

Infant Formula Requirements

OMB Control Number 0910-0256

Expiration Date: April 30, 2018

JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST

November 3, 2016

Request

The Food and Drug Administration (FDA) is submitting this nonmaterial/non-substantive change request (83-C) for changes to an OMB approved information collection under OMB No. 0910-0256, "Infant Formula Requirements." We are requesting this change to allow manufacturers of infant formula to use an electronic system, in addition to the current system, to submit reports and notifications to FDA. The information to be submitted via the electronic system is the same as the currently approved system.

Background

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. The reporting requirements include submitting formulation information and notifying FDA when a batch of infant formula may be adulterated or misbranded. As currently approved, respondents submit paper-based documentation via mail and email to FDA's Center for Food Safety and Applied Nutrition (CFSAN). Respondents call FDA for notifications but then submit a follow-up report via mail or email.

Processing of paper-based or email submissions are time-consuming due to their volume and non-standardized format. The use of an electronic system to receive information will standardize information, eventually leading to reduced burden for respondents and faster processing and response times for FDA. FDA will continue to allow paper submissions for those respondents who may not have access to FDA's electronic system.