



United States Food and Drug Administration

Laboratory Accreditation for Analyses of Foods

OMB Control No. 0910-0898

SUPPORTING STATEMENT

## **Part A: Justification**

### 1. Circumstances Making the Collection of Information Necessary

This information collection helps to support implementation of Food and Drug Administration (FDA or we) statutory and regulatory authority governing our laboratory accreditation for analysis of foods program under Section 422 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([21 U.S.C. 350k](#)) and [21 CFR part 1, subpart R](#). FDA has statutory authority to establish a program for the testing of food by accredited laboratories; to establish a publicly available registry of recognized accreditation bodies and laboratories recognized by an accreditation body; and to require reports of any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory.

The Laboratory Accreditation for Analysis of Foods (LAAF) regulations contains eligibility requirements for accreditation bodies to qualify for FDA recognition and requirements that accreditation bodies must meet once recognized, such as requirements related to assessing and overseeing laboratories, conflicts of interest, reporting, and records. The regulations also contains eligibility requirements for laboratories to qualify for LAAF-accreditation by a recognized accreditation body and requirements that laboratories must meet once LAAF-accredited, such as requirements related to conflicts of interest, analysis, reporting, and records. These requirements help ensure the effectiveness of the recognized accreditation bodies and LAAF-accredited laboratories under this program. These regulations contains procedures to recognize accreditation bodies under this program and procedures for accreditation bodies to follow to accredit LAAF laboratories under this program.

The laboratory accreditation program helps fulfill FDA's mandate to ensure the safety of the U.S. food supply and protect U.S. consumers by administering appropriate oversight of certain food testing that is of importance to public health. It also helps ensure that the testing is done in accordance with appropriate model standards, which helps to produce consistently reliable and valid test results. You may access additional information about the laboratory accreditation program at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fda-recognized-accreditation-bodies-laboratory-accreditation-analyses-foods-laaf-program>. The public registry is available at <https://datadashboard.fda.gov/ora/fd/laaf.htm>.

We therefore request OMB approval for the information collection provisions found in 21 CFR part 1, subpart R, and discussed in this supporting statement.

### 2. Purpose and Use of the Information Collection

The laboratory accreditation program assists in fulfilling FDA's mandate to ensure the safety of the U.S. food supply and protect U.S. consumers by administering appropriate oversight of certain food testing that is of importance to public health. It also helps ensure that the testing is done in accordance with appropriate model standards which helps to produce consistently reliable and valid test results.

Respondents to the information collection are accreditation bodies seeking recognition from FDA, recognized accreditation bodies, laboratories seeking accreditation from recognized accreditation bodies, and accredited laboratories. Participation in this program is voluntary for laboratories and accreditation bodies; however only recognized accreditation bodies are able to accredit laboratories to conduct food testing as specified in the regulations.

### 3. Use of Improved Information Technology and Burden Reduction

The regulations require respondents to maintain and electronically submit certain test results, reports, notifications, and other records to FDA.

We are clarifying that the information collection includes the use of an electronic information collection system. Respondents submit applicable information through the FURLS Laboratory Accreditation for Analyses of Foods Program portal (FDA Industry Systems) The portal is used for the Accreditation Bodies and LAAF-Accredited Laboratories utilize the portal to submit data for the program. The Accreditation Bodies submit data about the laboratories that they have assessed and the corresponding accreditation data. Accredited Laboratories utilize the portal to submit validation and verification data for the program. The FDA LAAF portal user guides can be found on the LAAF webpage at: <https://www.fda.gov/media/156097/download?attachment> (Step-by-Step Instructions for an Accreditation Body to Apply for and Manage Recognition Status in the Program) and <https://www.fda.gov/media/161685/download?attachment> (Step-by-Step Instructions for an Accredited Laboratory to Manage Accreditation Status in the Program). Respondents are required to report electronically (100% electronic reporting).

### 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

### 5. Impact on Small Businesses or Other Small Entities

Although we estimate that all respondents to the information collection are small businesses, we do not believe it poses undue burden on those entities. At the same time, FDA offers small business assistance through resources on our website at: [www.fda.gov/industry/small-business-assistance](http://www.fda.gov/industry/small-business-assistance).

### 6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with current statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Section 422(a)(7) of the FD&C Act provides that FDA shall reevaluate accreditation bodies recognized under the program no less than once every 5 years. Accordingly, the regulations provide for such a record retention schedule in 21 CFR 1.1124.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of August 15, 2024 (89 FR 66417). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent provided by law.

*The Privacy Act of 1974*

In preparing this supporting statement, we consulted with the FDA Privacy Office to ensure appropriate handling of information collected. This information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. Information is collected when LAAF-accredited laboratories submit information about the qualifications of laboratory analysts, such as a curriculum vitae, and documentation of an individual sampler's qualifications. The PII submitted is assumed to include typical curriculum vitae content such as name and contact information and professional background. This is collected in the context of the individual's professional capacity. The purpose of the collection is to help ensure that persons involved in the collection and analysis of food testing samples are qualified to perform those tasks. These information collections are described in 21 CFR §§ 1.1149(a)(1) and 1.1152(d)(12).

We determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to retrieve records from the information collected.

*Freedom of Information Act*

The collection does not specify confidentiality. However, reports and records submitted to FDA are subject to FDA regulations on the release of information found in 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA in accordance

with sections 5 U.S.C. 552(a) and (b) and by 21 CFR part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Table 1--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Part 1, Subpart R citation; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 1.1113 and 1.1114; Accreditation bodies (ABs) application for recognition (one-time submission)	8	44	352	2.2068 (2 hours and 12 minutes)	776.8
§§ 1.1113 and 1.1114; ABs-- application for renewal of recognition					
§ 1.1123; ABs-- reports, notifications, and documentation requirements					
§ 1.1116(a) and (b); ABs-- notices of intent to relinquish, records custodian	1	3	3	3	9

§§ 1.1138 and 1.1139; laboratories--submission of application for LAAF-accreditation (one-time submission)	160	63.5	10,160	1.8051 (1 hour and 49 minutes)	18,340
§§ 1.1149(a) and 1.1152(c)(1), (2); laboratories--submission of sampling plan, sample collection report, and sampler qualifications					
§§ 1.1152(d) and 1.1153(a); laboratories--qualification to submit abridged analytical reports (one-time submission)					
§ 1.1153; laboratories--abridged analytical reports submissions					
§ 1.1149(c); laboratories--advance notice of sampling submissions					
§ 1.1152(f); laboratories--immediate notification					
§ 1.1140(a); laboratories – notices of intent to relinquish, records custodian	2	3	6	1	6
§ 1.1152(c)(4) and (5); laboratories--validation and verification studies submissions	50	5	250	1.5 (1 hour and 30 minutes)	375
§§ 1.1142; 1.1171; 1.1173; and 1.1174; requests in response to FDA action	1	1	1	1	1
Total			10,772		19,508

Totals may not sum due to rounding.

*Reporting:* We estimate a total of 160 respondents that are laboratories participating in the program. We also estimate that 5 to 80 accreditation bodies could apply for FDA recognition under the regulations and to date, the program has received 8 applications for FDA recognition. In this analysis, we annualize the one-time submission burden using a 3-year

period horizon, for an annualized one-time reporting burden of 6,560 hours. Cumulatively, this results in a total annual reporting burden of 19,508 hours, as reflected in table 1.

Section 1.1114 requires an accreditation body seeking initial recognition to submit an application to FDA demonstrating it meets the eligibility requirements described in § 1.1113. The burden to prepare and submit an application is an initial burden and, once realized, would apply only to respondents new to the program. We estimate this process would take one analyst between 40 and 80 hours to compile all the relevant information, prepare for an assessment, complete the initial application process, and submit the application. For this analysis we assume a middle value of 60 hours. Section 1.1114 requires a recognized accreditation body to apply for renewal of recognition at least every 5 years. We believe renewal would take less time than an initial application because much of the information will have already been compiled and therefore assume between 20 and 40 hours. For this analysis we use a middle value and calculate that each recognized accreditation body spends 30 hours every 5 years to complete and submit an application for renewal of its recognition. This results in 6 hours per year ( $30 \text{ hours} \div 5 \text{ years}$ ) for each accreditation body. Section 1.1123 requires a recognized accreditation body to submit certain reports, notifications, and documentation to FDA, including significant changes affecting its accreditation program or the accreditation status of laboratories it LAAF-accredits, and ensure FDA has access to these and other records. In all, we estimate recognized accreditation bodies would incur a burden of 3.66 hours per month, or 44 hours per year, complying with the reporting requirements of § 1.1123 and the recordkeeping requirements of § 1.1124. For this analysis, we estimate 44 hours (i.e., 2 hours and 12 minutes or 2.2068 hours as the average burden per response per month). Annually, this results in 776.8 hours ( $8 \text{ recognized accreditation bodies} \times 44 \text{ responses per accreditation body} \times 2.2068 \text{ hours per response}$ ), as reflected in row 1.

Section 1.1116 requires that if a recognized accreditation body voluntarily chooses to relinquish or not renew its recognition, it must notify FDA and the laboratories it LAAF-accredits of its intention to depart the program at least 60 days ahead of the departure. The recognized accreditation body must also provide FDA with the name and contact information of the custodian who maintain and make available to FDA requisite program records. We estimate a 1% voluntary departure rate, which equates to the departure of 1 recognized accreditation body annually. We estimate it would take a recognized accreditation body three hours for each of the three required notices. Accordingly, with rounding, the estimate for the burden associated with § 1.1116 is 9 hours ( $1 \text{ recognized accreditation body} \times 3 \text{ notices} = 3 \text{ annual responses}$ , which rounds to 3;  $3 \text{ annual response} \times 3 \text{ hours} = 9 \text{ total hours}$ ), as reflected in row 2.

Section 1.1139 requires a laboratory seeking LAAF-accreditation to submit an application to a recognized accreditation body, demonstrating that it meets the eligibility requirements specified in § 1.1138. Section 1.1152(a) through (e) requires a LAAF-accredited laboratory to submit test results of testing required to be conducted under the LAAF program and include supporting documentation. As discussed in our supporting statement, only a percentage of that testing would be defined as information collection under the PRA. Section 1.1152(c)(1) requires a LAAF-accredited laboratory to submit a sample collection plan and sample collection report (the contents of which are described in § 1.1149(a)) with each test result.

Under § 1.1152(c)(2), a LAAF-accredited laboratory must include documentation of the sampler's qualifications the first time the sampler collects a sample. Section 1.1153(a) allows a LAAF-accredited laboratory to qualify to submit abridged analytical reports in lieu of full analytical reports. We estimate this as a one-time burden, but we may revisit this assumption in the future based on actual rates of revocation of permission to submit abridged analytical reports.

Under section 1.1149(c), FDA may require under certain circumstances, that a LAAF-accredited laboratory submit an advance notice of sampling to FDA before each of the next several occasions that the sampler collects a sample that the LAAF-accredited laboratory analyzes under the LAAF program. We assume that it would take a laboratory analyst between one and two hours to compile and submit the required information, and we assume that between one percent and five percent of all test results submitted annually under the LAAF program is subject to the advance notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Section 1.1152(f) requires a LAAF-accredited laboratory to notify FDA and the recognized accreditation body of any changes that affect the laboratory's LAAF-accreditation. Note, however, that a LAAF-accredited laboratory is not required to notify FDA of changes that the recognized accreditation body must provide to FDA under § 1.1123(d). As a conservative estimate, we assume that each LAAF-accredited laboratory has some change requiring notification of its recognized accreditation body, and for half of those changes the LAAF-accredited laboratory will also need to notify FDA.

In all, we estimate 160 laboratories apply and assume it would take one analyst an average of one hour and 49 minutes (1.8051 hours) to compile all the relevant information, with an estimated 63.5 response per laboratory. Annually, this results in 18,340 hours (160 laboratories × 63.5 responses per laboratory × 1.8051 hours per response), as reflected in row 3.

Section 1.1140 provides that if a laboratory voluntarily chooses to relinquish or not renew its LAAF-accreditation, it must notify FDA and its recognized accreditation body of its intention to do so at least 60 days ahead of the departure. If the laboratory is voluntarily relinquishing or not renewing all methods within its scope, it must also provide FDA with the name and contact information of the custodian who maintains and makes available to FDA requisite program records. We estimate a 1% program departure rate, which equates to the departure of 1.60 LAAF-accredited laboratories each year, which we round to 2. We estimate it would take a laboratory one hour for each of the three required notices. Accordingly, we estimate a burden of 6 hours per year under § 1.1140 (2 laboratories × 3 notices = 6 annual responses; 6 annual responses × 1 hour = 6 total hours), as reflected in row 4.

Section 1.1152(c)(4) and (5) require a LAAF-accredited laboratory to submit verification and validation studies to FDA as part of an analytical report. We estimate it would take a laboratory one and a half hours (1.5 hours) for each of the five required reports. Accordingly, we estimate a burden of 375 hours per year under Section 1.1152(c)(4) and (5) (50 laboratories × 5 reports = 250 annual responses; 250 annual responses × 1.5 hours = 375 total hours), as reflected in row 5.

Sections 1.1142, 1.1171, 1.1173, and 1.1174 provide for requests to FDA. Specifically, § 1.1142 provides for requests for reinstatement of LAAF accreditation; § 1.1171 provides for requests for reconsideration of denials; and §§ 1.1173 and 1.1174 provide for requests for hearings. We estimate a cumulative total of 1 respondent and 1 burden hour, as reflected in row 6.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR part 1, subpart R; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 1.1113; recordkeeping associated with ISO/IEC 17011:2017  § 1.1124; ABs--additional recordkeeping requirements a recognized accreditation body must maintain, for 5 years after the date of creation of the records, records created while it is recognized demonstrating its compliance with this subpart	8	2	16	22	176
§ 1.1138; laboratories--becoming accredited to ISO/IEC 17025:2017 (one-time); Laboratories adding ISO 17025 to become LAAF-accredited.	9	1	9	91.06 (91 hours and 4 minutes)	820

21 CFR part 1, subpart R; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 1.1138; laboratories-- maintaining ISO/IEC 17025: 2017 accreditation  § 1.1154; laboratories— additional recordkeeping requirements; a LAAF- accredited laboratory must maintain, for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart	160	2	320	450.765 (450 hours and 46 minutes)	144,245
Total			345		145,241

<sup>1</sup> Totals may not sum due to rounding.

Recordkeeping: We estimate the annual recordkeeping requirements be 145,241, as reflected in table 2.

Section 1.1113 requires a recognized accreditation body to meet the requirements of ISO/IEC 17011:2017. While ISO/IEC 17011:2017 includes recordkeeping requirements, as noted above, we know that all 8 of the accreditation bodies that have become recognized currently adhere to ISO/IEC 17011:2017. We therefore regard these activities as usual and customary; however, we include a place holder of one response and one burden hour for each respondent, for a total of 8 hours. Section 1.1124 requires maintenance of certain records in addition to those required by ISO/IEC 17011:2017. We estimate that a recognized accreditation body incur a burden of 12 hours per year to comply with both the recordkeeping requirements of § 1.1124 and the reporting requirements of § 1.1123. For this analysis, we identify the recordkeeping and reporting burdens separately, assuming 21 of those annual hours would be spent complying with the recordkeeping requirements of § 1.1124. Thus, the annual recordkeeping burden for the 8 recognized accreditation bodies to meet the additional recordkeeping requirements of § 1.1124 would be 168 hours. We combined the estimated burden of the aforementioned sections for a total of 176 hours as reflected in row 1.

Section 1.1138 requires a laboratory to be ISO/IEC 17025:2017-accredited, including meeting its recordkeeping requirements, to become LAAF-accredited under the regulations. We estimate that 7 to 10 laboratories not currently accredited to ISO/IEC 17025:2017 would become so accredited to participate in the LAAF program. For this estimate, we assume the middle value of 8.5 laboratories, which we round up to 9, would become ISO/IEC 17025-accredited to participate in the LAAF program. The burden to become ISO/IEC 17025:2017-

accredited is an initial burden and, once realized, would apply only to respondents becoming accredited to ISO/IEC 17025:2017 to participate in the LAAF program. We estimate that it would take a mean of 91.06 hours for the associated recordkeeping activities. In this analysis, we annualize this recordkeeping burden using a 3-year period horizon, for an annualized recordkeeping burden of 820, as reflected in row 2.

Section 1.1138 requires a LAAF-accredited laboratory to maintain conformance with ISO/IEC 17025:2017, including its recordkeeping requirements. Section 1.1154 requires maintenance of certain records in addition to those required by ISO/IEC 17025:2017. We estimate that a LAAF-accredited laboratory incurs a burden of about 1 hour per month (450 hours and 46 minutes per year) to maintain accreditation and comply with the recordkeeping requirements in §§1.1138 and 1.1154. This results in an annual burden of 144,245 hours, as reflected in row 3.

The **total burden** for this ICR is 167,749 hours.

#### *12b. Annualized Cost Burden Estimate*

We estimate that the annualized reporting cost burden under the regulations would be \$1,535,568.04 (see Table 3 below) and the annualized recordkeeping cost burden under the regulations would be \$11,887,310.64 (see Table 4 below), for a total annualized information collection burden cost estimate of \$13,422,878.68.

We believe that recordkeeping and reporting requirements of the information collection are conducted by personnel with differing wage rates. With respect to the reporting burden on accreditation bodies:

- We assume the reporting burden on accreditation bodies to apply for recognition or apply for renewal of recognition under §§ 1.1113 and 1.1114 to be conducted by personnel at the level of a Lawyer, as reported in the Bureau of Labor Statistics, May 2023 National Occupational Survey under occupation code 23-1011. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of \$169.68 for a Lawyer.
- We assume the reporting burden on accreditation bodies under § 1.1123 (reports, notifications, and documentation requirements) to be conducted by accreditation body personnel at the level of Microbiologist, as reported in the Bureau of Labor Statistics, May 2023 National Occupational Survey under occupation code 19-1022. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of \$89.78 for a Microbiologist.

With respect to the reporting burden on laboratories:

- We assume the reporting burden on laboratories under §§ 1.1138 and 1.1139 (the application for accreditation) to be conducted by laboratory personnel at the level of a Food Scientist and Technologist as reported in the Bureau of Labor Statistics, May

2023 National Occupational Survey under occupation code 19-1012 at the fully loaded hourly wage of \$84.96.

- We assume the reporting burden on laboratories under §§ 1.1149, 1.1152, and 1.1153 (submission of sampling plans, sample collection reports, sampler qualifications, analytical reports (including qualifying to submit abridged analytical reports and submission of abridged analytical reports), validation studies, verification studies, and advance notices of sampling) to be conducted by laboratory personnel at the level of a Food Scientist and Technologist, as reported in the Bureau of Labor Statistics, May 2023 National Occupational Survey under occupation code 19-1012. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of \$84.96 for a Food Scientist and Technologist.

With respect to the recordkeeping burden on accreditation bodies:

- We assume the recordkeeping burden on accreditation bodies under § 1.1124 (the recordkeeping requirements in addition to those of ISO/IEC 17011:2017) to be conducted by accreditation body personnel at the level of Microbiologist, as reported in the Bureau of Labor Statistics, May 2023 National Occupational Survey under occupation code 19-1022, at the fully loaded hourly wage of \$89.78.

With respect to the recordkeeping burden on laboratories:

- We assume the recordkeeping burden on laboratories under § 1.1138 (attaining and maintaining ISO/IEC 17025:2017-accreditation) and § 1.1154 (additional recordkeeping requirements) to be conducted by laboratory personnel at the level of Food Scientist and Technologist as reported in the Bureau of Labor Statistics, May 2023 National Occupational Survey under occupation code 19-1012, at the fully loaded hourly wage of \$84.96.

Type of Respondent	Total Burden Hours	Fully Loaded Hourly Wage	Total Respondent Costs
Lawyer	94.4	\$169.68	\$16,017.79
Microbiologist	294	\$89.78	\$26,395.32
Food Scientist and Technologist	19,508	\$84.96	\$1,657,399.68
<b>Total</b>			<b>\$ 1,699,812.79</b>

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Microbiologist	88	\$89.78	\$7,900.64
Food Scientist and Technologist	145,241	\$84.96	\$12,339,675.36
<b>Total</b>			<b>\$12,347,576</b>

### 13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

### 14. Annualized Cost to the Federal Government

Implementing the laboratory accreditation for analyses of food program requires allocating agency resources to administer the process, including the maintenance of the program, program administration document review, analytical data review, and information technology costs. Program coordinators and laboratory analysts will perform the work.

We base our estimate for personnel costs on the hourly rates for two full-time program administrative employees (one GS-14, one GS-13) and the three full time laboratory analysts performing data package reviews (2 GS-12 and one GS-13). GS levels for the Program Coordinators and laboratory analysts The estimates (based on the General Schedule locality pay table for Denver) are as follows:

- Two full-time employees at the GS-12/Step 3 level, which is \$49.41 per hour
- Two full-time employees at the GS-13/Step 3 level, which is \$58.76 per hour
- One full-time employee at the GS-14/Step 3 level, which is \$69.44 per hour
- Average hourly wage:  $((2 \times \$49.41) + (2 \times \$58.76) + \$69.44) \div 5 = \$57.16$

We also estimate the average annual IT cost for this program to be \$370,000 per year.

Thus, we estimate that the annual cost to the federal government would be approximately \$798,700 (5 FTEs  $\times$  1,500 hours  $\times$  \$57.16/hour (average hourly wage) + \$370,000 IT).

### 15. Explanation for Program Changes or Adjustments

Based on the number of applicants, we are able to more accurately calculate the number of food testing laboratories seeking accreditation and as a result the number of respondents to the information collection decreased (from 170 respondents in the currently approved collection to 160 respondents). Consequently, we have adjusted our burden estimate, which results in a decrease of 227 responses and 9,303 burden hours from the currently approved information collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Consistent with 21 CFR 1.1109 and provisions in section 422(a)(1)(B) of the FD&C Act, FDA maintains on its website a publicly available registry of recognized accreditation bodies and LAAF-accredited laboratories. The registry can be accessed at <https://datadashboard.fda.gov/ora/fd/laaf.htm>.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The regulations incorporate proprietary standards, and the OMB control number and expiration date do not appear on those documents. Specifically, the following proprietary standards are incorporated by reference:

- ISO/IEC 17011:2017, “*Conformity Assessment--Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies,*” Second edition, November 2017; and
- ISO/IEC 17025:2017, “*General Requirements for the Competence of Testing and Calibration Laboratories,*” Third edition, November 2017.

These standards may be examined at FDA’s Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. The standards are available for purchase from the International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, +41 22 749 01 11, central@iso.org (<https://www.iso.org/store.html>) or from any other source from which the user is assured that the copy to be received is an accurate version of the standard.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.