§ 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 or §571.1, for a new drug application in §314.50, for a request to establish or amend an import tolerance in §510.205, 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; 86 FR 52409, Sept. 21, 2021]

§ 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 nonelectronic 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).