

## § 10.35

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision under § 10.25(a).

(f) The decision on a petition for reconsideration is to be in writing and placed on public display as part of the docket file on the matter in the office of the Division of Dockets Management. A determination to grant reconsideration will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commissioner may consider a petition for reconsideration only before the petitioner brings legal action in the courts to review the action, except that a petition may also be considered if the Commissioner has denied a petition for stay of action and the petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of review. A petition for reconsideration submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for reconsideration will be considered as submitted on the day it is received by the Division of Dockets Management.

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under § 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior

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decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under § 10.25(a)(2) is subject to § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in § 10.30(i).

(2) The petition for reconsideration, including all information on which it relies, filed by the Division of Dockets Management.

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

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

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

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in § 10.30(i).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 66 FR 6467, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001]

### § 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be

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filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the date of decision.

(Date) \_\_\_\_\_

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**PETITION FOR STAY OF ACTION**

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

*A. Decision involved*

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

*B. Action requested*

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

*C. Statement of grounds*

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) \_\_\_\_\_

(Name of petitioner) \_\_\_\_\_

(Mailing address) \_\_\_\_\_

(Telephone number) \_\_\_\_\_

(c) A petition for stay of action relating to a petition submitted under §10.25(a)(2) is subject to the requirements of §10.30 (c) and (d), except that it will be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under §10.30 or a petition for reconsideration under §10.33 or a request for an advisory opinion under §10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighed by public health or other public interests.

(f) The Commissioner's decision on a petition for stay of action is to be in writing and placed on public display as part of the file on the matter in the office of the Division of Dockets Management. A determination to grant a stay will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for a stay of action is considered submitted on the day it is received by the Division of Dockets Management.

(h) The record of the administrative proceeding consists of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all information on which it relies, filed by the Division of Dockets Management.

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

(4) The Commissioner's decision on the petition under paragraph (e) of this

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section, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

(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."