

§ 12.130

(c) Any reply to the exceptions is to be filed and served within 60 days of the end of the period for filing exceptions.

(d) The Commissioner may extend the time for filing exceptions under paragraph (a) of this section or replies to exceptions under paragraph (c) of this section only upon a showing by a participant of extraordinary circumstances. Such an extension shall be requested by filing a written request with the Commissioner's Executive Secretariat (HF-40) and serving copies of the request on the Division of Dockets Management (HFA-305), the Chief Counsel (GCF-1), and all hearing participants.

(e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Division of Dockets Management, and serve on the participants, a notice of the Commissioner's determination to review the initial decision. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

[44 FR 22339, Apr. 13, 1979, as amended at 53 FR 29453, Aug. 5, 1988]

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner has all the powers given to make the initial decision. On the Commissioner's own initiative or on motion, the Commissioner may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal is the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as possible after the filing of briefs and any oral argument, the Commissioner will issue a final decision in the proceeding, which meets the

21 CFR Ch. I (4-1-04 Edition)

requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision.

(e) Notice of the Commissioner's decision will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

Sec.

13.1 Scope.

13.5 Notice of a hearing before a Board.

13.10 Members of a Board.

13.15 Separation of functions; ex parte communications; administrative support.