

§ 170.103

for public disclosure if the FCN is withdrawn under §170.103; and on the date of publication in the FEDERAL REGISTER of an FDA determination that an FCN is no longer effective.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification, or submitted in reference to an effective FCN. 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 or to FDA's determination that an FCN is no longer effective, except information that is exempt 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.

[67 FR 35729, May 21, 2002, as amended by 89 FR 20315, Mar. 22, 2024]

§ 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 objecting to the FCN or FDA has issued an objection letter.

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§ 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) FDA may determine that an FCN is no longer effective if:

(1) Data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended