

United States Food and Drug Administration

Registration of Food Facilities

OMB Control Number 0910-0502

Expiration Date: November 30, 2028

JUSTIFICATION MEMORANDUM FOR NON-SUBSTANTIVE CHANGE REQUEST

The Food and Drug Administration (FDA) is requesting a nonmaterial/non-substantive change request (83-C) to OMB control no. 0910-0502, “*Registration of Food Facilities*.” We are requesting to update Form FDA 3537, “*DHHS/FDA Food Facility Registration*” which includes the electronic version called the Food Facility Registration Module. FDA plans to make this change pursuant to its authority under section 415(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), which authorizes the Secretary to require food facility registrations to identify other food categories determined appropriate by the Secretary. The update involves creating subcategories for the food category for baby food. We intend to add three new subcategories under the existing “Baby (Infant and Junior) Food Products” category – a) Infant Formula (Powder), b) Infant Formula (Liquid), and c) Other Baby Food Products when respondents register or update their registrations with FDA. This enhanced categorization will allow FDA to respond more quickly and accurately to food safety emergencies by enabling targeted communications to specific types of infant formula manufacturers rather than all baby food facilities. Respondents already have this information readily available as part of its reporting activities for this information collection, and the change will entail no additional burden other than to identify the category of baby food. Therefore, we have made no adjustments to any of the IC elements. Accordingly, we are providing the draft paper form (see page 4) as well as screenshots of the related item in the system interface for OMB approval.

Dated: July 2026