(*c*) Manufacturing methods or processes, including quality control procedures.

(*d*) Production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(*e*) Quantitative or semiquantitative formulas.

(*f*) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.48.

(3) Material listed in paragraph (j)(2)(i) (*a*) and (*b*) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct of the hearing. The administrative law judge or presiding officer shall direct to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 49 FR 7363, Feb. 29, 1984; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994; 64 FR 69190, Dec. 10, 1999; 65 FR 56477, Sept. 19, 2000; 66 FR 56035, Nov. 6, 2001; 66 FR 66742, Dec. 27, 2001; 68 FR 25285, May 12, 2003; 81 FR 78505, Nov. 8, 2016]

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either:

(1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or

(2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a

person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with §10.20 and, if applicable, §10.31. The certification requirement in this section does not apply to petitions subject to the certification requirement of §10.31. The petition must also be submitted in accordance with the following paragraphs, as applicable:

(1) *Electronic submission.* Petitions (including any attachments) may be electronically submitted in accordance with paragraph (b)(3) of this section and §10.20 through *http://www.regulations.gov* at Docket No. FDA 2013–S–0610. It is only necessary to submit one copy.

(2) *Mail, delivery services, or other non-electronic submissions.* A petition (including any attachments), that is not electronically submitted under paragraph (b)(1) of this section, must be submitted in accordance with paragraph (b)(3) and §10.20 and delivered to this address: Division of Dockets Management, Department of Health and Human Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to submit two copies.

(3) *Petition format.* A petition submitted under paragraphs (b)(1) or (b)(2) of this section must be in accordance with §10.20 and in the following format:

CITIZEN PETITION

Date: _____

The undersigned submits this petition under ____ (relevant statutory sections, if known) of the ____ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to____ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action Requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of Grounds

(A full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental Impact

(A) Claim for categorical exclusion under §§25.30, 25.31, 25.32, 25.33, or §25.34 of this chapter or an environmental assessment under §25.40 of this chapter.)

D. Economic Impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition that appears to meet the requirements of paragraph (b)(3) of this section, §10.20, and, if applicable, §10.31, will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a unique docket number. The unique docket number identifies the docket file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer

to the assigned docket number assigned in this paragraph and will be filed in the established docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner of the filing and unique docket number of the petition.

(d) An interested person may submit comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and include, if applicable, the verification under §10.31, and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraphs (e)(4) and (5) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval;

(ii) Deny the petition;

(iii) Dismiss the petition if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or

(iv) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition. The petitioner is to be notified of the Commissioner's decision. The decision will be placed in the public docket file and may also be in the form of a notice published in the FEDERAL REGISTER.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by §314.93 of this chapter.

(5) The Commissioner intends to furnish a response to each petitioner within 150 days of receipt of a petition subject to section 505(q) of the Federal Food, Drug, and Cosmetic Act.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, §10.40 or §10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

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

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A FEDERAL REGISTER notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with §10.40 or §12.20.

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

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

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

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

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in §10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

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

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

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in §10.33(k) or §10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision 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 them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under §10.45.

(l) The Division of Dockets Management will maintain a chronological list of each petition filed under this section and §10.85, but not of petitions submitted elsewhere in the agency under §10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Division of Dockets Management;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 16656, Apr. 26, 1985; 54 FR 9034, Mar. 3, 1989; 57 FR 17980, Apr. 28, 1992; 59 FR 14364, Mar. 28, 1994; 62 FR 40592, July 29, 1997; 66 FR 6467, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001; 78 FR 76749, Dec. 19, 2013; 81 FR 78505, Nov. 8, 2016]

§10.31 Citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications.

(a) *Applicability*. This section applies to a citizen petition or petition for stay of action that meets all of the following criteria:

(1) The petition requests that the Commissioner take any form of action that could, if taken, delay approval of an abbreviated new drug application submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, a new drug application submitted through the pathway described by section 505(b)(2) of the Federal, Food, Drug and Cosmetic Act, or a biologics license application submitted under section 351(k) of the Public Health Service Act.

(2) The petition is submitted on or after September 27, 2007.

(3) The petition is submitted in writing and under §10.30 (for citizen petitions) or §10.35 (for petitions for stay of action).