

§ 170.101

21 CFR Ch. I (4–1–13 Edition)

(1) A use of a food contact substance that is the subject of a regulation in parts 173 through 189 of this chapter; or

(2) A use of a food contact substance that is the subject of an exemption under the threshold of regulation process described in §170.39.

(c) A petition must be submitted under §171.1 of this chapter to authorize the safe use of a food contact substance in either of the following circumstances, unless FDA agrees to accept an FCN for the proposed use.

(1) The use of the food contact substance increases the cumulative dietary concentration to a certain level. For a substance that is a biocide (e.g., it is intended to exert microbial toxicity), this level is equal to or greater than 200 parts per billion in the daily diet (0.6 milligram (mg)/person/day). For a substance that is not a biocide, this level is equal to or greater than 1 part per million in the daily diet (3 mg/person/day); or

(2) There exists a bioassay on the food contact substance, FDA has not reviewed the bioassay, and the bioassay is not clearly negative for carcinogenic effects.

(d) A manufacturer or supplier for which a notification is effective must keep a current address on file with FDA.

(1) The current address may be either the manufacturer's (or supplier's) address or the address of the manufacturer's (or supplier's) agent.

(2) FDA will deliver correspondence to the manufacturer's or supplier's current address.

§ 170.101 Information in a premarket notification for a food contact substance (FCN).

An FCN must contain the following:

(a) A comprehensive discussion of the basis for the manufacturer's or supplier's determination that the use of the food contact substance is safe. This discussion must:

(1) Discuss all information and data submitted in the notification; and

(2) Address any information and data that may appear to be inconsistent with the determination that the proposed use of the food contact substance is safe.

(b) All data and other information that form the basis of the determination that the food contact substance is safe under the intended conditions of use. Data must include primary biological data and chemical data.

(c) A good laboratory practice statement for each nonclinical laboratory study, as defined under §58.3(d) of this chapter, that is submitted as part of the FCN, in the form of either:

(1) A signed statement that the study was conducted in compliance with the good laboratory practice regulations under part 58 of this chapter; or

(2) A brief signed statement listing the reason(s) that the study was not conducted in compliance with part 58 of this chapter.

(3) Data from any study conducted after 1978 but not conducted in compliance with part 58 of this chapter must be validated by an independent third party prior to submission to the Food and Drug Administration (FDA), and the report and signed certification of the validating party must be submitted as part of the notification.

(d) Information to address FDA's responsibility under the National Environmental Policy Act, in the form of either:

(1) A claim of categorical exclusion under §25.30 or §25.32 of this chapter; or

(2) An environmental assessment complying with §25.40 of this chapter.

(e) A completed and signed FDA Form No. 3480.

§ 170.102 Confidentiality of information in a premarket notification for a food contact substance (FCN).

(a) During the 120-day period of the Food and Drug Administration (FDA) review of an FCN, FDA will not disclose publicly any information in that FCN.

(b) FDA will not disclose publicly the information in an FCN that is withdrawn prior to the completion of FDA's review.

(c) Once FDA completes its review of an FCN, the agency will make its conclusion about the FCN publicly available. For example, if FDA objects to a notification 90 days after the date of receipt, the agency would make available its objection at that time.