

UNITED STATES FOOD & DRUG ADMINISTRATION

Quality Facility Attestation
Forms FDA 3942a and 3942b

OMB Control Nos. 0910-0751 and 0910-0854

Request for Non-substantive Change and Request to Discontinue:

Generally, domestic and foreign food facilities that are required to register under section 415 of the Food, Drug, & Cosmetic Act must comply with requirements for risk-based preventive controls mandated by the Food Safety Modernization Act (FSMA); however, the applicability of the requirements is not dependent upon whether a facility is required to register. (Information collection associated with registration of food facilities is approved under OMB control no. 0910-0502.) Agency regulations in 21 CFR parts 117 and 507 govern Current Good Manufacturing Practice (CGMP) for covered facilities and set forth provisions intending to implement risk-based preventive controls and minimize hazards associated with human foods and food for animals. A business that meets the definition of a “*qualified facility*” is subject to modified requirements of the preventive controls regulations. To meet the modified requirements, Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food) (as applicable) should be completed and submitted in accordance with instructions. To assist respondents in this regard, we issued the guidance document, “[Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals](#)” (September 2018). The guidance was issued consistent with our Good Guidance Practice regulations in 21 CFR part 10.115, which provide for public comment at any time. The guidance explains how to determine whether a business meets the definition of “*qualified facility*,” and that Forms FDA 3942a and 3942b are submitted electronically at <https://www.access.fda.gov/> via the Qualified Facility Attestation Module.

Information collection associated with the instruments discussed above is currently approved under OMB control no. 0910-0854, while information collection associated with requirements applicable to food for animals is currently approved under OMB control no. 0910-0789. In the [Federal Register](#) of March 16, 2021 (86 FR 14436), we published a 60-day notice to revise and extend information collection under OMB control no. 0910-0751 to include all related information collection activity. We are currently proceeding with a 30-day notice and submission to OMB. Because OMB control no. 0910-0854 expires July 31, 2021 however, we are requesting approval to consolidate information collection associated with the submission of Forms FDA 3942a and 3942b at this time. We have adjusted our burden estimate by 9,564 hours and 19,127 responses annually to account for the completion and submission of the forms. Upon OMB approval we will discontinue control no. 0910-0854. Upon submission of our request to revise and extend control no. 0910-0751, expiring October 31, 2021, we will make further adjustments as may be necessary as it pertains to 0910-0789 (food for animals), which also expires October 2021.

Submitted: July 2021