§ 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.
(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.
Food and Drug Administration, HHS

§ 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