

§ 12.30

21 CFR Ch. I (4–1–04 Edition)

whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§ 12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in § 12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.

§ 12.32 Request for alternative form of hearing.

(a) A person with a right to request a hearing may waive that right and request one of the following alternatives:

(1) A hearing before a Public Board of Inquiry under part 13.

(2) A hearing before a public advisory committee under part 14.

(3) A hearing before the Commissioner under part 15.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commissioner.

(2) Must be submitted in the form of a citizen petition under § 10.30 before publication of a notice of hearing under § 12.35 or a denial of hearing under § 12.28; and

(3) Must be—

(i) In lieu of a request for a hearing under this part; or

(ii) If submitted after or with a request for hearing, in the form of a waiver of the right to request a hearing conditioned on an alternative form of hearing. Upon acceptance by the Com-

missioner, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing unless the Commissioner determines otherwise.

(c) When more than one person requests and justifies a hearing under this part, an alternative form of hearing may be used only if all the persons concur and waive their right to request a hearing under this part.

(d) The Commissioner will determine whether an alternative form of hearing should be used, and if so, which alternative is acceptable, after considering the requests submitted and the appropriateness of the alternatives for the issues raised in the objections. The Commissioner's acceptance is binding unless, for good cause, the Commissioner determines otherwise.

(e) The Commissioner will publish a notice of an alternative form of hearing setting forth the following information:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The time, date, and place of the hearing, or a statement that such information will be contained in a later notice.

(4) The parties to the hearing.

(5) The issues at the hearing. The statement of issues determines the scope of the hearing.

(6) If the hearing will be conducted by a Public Board of Inquiry, the time within which—

(i) The parties should submit nominees for the Board under § 13.10(b);

(ii) A notice of participation under § 12.45 should be filed; and

(iii) Participants should submit written information under § 13.25. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing before the Board. The portions listed will be placed on public display in the office of the Division of Dockets Management before the notice is published. Additional copies of material already submitted under § 13.25 need not be included with any later submissions.

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Division of Dockets Management, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Division of Dockets Management before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA,