

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) 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 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 pre-enforcement 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

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(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 are not joined or that it is an unconsented suit against the United States if the defect could be cured by amending the complaint.

(2) The Commissioner shall object to judicial review of a matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act; or

(ii) Review is not sought in a proper court.

(e) An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

(f) The Commissioner shall take the position in an action for judicial review under 5 U.S.C. 701 *et seq.*, whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action must be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(a) or the administrative record applicable to any decision or action under the regulations referenced in § 16.1(b), and that additional information or views may not be considered. An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single U.S. District court. If petitions are filed in more than one jurisdiction, the Commissioner will take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, under 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a);

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding;

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit; or

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h)(1) For the purpose of 28 U.S.C. 2112(a), a copy of any petition filed in any U.S. Court of Appeals challenging a final action of the Commissioner shall be sent by certified mail, return receipt requested, or by personal delivery to the Chief Counsel of FDA. The petition copy shall be time-stamped by the clerk of the court when the original is filed with the court. The petition copy should be addressed to: Office of the Chief Counsel (GCF-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The Chief Counsel requests that the purpose of all petitions mailed or delivered to the Office of Chief Counsel to satisfy 28 U.S.C. 2112(a) be clearly identified in a cover letter.

(2) If the Chief Counsel receives two or more petitions filed in two or more U.S. Courts of Appeals for review of any agency action within 10 days of the effective date of that action for the purpose of judicial review, the Chief Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period, in accordance with the applicable rule of the panel.

(3) For the purpose of determining whether a petition for review has been received within the 10-day period under paragraph (h)(2) of this section, the petition shall be considered to be received on the date of delivery, if personally delivered. If the delivery is accomplished by mail, the date of receipt shall be the date noted on the return receipt card.

(i) Upon judicial review of administrative action under this section:

(1) If a court determines that the administrative record is inadequate to

support the action, the Commissioner shall determine whether to proceed with such action. (i) If the Commissioner decides to proceed with the action, the court will be requested to remand the matter to the agency to reopen the administrative proceeding and record, or on the Commissioner's own initiative the administrative proceeding and record may be reopened upon receipt of the court determination. A reopened administrative proceeding will be conducted under the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action must be further explained:

(i) The Commissioner shall request either that further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened in accordance with paragraph (i)(1)(i) of this section; and

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further proceedings.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 57 FR 17980, Apr. 28, 1992; 65 FR 56477, Sept. 19, 2000]

**§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.**

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under part 12 whenever all of the following apply:

(1) The subject matter of the regulation or order is subject by statute to an

opportunity for a formal evidentiary public hearing.

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§ 314.200, 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever it would be in the public interest to do so.

(c) The provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing as listed below. The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.

(1) Section 401 on any action for the amendment or repeal of any definition and standard of identity for any dairy product (including products regulated under parts 131, 133, and 135 of this chapter) or maple sirup (regulated under § 168.140 of this chapter).

(2) Section 403(j) on regulations for labeling of foods for special dietary uses.

(3) Section 404(a) on regulations for emergency permit control.

(4) Section 406 on tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) on food additive regulations.

(6) Section 501(b) on tests or methods of assay for drugs described in official compendia.

(7) [Reserved]

(8) Section 502(h) on regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) on prescription drug advertising regulations.

(10) [Reserved]

(11) Section 507(f) on regulations for antibiotic drug certification.

(12) Section 512(n)(5) on regulations for animal antibiotic drugs and certification requirements.

(13) Section 721 (b) and (c) on regulations for color additive listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act on food, drug, device, and cosmetic labeling.