

**OMB Control Number:** 0583-0144.

**Title of Clearance:** Requirements to Notify FSIS of Adulterated or Misbranded Products, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments

**Summary of Changes:**

FSIS is requesting a non-substantive change to add details to Supporting Statement A regarding the estimate of burden for notification of adulterated or misbranded product (9 CFR 418.2).

The currently approved collection provides the burden estimate for the information collected from official establishments when they notify the District Office that they have shipped or received adulterated products. The new module for Adulterated Product Monitoring in the FSIS Public Health Information System (PHIS) does not change the information collected, but rather serves to add an additional medium establishments may use to provide the information. In lieu of verbally providing the information to the District Office or the District Office via the onsite inspector, the establishment may elect to provide the same information via PHIS.

The burden estimate of 15 hours annually for notification of adulterated or misbranded product does not change. In order to clarify the methods by which notification from the establishments can occur, FSIS is adding the phrase “either verbally or electronically through the Public Health Information System” to the burden estimate statement.

The clarifying changes to Supporting Statement A are as follows:

The Agency estimates that 60 establishments will respond one time annually taking each establishment 15 minutes to notify the District Office (either verbally or electronically through the Public Health Information System) that it has either received or shipped into commerce adulterated or misbranded product for an annual total of 60 responses and 15 burden hours.

**NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT**

**(9 CFR 418.2)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Ests.	60	1	60	15	15