UNITED STATES FOOD AND DRUG ADMINISTRATION
Non-substantive Change Request
OMB Control Nos. 0910-0508
Medical Device User Fee Small Business Qualification and Certification

Date: June 2026

**Request for Non-Substantive/Non-Material Change to an approved information collection:**

The Food and Drug Administration (FDA, us, we, or the agency) is requesting a non-substantive change to implement Form 3602N, "MDUFA Small Business Determination Request", as the FDA 3602 and FDA 3602A into a single webform, the "MDUFA Small Business Determination Request", the single consolidated submission for foreign and domestic businesses requesting MDUFA small business status.

Form FDA 3602N was approved as part of the currently approved revision package under OMB Control No. 0910-0508. Under the approved collection, FDA consolidated Forms FDA 3602 and FDA 3602A into a single form for use by both domestic and foreign businesses. This change request is being submitted to implement the finalized version of Form FDA 3602N and remove references to Forms FDA 3602 and FDA 3602A to the consolidated Form FDA 3602N.

The finalized form includes updates associated with electronic submission through the CDRH Customer Collaboration Portal (CDRH Portal), revised terminology and instructions, and fields associated with the registration fee waiver provisions under section 738(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Specifically, the form includes a section for businesses requesting a registration fee waiver based on financial hardship, including identification of previously registered facilities and submission of supporting bankruptcy documentation. These elements were previously described in the approved supporting statement and are already reflected in the approved burden estimate.

FDA is not requesting any changes to the currently approved reporting requirements, burden hours, or burden estimates associated with this collection. The changes reflected in this request are limited to implementation of the approved consolidated form, removal of references to Forms FDA 3602 and FDA 3602A, and related formatting and instructional updates associated with the electronic submission process.