in those instances where it believes in good faith after properly conducting an investigation that violations have occurred sufficient to warrant civil money penalties. The comment did not identify what those safeguards should be. Although FDA declines to change § 17.5, as the answer to comment 15 makes clear, FDA's review process for assessing civil money penalties should ensure that the agency will bring such actions only under the circumstances stated in the comment.

24. One comment argued that a complaint should specify ''all facts'' on which FDA is relying. FDA believes that the requirement regarding the contents of the complaint filed under part 17, as proposed, is consistent with other civil processes. For example, a complaint filed under Rule 8(a) of the ''Federal Rules of Civil Procedure,'' requires only ''* * * (2) a short and plain statement of the claim showing that the pleader is entitled to relief * * *.'' The requirements for a complaint are also consistent with the previously cited EPA and HHS Program Fraud Civil Remedies regulations.

FDA intends to file complaints that provide a reasonable description in sufficient detail for a respondent to have a fair understanding of the bases for the action. Moreover, the regulations requiring production of documents (§ 17.23) and exchanges of witness statements and exhibits (§ 17.25) provide for detailed presentations of factual information.

25. The same comment argued that the complaint should justify the amount of civil penalties being sought in accordance with factors identified in § 17.34. Again, FDA believes that a complaint filed under part 17 satisfies the requirements of notice pleading.

FDA recognizes that under the Administrative Procedure Act (APA) (5 U.S.C. 556(d)), as interpreted by the Supreme Court in *Director, OWCP* v. *Greenwich Collieries,* 114 S. Ct. 2251, 2257 (1994), the agency has the burden of proof on the respondent's liability and on the appropriateness of the penalty in light of the factors specified in the statute to be taken into account in determining the penalty. However, the proof that is required by the APA and specified in § 17.33(b) is to be presented by the Center at the time of the hearing, not, as the comment suggests, in the complaint. In order to clarify that the burden of proof referenced in the APA requires the Center to prove the respondent's liability and the appropriateness of the penalty under the applicable statute, § 17.33(b) has been revised to state that ''in order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.''

26. This same comment called for ''the intervention of [an] impartial, non-investigating party regarding whether an administrative complaint is sustainable.'' FDA believes that part 17 already provides for such an ''impartial non-investigating party'' in the form of a presiding officer, who is an administrative law judge qualified under 5 U.S.C. 3105.

27. Another comment objected that the regulation does not provide for a separation of investigatory and adjudicatory functions and stated that civil money penalty proceedings should be among those hearings to which separation of functions applies. FDA has added § 17.20 to provide restrictions on ex parte communications with the presiding officer. Since the DAB will be adjudicating appeals in civil money penalties proceedings, there is no need to adopt separation-of-functions rules in these proceedings.

28. Yet another comment complained that § 17.5(a) fails to identify anyone in FDA management who must approve the decision to impose a civil money penalty. Further, the author of the comment stated a belief that an initial determination of whether or not civil money penalties should be imposed should be made prior to the service of a complaint.

FDA advises that such an initial determination is in fact made. As described in paragraph 15, FDA has an established review procedure for enforcement cases, and that process will have added coordination for civil money penalties cases due to the newness of the authority and the lack of FDA precedents. However, since this is an institutional decision, it is not appropriate to designate a single individual as the agency's decisionmaker.

29. Yet another comment argued that notice pleading such as that provided for in § 17.5(b)(1) is inappropriate in light of the limited discovery provided for under these regulations. The comment called for either a more detailed notice in the complaint or greater discovery.

As discussed in paragraphs 24 and 61, FDA believes expanded discovery and pleading are not necessary. FDA intends to file complaints that provide a reasonable description in sufficient detail for respondents to have a fair understanding of the bases for the action.

30. One comment requested that FDA first put a respondent on notice via a warning letter before it files a claim for civil money penalties. FDA advises that as with FDA's judicial enforcement remedies, it will normally give prior notice by a warning letter or other means, although there may be exceptional circumstances where no prior warning would be given.

Section 17.7—Service of Complaint

31. One comment stated that an affidavit as proof of service should suffice only when service is made by personal delivery. FDA agrees that an affidavit is most appropriate when service is made by personal delivery, and has amended § 17.7(b)(1) to refer to ''personal delivery.''

32. A comment expressed concerns about the costs to be incurred by both the Center and the respondent as a result of these administrative procedures. FDA was mindful of the costs of litigation when it proposed part 17, and has sought to draft these procedures to minimize costs to all concerned. For example, providing for written direct testimony rather than oral direct testimony will significantly reduce the time and costs associated with hearings before the presiding officer.

Section 17.9—Answer

33. One comment argued that § 17.9 should provide for amendments to an answer after submission. FDA advises that it intends that complaints and answers may be amended on motion of the parties throughout the proceeding to conform to proof as justice may require. The ''Federal Rules of Civil Procedure'' follow this method for amendment of pleadings, allowing the motions to be ruled on by the district judge. Similarly, the presiding officer has been given this authority, which is so provided in the final rule (§ 17.9(d)).

34. A comment argued that 30 days is not sufficient to file an answer and that 60 days should be allowed for this purpose. FDA advises that if 30 days is not sufficient, a respondent may apply for more time upon a showing of good cause. (See § 17.9(c).)

35. One comment observed that § 17.9(c) provides for a request for an extension of time within which to file an answer, which request is to be ruled on by the presiding officer, who at that stage will not have been appointed. Under proposed § 17.12, the presiding officer is appointed only after the respondent has answered. The comment requested that the final rule change the procedure.

FDA agrees and is changing the rules to eliminate § 17.12, which is unnecessarily repetitious, to include the