

(d) By submitting an FCN to FDA, the manufacturer or supplier waives any claim to confidentiality of the information required to adequately describe the food contact substance and the intended conditions of use that are the subject of that FCN.

(e) The following data and information in an FCN are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by FDA, except that no data or information are available for public disclosure if the FCN is withdrawn under §170.103.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food contact substance for establishing identity, stability, purity, potency, performance, and usefulness.

(2) A protocol for a test or study, unless it is exempt from disclosure under §20.61 of this chapter.

(3) A list of all ingredients contained in a food contact substance, excluding information that is exempt from disclosure under §20.61 of this chapter. Where applicable, an ingredient list will be identified as incomplete.

(4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is exempt from disclosure under §20.61 of this chapter.

(5) All correspondence and written summaries of oral discussions relating to the notification, except information that is exempt for disclosure under §20.61 of this chapter.

(6) All other information not subject to an exemption from disclosure under subpart D of part 20 of this chapter.

§170.103 Withdrawal without prejudice of a premarket notification for a food contact substance (FCN).

A manufacturer or supplier may withdraw an FCN without prejudice to a future submission to the Food and Drug Administration (FDA) if FDA has not completed review of the FCN. For the purpose of this section, FDA's review is completed when FDA has allowed 120 days to pass without object-

ing to the FCN or FDA has issued an objection letter.

§ 170.104 Action on a premarket notification for a food contact substance (FCN).

(a) If the Food and Drug Administration (FDA) does not object to an FCN within the 120-day period for FDA review, the FCN becomes effective.

(b) If an FCN is complete when received, the 120-day review period begins on the date FDA receives the FCN.

(1) If any element required under §170.101 is missing from an FCN, then FDA will not accept that FCN and FDA will send an FCN nonacceptance letter to the manufacturer or supplier. If the manufacturer or supplier submits the missing information before FDA sends an FCN nonacceptance letter, the 120-day review period begins on the date of receipt of the missing information.

(2) If FDA accepts an FCN, then FDA will acknowledge in writing its receipt of that FCN.

(c) Objection to an FCN:

(1) If FDA objects to an FCN, then FDA will send an FCN objection letter. The date of the letter will be the date of FDA's objection for purposes of section 409(h)(2)(A) of the act.

(2) If FDA objects to an FCN within the 120-day period for FDA review, the FCN will not become effective.

(3) FDA may object to an FCN if any part of FDA's 120-day review occurs during a period when this program is not funded as required in section 409(h)(5) of the act.

(d) If FDA and a manufacturer or supplier agree that the notifier may submit a food additive petition proposing the approval of the food contact substance for the use in the manufacturer's or supplier's FCN, FDA will consider that FCN to be withdrawn by the manufacturer or supplier on the date the petition is received by FDA.

§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

(a) If data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of the food contact substance is no

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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