UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device User Fee Program:

OMB Control Number 0910-0511

Request for Non-Substantive/Non-Material Change to an Approved Information Collection:

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), authorized FDA to establish a third-party inspection program for medical device facilities. Under the program (§ 704(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 374(g)), FDA may accredit persons to inspect qualified manufacturers of class II and class III devices. An eligible establishment is permitted to select any FDA-accredited person to conduct an inspection in lieu of an FDA inspection, but FDA must approve each selection. (See 21 USC 374(g)(1) and 374(g)(6)(B)). Referred to as the "third-party inspection" program, FDA publishes a complete list of accredited persons, and the activities for which they are accredited, on our website at Third Party Device Inspection, along with additional information about the AP Program. Device establishments interested in participating in the program may contact the FDA at CDRH_Accredited_Persons_Inspection@fda.hhs.gov.

Although we issued two guidance documents: "*Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria*," and "*Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA): Guidance for Industry, FDA Staff, and FDA*," in 2009 to assist respondents with the information collection; fewer than 10 persons have participated in the program. We withdrew the guidance documents in May 2021. Upon evaluation of the currently approved information collection inventory and for efficiency of agency operations therefore, we are requesting to include burden attributable to accreditation under our third party device inspection program – currently approved in OMB control no. 0910-0886 – with other activities related to our Medical Device User Fee Program. We have therefore adjusted the information collection to reflect an additional 1 response and 80 hours annually to account for potential requests for accreditation.

Relatedly, section 704(h) (21 USC 374(h)) of the FD&C Act provides for communications between FDA and respondents regarding establishment inspections. Specifically FDA provides non-binding feedback upon request following the inspection of an establishment other than for cause. Because the feedback pertains to and is requested only after the issuance of Form FDA 483 – *List of Observations*, we believe the associated information collection is not subject to review and approval by OMB under the PRA. We do, however, acknowledge the scope of coverage we intend for the information collection includes these requests. Upon OMB approval, we intend to discontinue control no. 0910-0886

Also for efficiency of agency operations, we are requesting to include burden associated with requests for information as discussed in the guidance document entitled, "*FDA and Industry Procedures for Section 513(g) Requests for Information under the -Federal Food, Drug, and Cosmetic Act*," (December 2019). Section 738 of the FD&C Act authorizes FDA to collect user fees for 513(g) requests for information. See section 738(a)(2)(A)(ix) ((21 U.S.C. 379j(a)(2)(A)(ix)). Instructions for submission and specific content elements are discussed in the guidance document in sections IV and V, respectively. Respondents may elect to utilize CDRH's e-STAR voluntary guided submission preparation tool for submission of the information, developed to improve submission consistency and enhance efficiency in the review process. Accordingly, we have added a new element to account for 118 responses and 1,416 hours annually attributable to 513(g) requests for information. Upon OMB approval of the non-substantive change request, we intend to discontinue control no. 0910-0705.

Submitted: March 2023