

## **“Small Business Qualification Certification”**

**(OMB Control Number 0910-0508)**

### **Change Request (83-C)**

**August 30, 2016**

The Food and Drug Administration is submitting this change request (83-C) in order to make a non-substantial change to forms FDA 3602, “FY 2017 MDUFA Small Business Qualification and Certification For a Business Headquartered in the United States,” and 3602A, “FY 2017 MDUFA Foreign Small Business Qualification and Certification For a Business Headquartered Outside the United States,” which are approved under OMB control number 0910-0508.

We are requesting to add a box (2a) for the Organization ID number (Org ID) in order to assist FDA to process the application in a more efficient manner. We have also made conforming changes to the form instructions.

The organization number (Org ID) uniquely identifies the business in the FDA User Fee Website. The Org ID enables FDA to track information about Medical Device User Fee payments made by the respondent. The creation of the Org ID is not a new information collection, rather it is a system-generated number assigned to a new organization during the account creation process. By providing a reference to the Org ID on forms FDA 3602 and 3602A, FDA will be able to easily locate information already collected during the User Fee application process (approved under OMB control number 0910-0511) and, therefore, process forms FDA 3602 and 3602A more efficiently.

We do not expect the addition of box (2a) for the Org ID to change the estimated hour or cost burden of OMB control number 0910-0508.