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(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) _____

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

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

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

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

(4) Reconsideration is not outweighed by public health or other public interests.

(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 re-

view 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 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.

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(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 (except that a request for stay subject to § 10.31 must also include the certification provided in § 10.31(c)) 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 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.)

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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. 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 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.