

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for the Revision of OMB Control Number 0910-0645 to Add Data Elements to the Reportable Food Registry Reports (RFR) and the Revision of OMB Control Number 0910-0643 to Add the Requirement for Grocery Stores to Post a One Page Notice

Request for Emergency Clearance

FDA's Center for Food Safety and Applied Nutrition (CFSAN) is requesting that 1) a Paperwork Reduction Act (PRA) package for the revision of OMB Control Number 0910-0645 to add data elements to the Reportable Food Registry reports and 2) a PRA package for the revision of OMB Control Number 0910-0643 to add the requirement for grocery stores to post a one page notice be approved using the emergency clearance process under 5 C.F.R. § 1320.13(a)(2)(i). Public harm is reasonably likely to ensue if the normal clearance procedures are followed.

Public Harm is Reasonably Likely to Occur if Normal Clearance Procedures are Followed

The FDA Food Safety Modernization Act (P.L. 111-353) (FSMA) requires FDA to collect additional information in the agency's Reportable Food Registry (RFR) reports that it requires for a food that poses the risk of a serious adverse health consequence or death to humans or animals, also referred to as a "reportable food." FSMA also requires FDA to generate one page notices from the reports to post on www.fda.gov for grocery stores to display to consumers when a reportable food has been sold in the store. If consumers are not notified that the grocery store has sold a reportable food, they may be at risk of consuming food that poses a risk of serious adverse health consequences or death.

If FDA receives the FSMA-required data elements, it will be able to issue the one page notice to prevent the public from potentially consuming hazardous food products that could cause serious adverse health consequences or death. In the absence of immediate approval of the new data elements, the Agency will not be able to issue one-page notices. The Agency will be at risk of not fulfilling its FSMA mandate and public harm is reasonably likely to occur.

FDA believes that public harm will occur if normal PRA clearance procedures are followed. In the six months or more it can take to obtain a full PRA clearance to authorize the new data elements and the new one page notice, a significant number of consumers could be exposed to serious adverse health consequences or death. FDA believes that these circumstances can be mitigated or prevented through prompt FDA generation of one-page notices based on the information provided by responsible parties. Accordingly, FDA is requesting that OMB use its emergency clearance process to **immediately approve** the PRA package requesting the revision of OMB Control Number 0910-0645 to add data elements to the Reportable Food Registry reports and the PRA package requesting the revision of OMB Control Number 0910-0643 to add the requirement for grocery stores to post a one page notice.



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