

of proof of any applicable prior sanction for use of the ingredient under conditions different from those proposed to be determined to be GRAS. The failure of any person to come forward with proof of such an applicable prior sanction in response to the notice of filing will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice of filing will also constitute a proposal to establish a regulation under this subchapter E, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the notice of filing.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 10, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 54 FR 18281, Apr. 28, 1989; 62 FR 40600, July 29, 1997]

§ 570.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 570.35 (b)(4) or (c)(5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the act.

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 571.130(b) of this chapter. The Commissioner will place all of the data and information on which he relies on public file in the Division of Dockets Management and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Division of Dockets Management. Copies of all comments shall be made available for examination in the Division of Dockets Management.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food-contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under this subchapter E. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this subchapter E, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of

submission of proof of such an applicable prior sanction in response to the proposal.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 14, 1977; 54 FR 18281, Apr. 28, 1989]

PART 571—FOOD ADDITIVE PETITIONS

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AUTHORITY: 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

SOURCE: 41 FR 38647, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 571.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such informa-

tion is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food-additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)
Name of petitioner _____
Post office address _____
Date _____
Name of food additive and proposed use _____

Food and Drug Administration
CENTER FOR VETERINARY MEDICINE,
Director, Division of Animal Feeds (HFV-220),
7500 Standish Pl., Rockville, MD 20855.

DEAR SIRs: The undersigned, _____

submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and

Cosmetic Act with respect to _____

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in