

§ 170.106

longer safe, FDA may determine that the authorizing FCN is no longer effective.

(b) If FDA determines that an FCN is no longer effective, FDA will inform the manufacturer or supplier in writing of the basis for that determination. FDA will give the manufacturer or supplier an opportunity to show why the FCN should continue to be effective and will specify the time that the manufacturer or supplier will have to respond.

(c) If the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the FCN is no longer effective. FDA will publish this notice in the FEDERAL REGISTER, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request. The date that the notice publishes in the FEDERAL REGISTER is the date on which the notification is no longer effective.

(d) FDA's determination that an FCN is no longer effective is final agency action subject to judicial review.

§ 170.106 Notification for a food contact substance formulation (NFCSF).

(a) In order for the Food and Drug Administration (FDA) to accept an NFCSF, any food additive that is a component of the formulation must be authorized for its intended use in that NFCSF.

(b) FDA may publish a notice in the FEDERAL REGISTER stating that the agency has insufficient resources to review NFCSFs. From the date that this notice publishes in the FEDERAL REGISTER, FDA will no longer accept NFCSFs.

(c) An NFCSF must contain the following:

(1) A completed and signed FDA Form No. 3479; and

(2) Any additional documentation required to establish that each component of the formulation already may be marketed legally for its intended use.

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PART 171—FOOD ADDITIVE PETITIONS

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

SOURCE: 42 FR 14489, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the act) shall be submitted in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product). 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 information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food