

Infant Formula Requirements
OMB Control No. 0910-0256

Justification for Non-substantive/Non-material Change:

Food and Drug Administration (FDA) regulations at 21 CFR Parts 106 and 107 set forth requirements for the development, manufacture, and labeling of infant formula. The requirements are intended to protect newborns who are at an increased risk of contracting diseases from contaminated food. Included among the requirements is the submission to FDA of specific reporting data corresponding to individual quality control measures intended to ensure the safety of and prevent against the adulteration of infant formula, as articulated in the regulations. To more efficiently process these submissions at the agency and reduce burden on respondents, we have developed DRAFT Form FDA 3978 entitled, “*Infant Formula Tracking Application*.” We developed Form FDA 3978 in response to informal industry requests to provide for electronic submissions. No new information will be collected using Form FDA 3978. Instead, it provides a standardized, electronic format that manufacturers may voluntarily use to submit required information to the agency. Because there are few respondents to the information collection, because we have used our informal communications with respondents to develop the alternative collection method, and because many of the current paper submissions are sent via e-mail, we believe this represents a non-substantive, non-material change. Approval of the existing information collection provisions under OMB Control No. 0910-0256 expires April 30, 2018. In the interim period, FDA would like to deploy Form FDA 3978 as a pilot measure such that those respondents who wish to utilize this reporting method may do so. Upon our request to extend the information collection in approximately one year, we can then evaluate its efficiency and refine, revise, or otherwise make improvements to the alternative reporting method. At this time, the agency has no plans to eliminate paper-reporting, but rather, we wish to provide an electronic alternative to respondents at the earliest opportunity.