

## § 12.30

section 721(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Division of Dockets Management;

(iii) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the transcript of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the FEDERAL REGISTER.

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

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

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the FEDERAL REGISTER. (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and

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issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue, regardless 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—

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(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 Commissioner, 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.