

UNITED STATES FOOD & DRUG ADMINISTRATION

Food Contact Substance Notification Program

OMB Control Number 0910-0495

Request for Non-material/non-substantive Modification:

The information collection supports the Food and Drug Administration's substance notification program and applicable regulations, forms, and agency guidance. Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a "food contact substance" as "*any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.*" Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

For efficiency of agency operations, we are requesting to incorporate related information collection activity currently approved in OMB control no. 0910-0298 and applicable to regulatory requirements found in 21 CFR 170.39 (*threshold of regulation for substances used in food-contact articles*) into this ICR. We have therefore added a new IC element corresponding with the regulation into our summary table to reflect 7 responses and 336 hours annually, burden we attribute to information collection activity under 21 CFR 170.39. Upon OMB approval, we intend to discontinue control no. 0910-0298.

Submitted: December 2025