mail (paragraph 65).

17. Section 17.28(b) was revised to clarify that a protective order may be issued to protect information that would be withheld from public disclosure under the agency's public information regulations in 21 CFR part 20 (paragraph 63).

18. For clarification, § 17.31(b) was changed to provide that an opposing party must be served with a copy of a document no later than when the document is filed in the docket. Section 17.32(a) now requires that the presiding officer also be served with a copy of documents filed with the Dockets Management Branch.

19. For clarification, in § 17.33(b) and (c) "is to" was replaced with "must".

Section 17.33(b) has been clarified to add that the Center has the burden of proof to establish that the proposed penalty is appropriate under the applicable statute (paragraph 25). Section 17.33(d) was revised to include a reference to information that would be withheld from public disclosure under 21 CFR part 20.

20. Section 17.34 has been changed to refer to the statute under which the penalty is assessed for purposes of determining the amount of the penalty. The DAB has been referenced as the entity currently designated by the Commissioner to decide appeals under this part in § 17.34(a) and (c) (paragraph 101).

21. Proposed § 17.35(g), which authorized the presiding officer to order the payment of costs as a sanction, has been deleted (paragraph 75). New § 17.35(g) now provides for

interlocutory appeal to the entity designated by the Commissioner to decide appeals (currently the DAB) of sanctions imposed by the presiding officer (paragraph 72).

22. Section 17.37(b) now requires, rather than permits, that direct testimony of witnesses be submitted by written declaration under penalty of perjury. The proposed provision in § 17.37(b) on "sufficient time for other parties to subpoena witness" has been deleted in light of the addition of new § 17.37(g) (paragraph 76). For clarity, § 17.37(f)(2) was modified to explain more clearly that an officer or employee of a party who is "designated to be the party's sole representative for purposes of the hearing" may not be excluded from hearing the testimony of other witnesses. Section 17.37(f)(3) has also been revised to make clear that each party may also have an individual, such as an expert witness, present at the hearing who would not be excluded from hearing other witnesses' testimony. New § 17.37(g) was added to clarify that a cross-examining party need not subpoena the witness, and to require that a sponsoring party produce a witness at its own expense (paragraph 76).

23. In § 17.39(f), a modified version of the language of Rule 408 of the "Federal Rules of Evidence" has been substituted for the proposed reference to Rule 408 (paragraph 80). For clarification, in § 17.39(g) a reference to the discretion of the presiding officer was added.

24. In § 17.41(a) a provision has been added to allow for corrections for transcription errors (paragraph 82). Section 17.41(b) has been changed to reference the DAB as the entity currently designated by the Commissioner to decide appeals under this part. Section 17.41(c) has been revised to clarify that upon motion of any party the presiding officer shall protect from disclosure documents that would be withheld from public disclosure under the agency's public information regulations at 21 CFR part 20 (paragraph 81).

25. Section 17.43 has been revised to add a page limit provision for filing of proposed findings of fact and conclusions of law (paragraph 83).

26. Section 17.45(c) has been changed to reference "the Commissioner or the entity deciding the appeal."

27. Section 17.47 has been changed to authorize appeals to the DAB instead of to the Commissioner (paragraph 101). Section 17.47(b)(2) now provides that the Commissioner or other entity designated by the Commissioner to hear appeals (currently the DAB) has discretion to extend the 30-day time

limit to file an appeal upon request of a party and a showing of good cause.

Section 17.47(c) has been revised to add a page limitation for briefs in support of appeals and a requirement that exceptions listed in the notice of appeal be explicitly supported by citations to the record (paragraph 94). The prohibition on the filing of an appellant's reply brief in proposed § 17.47(d) has been deleted. Section 17.47(d) has been changed to allow the Commissioner or the entity designated by the Commissioner to hear appeals, currently the DAB, to extend the 30-day time limit for the filing of a brief opposing the appeal upon request of the party and a showing of good cause. New § 17.47(e) has been added to provide the right of an appellant to file a reply brief within 10 days of being served with the appellee's brief (paragraph 99). Section 17.47(h) has been renumbered as § 17.47(k) and has been revised to add that the standard of review on a disputed issue of law is whether the initial decision is erroneous (paragraph 101). Proposed § 17.47(e) through (i) have been renumbered. New § 17.47(h) has been added to authorize the entity deciding the appeal (currently the DAB) to request additional briefing by the parties (paragraph 95). Section 17.47(j) has added "if practicable" to the 60-day deadline for the decision on appeal. For consistency of language, "summary judgment" was changed to "summary decision" in § 17.47(j), which was proposed § 17.47(i). In § 17.47(j) explicit language authorizing the entity deciding the appeal (currently the DAB) to reverse the initial decision or decision granting summary decision has been added (paragraph 100). Section 17.47(j) now clarifies that a decision by the entity deciding the appeal (currently the DAB) to decline to review the case shall be the final action of the agency and the initial decision shall be final and binding on the parties 30 days after the declination.

28. Section 17.48 has been changed to reference the DAB as the entity currently designated by the Commissioner to decide appeals under this part.

29. Section 17.49 has been deleted.

30. Section 17.51(a) now states that only a respondent may petition for judicial review or file a petition for stay of a decision by the Commissioner (paragraph 105). New § 17.51(c) makes explicit that exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review (paragraph 12).

31. Section 17.54 has been revised to state amounts assessed under part 17 are to be delivered to the Director of FDA's