UNITED STATES FOOD & DRUG ADMINISTRATION

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

OMB Control No. 0910-0510

January 2021

Request for non-substantive, non-material change:

The Food and Drug Administration (FDA) requests consolidation of the information collection burden currently approved under OMB control number 0910-0569, into the information collection associated with FDA's Inspection by Accredited Persons Program, approved under OMB Control Number 0910-0510.

Background on the AP Program and Associated Information Collection

Under section 704(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374(g)), as amended by section 201 of the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007, FDA established a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. Under the Inspection by Accredited Persons Program (or AP Program), eligible manufacturers may elect to have third parties that have been accredited by FDA (Accredited Persons) conduct some of their inspections instead of FDA. This is a voluntary program.

OMB Control Number 0910-0510 supports the requirements of section 704(g) of the FD&C Act, as amended, including the request to become an Accredited Person under the AP Program. The guidance document "*Guidance for Industry, FDA Staff, and Third Parties – Inspection by Accredited Persons under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007: Accreditation Criteria*" describes, among other things, the information an applicant should include in their request for accreditation to demonstrate that they meet the qualifications necessary to become an Accredited Person.

Under section 510(h) of the FD&C Act (21 U.S.C. 360(h)), domestic manufacturers of class II or class III medical devices are subject to inspection for compliance with the Quality System Regulations (21 CFR Part 820) and other applicable requirements. The AP Program permits eligible manufacturers to use Accredited Persons to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person. Currently, OMB Control Number 0910-0569 supports notification to FDA of a manufacturer's intent to use an Accredited Person under the AP Program.

To assist respondents, FDA developed the guidance document, "*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*." The guidance provides recommendations to respondents on notifying FDA of their intent to request inspection under the AP

Program. The information submitted to FDA in the notification is used to determine whether respondents satisfy the eligibility criteria for participation in the AP Program.

Request for Consolidation of OMB Control Nos. 0910-0510 and 0910-0569

Because these two information collections are related to the same program, authorized under section 704(g) of the FD&C Act, we believe the estimated burdens described above are most appropriately expressed under one ICR. Additionally, this consolidation may increase administrative efficiency by reducing FDA's active ICR inventory. Therefore, we request the addition of the information collection in OMB Control No. 0910-0569 to OMB Control No. 0910-0510. Upon approval of this consolidation, we would then terminate OMB Control No. 0910-0569.

A Note Regarding the Guidance Documents

As noted on the coversheet for both guidance documents described above, the FDA Reauthorization Act of 2017 (FDARA), signed into law on August 18, 2017, amended several sections of the FD&C Act. The guidance documents were developed and issued prior to the enactment of FDARA, and certain sections may no longer be current as a result. FDA is assessing how to revise the guidance documents to represent our current thinking on this topic.

We note that, while the guidances are intended to assist respondents regarding the AP Program, section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements an Accredited Person must meet. Section 704(g) also provides for a manufacturer's notice of their intention to use an Accredited Person to conduct inspections and provides the other conditions for a device establishment to be eligible for inspection by Accredited Persons. Further, a person who intends to participate in the AP Program can, under section 704(g) of the FD&C Act, request accreditation to conduct inspections or provide notice of their intention to use an Accredited Person to perform inspections.

Therefore, we regard section 704(g) of the FD&C Act to be the primary collection instrument for both OMB Control No. 0910-0510 and 0910-0569. We have edited the supporting statement for OMB Control No. 0910-0510 to reflect that section 704(g) is the primary collection instrument.

Resultant Burden Estimate

The burden estimate for requests for accreditation is based on the number of applications we've received to date. We have not changed this estimate.

We request the addition of "Notification of the intent to use an Accredited Person" to OMB Control No. 0910-0510. We have not changed the burden estimate from what is currently approved under OMB Control No. 0910-0569 for this information collection.

The following burden table reflects the consolidation of these two ICRs:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Request for accreditation	1	1	1	80	80
Notification of the intent to use an Accredited Person	10	1	10	15	150
Total			11		230