UNITED STATES FOOD & DRUG ADMINISTRATION

Laboratory Accreditation for Analyses of Foods

OMB Control No. 0910-0898

RIN: 0910-AH31

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

   This information collection supports agency rulemaking. The FDA Food Safety Modernization Act ("FSMA") (Public Law 111-353) section 202(a) added section 422 (codified at 21 U.S.C. 350k) to the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Section 422 of the FD&C Act requires FDA 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 to the Secretary of any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory. Accordingly, we are proposing regulations in 21 CFR part 1 subpart R: *Laboratory Accreditation for Analyses of Foods*. 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 would be able to accredit laboratories to conduct food testing as specified in the regulations.

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

2. Purpose and Use of the Information Collection

   Establishing the laboratory accreditation program will help 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 will also help ensure that the testing is done in accordance with appropriate model standards which will help produce consistently reliable and valid test results.

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 currently planning and developing information technology system improvements to facilitate the information collection for both FDA and respondents.

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.

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 establish 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 44 U.S.C. 3505(c)(2)(B), we published a notice of proposed rulemaking in the Federal Register of November 4, 2019 (84 FR 59452) soliciting public comment on the information collection. In response to requests from interested parties, we extended the comment period to July 6, 2020 (see 85 FR 11893 and 85 FR 19114) to provide additional time for public comment. Although about 70 comments were received in response to the proposed rulemaking, none suggested that FDA revise its burden estimate of the information collection or offered alternative figures. A small number of comments suggested that only 8-10 accreditation bodies would apply to be recognized based on experience with accreditation bodies that participate in the Accredited Third-Party Certification program. As a result of the comments regarding accreditation body participation and upon further review of laboratories that currently conduct food testing covered by the regulations, we have adjusted the number of respondents to better reflect our estimates of the number of accreditation bodies (4) and laboratories (170) that may decide to participate. The change in the number of respondents also impacted the number of responses per respondent for recognized accreditation bodies under § 1.1123, which increased from 12 to 48 in the final rule to account for fewer recognized accreditation bodies submitting reports regarding a greater number of LAAF-accredited laboratories. We included additional reporting burden for §§ 1.1116 and 1.1140 to account for notices of intent to relinquish recognition and LAAF-accreditation, respectively. We also included recordkeeping burden for LAAF-accredited laboratories §1.1154 which was inadvertently omitted from the proposed rule supporting statement.

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

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.

Privacy Act

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 expected 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.

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

21 CFR Part 1, Subpart R citation; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§§ 1.1113 and 1.1114; Accreditation bodies (ABs) application for recognition (one-time submission)	4	1	4	20	80
§§ 1.1113 and 1.1114; ABs-- application for renewal of recognition	4	1	4	3.6	14.4
§ 1.1116(a) and (b); ABs-- notices of intent to relinquish, records custodian	0	3	0	3	0
§ 1.1123; ABs-- reports, notifications, and documentation requirements	4	42	168	1.75	294
§§ 1.1138 and 1.1139; laboratories-- submission of application for LAAF-accreditation (one-time submission)	170	1	170	20	3,400
§ 1.1140(a); laboratories – notices of intent to relinquish, records custodian	2	3	6	1	6
§§ 1.1149(a) and 1.1152(c)(1), (2); laboratories--submission of sampling plan, sample collection report, and sampler qualifications	170	25	4,250	1.75	7,437.5
§§ 1.1152(d) and 1.1153(a); laboratories--qualification to submit abridged analytical reports (one-time submission)	170	10	1,700	2	3,400
§ 1.1153; laboratories--abridged analytical reports submissions	170	25	4,250	1.16	4,930
§ 1.1152(c)(4) and (5); laboratories-- validation and verification studies submissions	9	1	9	.25 (15 mins.)	2.25
§ 1.1149(c); laboratories--advance notice of sampling submissions	170	1	170	1.5	255
§ 1.1152(f); laboratories--immediate notification	170	1.5	255	.25	63.75
§§ 1.1142; 1.1171; 1.1173; and 1.1174; requests in response to FDA action	1	1	1	1	1
Total			0		19,883.9

Reporting: Consistent with estimates in our final regulatory impact analysis (FRIA) (see section II.F, Costs of this Rule), we estimate a total of 174 respondents. We estimate that 5 to 80 accreditation bodies could apply for FDA recognition under the regulations and assume that 4 accreditation bodies will apply for FDA recognition. We estimate 170 laboratories will participate in the program. The reporting burden includes a burden of 20,640 hours associated with one-time submissions. In this analysis, we annualize the one-time submission burden using a 3-year period horizon and zero percent discount rate, for an annualized one-

time reporting burden of 6,880 hours. Cumulatively, this results in a total annual reporting burden of 19,883.9 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. Also for this analysis, we use a 3-year period horizon and zero percent discount rate to convert the one-time submission burden to an annualized figure (i.e., 60 hours ÷ by 3 = 20 hours). Annually this results in 80 hours of burden for initial applications submitted by 4 accreditation bodies (4 applications × 20 hours per application), as reflected in row 1.

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 will spend 30 hours every 5 years to complete and submit an application for renewal of its recognition. This results in 6 hours per year (30 hours ÷ 5 years) for each accreditation body. Because we use a 3-year period horizon and zero percent discount rate for this analysis, we annualize that figure to three-fifths or 3.6. We multiply this figure by 4 accreditation bodies for a total of 14.4 hours annually for the submission of renewal of applications (4 applications × 3.6 hours per application), as reflected in row 2.

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 will maintain and make available to FDA requisite program records. We estimate a 1% voluntary departure rate, which equates to the departure of 0.04 recognized accreditation body annually. We estimate it would take a recognized accreditation body one hour for each of the three required notices. Accordingly, with rounding, the estimate for the burden associated with § 1.1116 is zero (0.04 recognized accreditation body × 3 notices = .12 annual responses, which rounds to 0; 0 annual response × 3 hours = 0 total hours), as reflected in row 3.

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. We estimate recognized accreditation bodies would incur a burden of 3.5 hours per month, or 42 hours per year, complying with the reporting requirements of § 1.1123 and the recordkeeping requirements of § 1.1124. For this analysis, we identify recordkeeping and reporting burdens separately and assume 21 of the 42 hours (i.e., 1.75 hours per month) would be spent meeting the reporting requirements of §

1.1123. Annually, this results in 294 hours (4 recognized accreditation bodies × 42 responses per accreditation body × 1.75 hours per response), as reflected in row 4.

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. We estimate 170 laboratories will apply and assume it would take one analyst an average of 60 hours to compile all the relevant information; however, we regard the burden as a one-time burden and therefore have annualized it by 3 years (20 hours annually). This results in an annual reporting burden for initial applications by 170 laboratories would be 3,400 hours (170 applications × 20 hours per application), as reflected in row 5.

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 will maintain and make available to FDA requisite program records. We estimate a 1% program departure rate, which equates to the departure of 1.70 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 6.

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. For this analysis we assume a mean figure of 4,065 test result and supporting documentation submissions (4,065.2 rounded to the nearest integer) as the basis for factoring a corresponding information collection burden. This figure is derived using lower and upper bound estimates of submissions we expect under the regulations. To allow for adjustment and potential increase we have added 50 submissions for a total of 4,115.

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. We assume that it would take 30 minutes to 1 hour to compile a sampling plan, 30 minutes to 1 hour to compile a sample collection report, and an average of 10 to 20 minutes to obtain the sampling plan, sample collection report, and sampler's qualifications. Using a middle value of 1.5 hours to generate the sampling plan and the sample collection report, and a middle value of 15 minutes (.25 hours) to obtain those two documents and documentation of the sampler's qualifications, we calculate a total of time per test results of 1.75 hours (1.5 + .25). When multiplied together the total reporting burden for the submission of sampling plans, sample collection reports, and sampler qualification requirements (170 accredited laboratories × 25 sampling plans and sample collection reports × 1.75 hours) is 7,437.5 hours, as reflected in row 7.

Section 1.1153(a) allows a LAAF-accredited laboratory to qualify to submit abridged analytical reports in lieu of full analytical reports. We expect this will be 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. We assume that each LAAF-accredited laboratory would submit 10 consecutive full analytical reports (for the middle value of 2 major food testing disciplines per laboratory) to qualify to submit abridged analytical reports. We also assume that a LAAF-accredited laboratory will spend 4 to 8 hours to compile and submit a full analytical report, and we use the middle value of 6 hours for this analysis. For initial or one-time burdens we use a 3-year period horizon and zero percent discount rate to convert the one-time burden to an annualized figure (2 hours). When multiplied together, this results in a total reporting burden for the LAAF-accredited laboratories to qualify to submit abridged analytical reports of 3,400 hours (170 laboratories × 10 full analytical reports each × 2 hours per analytical report), as reflected in row 8.

Once a LAAF-accredited laboratory qualifies to submit abridged analytical reports, we assume it will submit abridged analytical reports to us thereafter. We may revisit this assumption in the future based on actual rates of revocation of permission to submit abridged analytical reports. We estimate the burden to compile and submit an abridged analytical report to be between 25 percent and 33 percent of the burden of compiling and submitting a full analytical report, and we use a middle value of 29 percent here. Thus, using these figures we calculate it would take a LAAF-accredited laboratory 1.16 hours to compile and submit an abridged analytical report (29 percent × 4 hours). This results in an annual total reporting burden for the 170 LAAF-accredited laboratories to compile and submit abridged analytical reports of approximately 4,930 hours (170 laboratories × 25 abridged analytical reports × 1.16 hours per abridged analytical report), as reflected in row 9.

The regulations require a LAAF-accredited laboratory to submit verification and validation studies to FDA as part of an analytical report. The ISO/IEC 17025:2017 standard requires the use of validated and verified methods for food testing. However, the regulations require additional verification studies over and above the requirements of ISO/IEC 17025:2017. Additional studies may include information to verify that a method previously validated for a specific food item is also valid for a different food item, in what is called a "matrix extension." We estimate that the additional time burden of requiring a LAAF-accredited laboratory to submit verification studies such as matrix extensions under the regulations to be a middle value of approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025:2017 (the FRIA estimates a range of 1 percent to 5 percent). In the FRIA we also note that internal FDA experts suggest that between 5 percent and 30 percent of import food testing results require verification studies such as matrix extensions. We use a middle value of 17.5 percent for this analysis.

Regarding validation requirements, we assume that methods used to test shell eggs, sprouts, and bottled drinking water are either already validated or the costs of doing so would be included in the costs to maintain ISO/IEC 17025:2017 accreditation. Consequently, we assume that shell eggs, sprouts, and bottled drinking water producers would incur no burden

from this requirement beyond the requirement to meet the validation requirements of ISO/IEC 17025:2017.

We estimate the time required to perform a matrix extension is a middle value of 34 hours (the FRIA estimates a range of 22 to 46 hours). We do not distinguish between the burden of reporting the study and the burden of conducting the study. We assume 25 percent of the 34 hours (8.5 hours) is attributable to the associated reporting burden. Because we estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under the regulations would be approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025:2017, we multiply 8.5 hours by 3 percent to get the additional reporting burden of .255 hours (15.3 minutes, which we round to 15 minutes, which is .25 hours) per study imposed by the verification study submission requirements. To estimate the number of test results that would require matrix extensions, we multiply the number of import testing results that would be submitted to us under the regulations annually that are subject to PRA requirements (50) by the share of test results submitted to us for import food testing that require matrix extensions (17.5 percent), for a total of 8.75 matrix extensions per year. This equates to an average of .3241 matrix extensions per LAAF-accredited laboratory conducting food testing for imports (8.75 ÷ 27). Because the number of respondents and the annual responses per respondent in a PRA analysis must be whole numbers, we instead estimate that nine LAAF-accredited laboratories (27 × .3241, rounded to 9 from 8.75) will submit one full verification study to FDA annually. Therefore, the annual reporting burden of requiring the submission of validation and verification studies is 2.25 hours (9 accredited laboratories × 1 verification studies × .25 hours per study), as reflected in row 10.

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 will a collect a sample that the LAAF-accredited laboratory will analyze 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 will be subject to the advance notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Thus, we estimate that 123.45 test results (4,115 × 3%) will require submission of advance notice of sampling under the regulations. For this analysis we assume that each of the estimated 170 LAAF-accredited laboratories will be required to submit three advance notices sampling annually. (123.45 ÷ 170 = 0.74; rounded to 1). Thus, the annual reporting burden on LAAF-accredited laboratories for the advance notice of sampling requirement would be 255 hours (170 laboratories × 1 advance notices of sampling × 1.5 hours), as reflected in row 11.

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 will have 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. We estimate it will take a LAAF-accredited laboratory 15 minutes per notification. Thus, we estimate the burden associated with § 1.1152(f) would be 63.75 hours (170 accredited laboratories × 1.5 notifications × 0.25 hours per notification), as reflected in row 12.

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. Because this is a new collection, we estimate a cumulative total of 1 respondent and 1 burden hour, as reflected in row 13.

Table 2--Estimated Annual Recordkeeping Burden

21 CFR part 1, subpart R; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§ 1.1113; recordkeeping associated with ISO/IEC 17011:2017	4	1	4	1	4
§ 1.1124; ABs--additional recordkeeping requirements	4	1	4	21	84
§ 1.1138; laboratories--becoming accredited to ISO/IEC 17025:2017 (one-time)	9	1	9	91.06	819.54
§ 1.1138; laboratories--maintaining ISO/IEC 17025:2017 accreditation	170	1	170	889.53	151,220.10
§ 1.1154; laboratories—additional recordkeeping requirements	170	1	170	12	2,040
Total			0		154,167.64

Recordkeeping: We estimate the annual recordkeeping requirements be 154,167.64, 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 estimate that all 4 of the accreditation bodies that we estimate will apply to 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, as reflected in row 1.

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 will 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 42 annual hours would be spent complying with the recordkeeping requirements of § 1.1124. Thus, the annual recordkeeping

burden for the 4 recognized accreditation bodies to meet the additional recordkeeping requirements of § 1.1124 would be 84 hours, as reflected in row 2.

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 and zero percent discount rate, for an annualized recordkeeping burden of 819.54, as reflected in row 3.

Section 1.1138 requires a LAAF-accredited laboratory to maintain conformance with ISO/IEC 17025:2017, including its recordkeeping requirements. As discussed in our NPRM, we estimate a mean of 889.53 hours for this recordkeeping. This results in an annual burden of 151,220.10 hours, as reflected in row 4.

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 will incur a burden of about 1 hour per month (12 hours per year) to comply with the recordkeeping requirements in § 1.1154. This results in an annual burden of 2,040 hours, as reflected in row 5.

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 final regulations are conducted by personnel with differing wage rates, in accordance with the FRIA. With respect to the reporting burden on accreditation bodies under the regulations:

- We expect 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 (see FRIA at p. 88), as reported in the Bureau of Labor Statistics, May 2020 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 $143.18 for a Lawyer.

- We expect 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 (see FRIA at p. 92-93), as reported in the Bureau of Labor Statistics, May 2020 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 $88.30 for a Microbiologist.

With respect to the reporting burden on laboratories under the regulations:

- We expect 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 (see FRIA at p. 103), as reported in the Bureau of Labor Statistics, May 2020 National Occupational Survey under occupation code 11-9121, at the fully loaded hourly wage of $77.10.

- We expect 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 (see FRIA at pp. 107-113), as reported in the Bureau of Labor Statistics, May 2020 National Occupational Survey under occupation code 11-9121. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of $77.10 for a Food Scientist and Technologist.

With respect to the recordkeeping burden on accreditation bodies under the regulations:

- We expect 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 (see FRIA at p. 92-93), as reported in the Bureau of Labor Statistics, May 2020 National Occupational Survey under occupation code 19-1022, at the fully loaded hourly wage of $88.30.

With respect to the recordkeeping burden on laboratories under the regulations:

- We expect 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 (in accordance with the FRIA's assumptions about who would conduct analytical activities for accredited laboratories, see FRIA at p. 95), as reported in the Bureau of Labor Statistics, May 2020 National Occupational Survey under occupation code 11-9121, at the fully loaded hourly wage of $77.10.

Table 3--Estimated Annual Reporting Burden Cost

Type of Respondent	**Total Burden Hours**	**Fully Loaded Hourly Wage**	**Total Respondent Costs**
Lawyer	94.4	$143.18	$13,516.19
Microbiologist	294	$88.30	$25,960.20

Food Scientist and Technologist	19,488.5	$77.10	$1,502,563.35
Total			**$1,535,568.04**

Table 4--Estimated Annual Recordkeeping Burden Cost			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Microbiologist	88	$88.30	$7,770.40
Food Scientist and Technologist	154,079.64	$77.10	$11,879,540.24
Total			**$11,887,310.64**

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

Management of the information collection is covered by existing resource allocations for full time employees and information technology development. Therefore, we estimate no costs to the Federal government.

15. Explanation for Program Changes or Adjustments

This is a new information collection request. We have adjusted estimates from our proposed rule as discussed in *Question 8*, above.

16. Plans for Tabulation and Publication and Project Time Schedule

Upon implementation of 21 CFR 1.1109 and consistent with provisions in section 422(a)(1)(B) of the FD&C Act, FDA will maintain on its website a publicly available registry of recognized accreditation bodies and LAAF-accredited laboratories.

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

As described above in *Question 3*, to support implementation of the regulatory requirements regarding maintenance and electronic submission of certain test results, reports, notifications, and other records to FDA, we are currently developing information collection systems. FDA will incorporate both the OMB control number and expiration date into the technological components of the information collection.

At the same time, we note that the regulations incorporate proprietary standards, and the OMB control number and expiration date would 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.