

## § 10.40

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(6) All documents filed with the Division of Dockets Management under §10.65(h).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 54 FR 9034, Mar. 3, 1989; 59 FR 14364, Mar. 28, 1994; 66 FR 6468, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001]

### § 10.40 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by FDA whenever it is necessary or appropriate to do so. The issuance, amendment, or revocation of a regulation may be initiated in any of the ways specified in §10.25.

(1) This section applies to any regulation: (i) Not subject to §10.50 and part 12, or (ii) if it is subject to §10.50 and part 12, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted under §10.25(a) will be published in the FEDERAL REGISTER as a proposal if:

(i) The petition contains facts demonstrating reasonable grounds for the proposal; and

(ii) The petition substantially shows that the proposal is in the public interest and will promote the objectives of the act and the agency.

(3) Two or more alternative proposed regulations may be published on the same subject to obtain comment on the different alternatives.

(4) A regulation proposed by an interested person in a petition submitted under §10.25(a) may be published together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraph (e) of this section, each regulation must be the subject of a notice of proposed rulemaking published in the FEDERAL REGISTER. (1) The notice will contain:

(i) The name of the agency;

(ii) The nature of the action, e.g., proposed rule, or notice;

(iii) A summary in the first paragraph describing the substance of the document in easily understandable terms;

(iv) Relevant dates, e.g., comment closing date, and proposed effective date(s);

(v) The name, business address, and phone number of an agency contact person who can provide further information to the public about the notice;

(vi) An address for submitting written comments;

(vii) Supplementary information about the notice in the form of a preamble that summarizes the proposal and the facts and policy underlying it, includes references to all information on which the Commissioner relies for the proposal (copies or a full list of which are a part of the docket file on the matter in the office of the Division of Dockets Management), and cites the authority under which the regulation is proposed;

(viii) Either the terms or substance of the proposed regulation or a description of the subjects and issues involved;

(ix) A reference to the existence or lack of need for an environmental impact statement under §25.52 of this chapter; and

(x) The docket number of the matter, which identifies the docket file established by the Division of Dockets Management for all relevant submissions.

(2) The proposal will provide 60 days for comment, although the Commissioner may shorten or lengthen this time period for good cause. In no event is the time for comment to be less than 10 days.

(3) After publication of the proposed rule, any interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the Division of Dockets Management stating the grounds for the request. The request is submitted under §10.35 but should be headed "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) A request must discuss the reason comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny the request or may grant an extension for

a time period different from that requested. An extension may be limited to specific persons who have made and justified the request, but will ordinarily apply to all interested persons.

(ii) A comment time extension of 30 days or longer will be published in the FEDERAL REGISTER and will be applicable to all interested persons. A comment time extension of less than 30 days will be the subject either of a letter or memorandum filed with the Division of Dockets Management or of a notice published in the FEDERAL REGISTER.

(4) A notice of proposed rulemaking will request that four copies of all comments be submitted to the Division of Dockets Management, except that individuals may submit single copies. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include their preferred alternative wording.

(c) After the time for comment on a proposed regulation has expired, the Commissioner will review the entire administrative record on the matter, including all comments and, in a notice published in the FEDERAL REGISTER, will terminate the proceeding, issue a new proposal, or promulgate a final regulation.

(1) The quality and persuasiveness of the comments will be the basis for the Commissioner's decision. The number or length of comments will not ordinarily be a significant factor in the decision unless the number of comments is material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner on the matter will be based solely upon the administrative record.

(3) A final regulation published in the FEDERAL REGISTER will have a preamble stating: (i) The name of the agency, (ii) the nature of the action e.g., final rule, notice, (iii) a summary first paragraph describing the substance of the document in easily understandable terms, (iv) relevant dates, e.g., the rule's effective date and comment closing date, if an opportunity for comment is provided, (v) the name,

business address, and phone number of an agency contact person who can provide further information to the public about the notice, (vi) an address for the submission of written comments when they are permitted, (vii) supplementary information about the regulation in the body of the preamble that contains references to prior notices relating to the same matter and a summary of each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each. The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue.

(4) The effective date of a final regulation may not be less than 30 days after the date of publication in the FEDERAL REGISTER, except for:

(i) A regulation that grants an exemption or relieves a restriction; or

(ii) A regulation for which the Commissioner finds, and states in the notice good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section apply only to the extent required by the Administrative Procedure Act (5 U.S.C. 551, 552, and 553). As a matter of discretion, however, the Commissioner may voluntarily follow those provisions in circumstances in which they are not required by the Administrative Procedure Act.

(e) The requirements of notice and public procedure in paragraph (b) of this section do not apply in the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In these cases, the notice promulgating the regulation will state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may, but need not, provide additional opportunity for public comment.

(2) Food additive and color additive petitions, which are subject to the provisions of § 12.20(b)(2).

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(3) New animal drug regulations, which are promulgated under section 512(i) of the act.

(f) In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a proposed or final regulation, before or after publication in the FEDERAL REGISTER, to the following additional procedures:

(1) Conferences, meetings, discussions, and correspondence under §10.65.

(2) A hearing under parts 12, 13, 14, or 15.

(3) A notice published in the FEDERAL REGISTER requesting information and views before the Commissioner determines whether to propose a regulation.

(4) A draft of a proposed regulation placed on public display in the office of the Division of Dockets Management. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments on the draft proposal may be submitted orally or in writing.

(5) A revised proposal published in the FEDERAL REGISTER, which proposal is subject to all the provisions in this section relating to proposed regulations.

(6) A tentative final regulation or tentative revised final regulation placed on public display in the office of the Division of Dockets Management and, if deemed desirable by the Commissioner, published in the FEDERAL REGISTER. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation. The Commissioner shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation if one has been published.

(7) A final regulation published in the FEDERAL REGISTER that provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section.

(8) Any other public procedure established in this chapter and expressly applicable to the matter.

(g) The record of the administrative proceeding consists of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in §10.30(i).

(2) If a petition for reconsideration or for a stay of action is filed, the administrative record specified in §§10.33(k) and 10.35(h).

(3) The proposed rule published in the FEDERAL REGISTER, including all information identified or filed by the Commissioner with the Division of Dockets Management on the proposal.

(4) All comments received on the proposal, including all information submitted as a part of the comments.

(5) The notice promulgating the final regulation, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the administrative record of the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the procedures specified in paragraph (f) of this section, but not the transcript of a closed portion of a public advisory committee meeting.

(7) All documents submitted to the Division of Dockets Management under §10.65(h).

(h) The record of the administrative proceeding closes on the date of publication of the final regulation in the FEDERAL REGISTER unless some other date is specified. Thereafter, any interested person 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 it to the Commissioner with a new petition to modify the final regulation.

(i) The Division of Dockets Management shall maintain a chronological list of all regulations proposed and promulgated under this section and §10.50 (which list will not include regulations resulting from petitions filed and assigned a docket number under §10.30) showing—

(1) The docket number (for a petition submitted directly to a center, the list also includes the number or other designation assigned by the center, e.g., the number assigned to a food additive petition);

(2) The name of the petitioner, if any;

(3) The subject matter involved; and

(4) The disposition of the petition.

[44 FR 22323, Apr. 13, 1979, as amended at 52 FR 36401, Sept. 29, 1987; 54 FR 9034, Mar. 3, 1989; 56 FR 13758, Apr. 4, 1991; 62 FR 40592, July 29, 1997; 66 FR 6468, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001]

**§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.**

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§10.25 through 10.40 and §16.1(b), except action subject to §10.50 and part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under §10.25(a) or, where applicable, a hearing under §16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under §10.25(a) or, where applicable, a hearing under §16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 *et seq.*, and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) A request that administrative action be stayed must first be the subject of an administrative decision based upon a petition for stay of action submitted under §10.35 before a request is made that a court stay the action. If a court action is filed requesting a stay of administrative action before the Commissioner's decision on a petition submitted in a timely manner pursuant to §10.35, the Commissioner shall request dismissal of the court action or

referral to the agency for an initial determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 *et seq.*, and the lack of an actual controversy as required by 28 U.S.C. 2201. If a court action is filed requesting a stay of administrative action after a petition for a stay of action is denied because it was submitted after expiration of the time period provided under §10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of the court action on the ground of a failure to exhaust administrative remedies.

(d) Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under §10.25(a), on a petition for reconsideration submitted under §10.33, on a petition for stay of action submitted under §10.35, on an advisory opinion issued under §10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under §16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with §10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and §314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

(1) It is the position of FDA except as otherwise provided in paragraph (d)(2) of this section, that:

(i) Final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of the final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available;

(ii) An interested person is affected by, and thus has standing to obtain judicial review of final agency action; and

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of final agency action on the ground that indispensable parties