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).

(b) *Date of submission*. A petition subject to this section and submitted in accordance with §10.20, §10.30, §10.31, or §10.35 is regarded as submitted on the date on which the petition is received by the Division of Dockets Management.

(c) *Certification*. (1) FDA will not consider for review a petition that is subject to this section unless the petition is in writing and contains the following certification:

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to the person submitting the petition]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

(2) The certification in paragraph (c)(1) of this section must contain one or more specific dates (month, day, and year) in the first blank space provided. If different categories of information become known at different times, the certification must contain each estimated relevant date. The information associated with a particular date must be identified.

(d) *Verification.* (1) FDA will not accept for review any supplemental information or comments on a petition that is subject to this section unless the supplemental information or comments are in writing and contain the following verification:

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____[in the blank space, provide the date on which such information first became known to the person submitting the document]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this document.

(2) The verification in paragraph (d)(1) of this section must contain one or more specific dates (month, day, and year) in the first blank space provided. If different categories of information become known at different times, the verification must contain each estimated relevant date. The information associated with a particular date must be identified.

[81 FR 78506, Nov. 8, 2016]

§ 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under §10.25. Each request for reconsideration 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 filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the day of decision.

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, rm. 1–23, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

PETITION FOR RECONSIDERATION

[Docket No.]

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. ____.

A. Decision involved

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. Action requested

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.

(No new information or views may be included in a petition for reconsideration.)

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____