U.S. Food and Drug Administration

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control No. 0910-0865

November 1, 2019

Change Request (83-C)

The United States Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to request a change in the type of information collection currently approved under OMB's Electronic submission system, ROCIS. When this collection of information was approved by OMB's Authorizing Official Neomi Rao through the issuance of an OMB Notice of Office of Management and Budget Action (NOA) on February 8, 2019, it was thought that it had been approved as a generic collection. The NOA's terms of clearance stated, "FDA will submit individual collections under this generic clearance to OMB. Individual collections will also undergo review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Center for Food Safety and Applied Nutrition, and Paperwork Reduction Act (PRA) specialists. FDA will prepare a report during the OMB collection renewal summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance."

However, recent attempted submissions of individual generic packages were rejected by ROCIS because the collection under OMB Control Number 0910-0865 was not classified as a generic collection. Our ROCIS tech support technician, Julio Baez, indicated that FDA must create a new ICR for OMB Control No. 0910-0865 and instruct ROCIS to change the collection to a Generic ICR and obtain approval from OIRA. This change request is FDA's attempt to convert the previously approved OMB Control Number 0910-0865 from a regular collection to a generic collection.

The number of responses and burden hours previously approved by OMB for this collection will remain the same when converted from a regular to a generic collection – 93,744 responses and 10,498 burden hours.