2020 SUPPORTING STATEMENT

Laboratory Approval Programs
OMB No. 0581-0251

A. Justification.

1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.

Under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621-1627), The Agricultural Marketing Service (AMS) administers programs that create domestic and international marketing opportunities for U.S. producers of food, fiber, and specialty crops. AMS also provides the agricultural industry with valuable services to ensure the quality and availability of wholesome food for consumers across the country and around the world.

AMS' Science & Technology Program (S&T) provides scientific, certification and analytical services to the agricultural community to improve the quality, wholesomeness and marketing of agricultural products domestically and internationally. S&T provides support to USDA Agencies, Federal and State agencies, and private sector food and agricultural industries. S&T is organized into four divisions: Laboratory Approval & Testing Division (LATD); Monitoring Programs Division (MPD); the Plant Variety Protection Office (PVPO); and the Seed Regulatory and Testing Division (SRTD).

AMS' S&T, LATD provides lab testing and approval services to facilitate domestic and international marketing of food and agricultural commodities. LATD's Laboratory Approval Service (LAS) approves, or accredits, other labs to perform testing services in support of domestic and international trade. At the request of industry, other Federal agencies, or foreign governments, AMS develops and administers laboratory approval programs (LAPs) to verify that the analysis of food and agricultural products meet country or customer-specified requirements.

Regulation 7 CFR parts 90-91 address administration of LAPs. LAS ensures the testing of products marketed is conducted by qualified and approved laboratories. LAP requirements include good laboratory, quality assurance and control practices; applicable domestic and international standards (such as ISO/IEC 17025); established methods and accepted equipment; and on-site audits. Laboratories voluntarily participate and pay program fees. Currently, AMS' LAS administers four LAPs with 60 participants.

1. Aflatoxin Program — this program approves laboratories to perform aflatoxin testing in support of domestic and/or export trade of almonds, peanuts, and

pistachio nuts. (a) Almond. At the request of the Almond Board of California (ABC), AMS administers the program for aflatoxin testing of almonds destined for export to the European Union (EU) through the Pre-Export Certification (PEC) program of ABC. (b) Peanuts. AMS administers Minimum Quality and Handling Standards for Domestic and Imported Peanuts Marketed in the United States (7 CFR 996 Parts 996.1 – 996.75). The regulation requires domestically marketed peanuts for human consumption to be analyzed for aflatoxin by a USDA or USDA-approved laboratory. AMS consults with the Peanut Standards Board on program requirements. (c) Pistachio. AMS administers mandatory domestic and import aflatoxin requirements for pistachio nuts under Pistachios Grown in California, Arizona, and New Mexico (7 CFR Part 983) and Specialty Crops, Import Regulations (7 CFR Part 999, Section 999.600), respectively. All domestic and import shipments of pistachio nuts intended for human consumption must be tested for aflatoxin contamination. At the request of the Administrative Committee for Pistachios (ACP), laboratories may also participate in the program for pistachio nuts destined for EU through the Pistachio Export Aflatoxin Reporting (PEAR) program of ACP.

2. Export Program — this program approves laboratories to perform testing of meat and poultry products offered for export certification by the Food Safety and Inspection Service (FSIS). LAS collaborates with FSIS, the Foreign Agricultural Service, and the meat and poultry industries to administer a flexible and comprehensive program to provide reliable analyses of pesticide residues, environmental contaminants, veterinary drug residues, antibiotic residues, microorganisms, and parasites.
3. Microbiological Testing of Poultry Products for the Federal Purchase Program (FPP) — this program approves laboratories to perform microbiological testing of frozen, cooked, diced chicken procured for the Federal Purchase Program and is limited to the analysis of aerobic plate counts, coliform counts, coagulase positive *Staphylococcus aureus*, generic *Escherichia coli*, *Salmonella* species, and *Listeria monocytogenes*.
4. Dairy Program - this program supports the Dairy Grading Branch for laboratories testing butter for quality and grading standards. LAS collaborates with the Dairy Grading Branch and the dairy industry to administer an audit program to provide reliable analysis for the grading of butter.

2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.

The Laboratory Approval Service (LAS) collects, voluntarily from the applicant (laboratory applying to be approved or accredited) or participant (laboratory approved or accredited), customer/business information and quality management system (QMS) documentation essential to examine their ability to meet laboratory approval program (LAP) requirements. Program requirements include demonstrating

analytical testing competency and defensibility, and customer and country specific requirements. Each LAP is administered using the same general policies and procedures. An applicant or participant submits information through applicable information technologies directly to LAS. Information collected from an applicant is not shared with any organizations inside or outside USDA or the government without the participant's knowledge and permission.

The application process occurs when an applicant seeks approval into a program and when a participant seeks to expand their scope of approval. The application process includes, submission of an application letter and application package, including customer/business information for billing and QMS documentation; and receive an audit by AMS. The customer/business information collected includes business legal name, Federal Tax ID Number, mailing address, billing address, management contacts and accounts payable contact. QMS documentation includes policies, procedures, and records addressing management of documents, records, risk and opportunities, improvement, corrective actions, internal audits, and management reviews; personnel, facilities and environmental conditions, equipment, metrological traceability, externally provided products and services, and analytical testing methodology; and analytical methodology, handling of test items, technical records, evaluation of measurement uncertainty, ensuring validity of results, reporting of results, complaints, nonconforming work and control of data and information management. An on-site audit is conducted on the premises of a business to witness implementation of the policies and procedures provided in the application package to verify compliance to LAP requirements.

Once an applicant is approved into the program, the information collection burden decreases for the continual participation process. The continued participation process includes, verification of intent to continue participation and its customer/business information, submission of analytical proficiency information, and QMS documentation in response to audits by AMS, maintaining records for 3 years. LAS collects from the participant verification of commitment to continue participation on an annual basis. LAS collects from the participant analytical proficiency information for each approved method at a frequency designated in the LAP; (a) Aflatoxin Program - quarterly, (b) Export Program - at least annually for all but one method which is quarterly (c) Microbiological Testing of Poultry Products for the Federal Purchase Program (FPP) - at least annually. (d) Dairy Program - monthly. LAS collects from the participant current customer/business information and QMS documentation in preparation for an on-site audit and during an on-site audit at the frequency defined in the LAP, typically on a biennial basis. An on-site audit is conducted on the premises of a business to witness implementation of the policies and procedures to verify continued compliance to LAP requirements. A participant maintains records for at least three years for compliance to program requirements.

Occasionally, a participant withdraws, is suspended, or is dismissed from a program. A participant requests withdrawal or voluntary suspension by submitting a letter of request to LAS. A participant may request reinstatement from a suspension by submitting a letter of request to LAS. The reinstatement process from suspension includes an evaluation using the continual participation process. On the rare occasion a participant fails to continually meet program requirements, LAS notifies the participant of its danger of being dismissed. The dismissal process includes an evaluation using the continual participation process to substantiate reason for dismissal.

This is an ongoing collection. The type, amount, and frequency of information collected has not changed; however, the processes of collection have been refined and made more efficient through adoption of additional information technologies.

3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO, DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.

Laboratory approval programs (LAP) use information technologies and witnessing for the collection of information. Information technologies include internet applications, webpages, email, and phone. Since the last approval of this information collection, email has been utilized by all potential applicants, applicants, and participants for submitting information; and electronically signed documents are accepted. Laboratory Approval Service is currently developing new information technologies, a web-based client management system to facilitate LAP administration.

Specifically, the USDA, AMS, Science and Technology (S&T), Laboratory Approval and Testing Division (LATD) website (link) provides the user direct access to the source of Laboratory Approval Programs information and is accessible by anyone with a computer and internet service. LAS services can be accessed at: https://www.ams.usda.gov/services/lab-testing/lab-approval. Inquiries can be made utilizing contact information on this webpage. Applicants are encouraged to use the email address LAS@usda.gov for service inquires to LAS and directly to LAS staff for the application process and the continual participation process.

4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY

AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.

The Laboratory Approval Service (LAS) collects, voluntarily from the applicant (laboratory applying to be approved or accredited) or participant (laboratory approved or accredited), business information and quality management system (QMS) documentation essential to examine respondent's ability to meet program requirements of a LAP. The information LAS collects is only available from the applicant or participant as the information is owned by them. Many applicants and participants share portions of the same QMS documentation with 3rd party accreditation bodies (AB); however, the AB does not share the information due to confidentiality agreements.

5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-1), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.

The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service businesses as those having annual receipts of no more than $6.5 million. Under these definitions, some of our participants are considered small laboratories. We currently have 60 respondents for these collections, and we estimate that 30 are considered small businesses.

Information collected is the same for small businesses and there is no additional burden placed on small businesses to participate.

6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTICLES TO REDUCING BURDEN.

If the information is not collected, the Laboratory Approval Service (LAS) cannot examine and determine a laboratory's ability to meet laboratory approval programs (LAP) requirements to provide accurate and defensible analytical testing services to support trade of a commodity which could directly impact marketability of a product in a timely manner. If the information was collected less frequently LAS could not administer the LAP to evaluate an applicant's ability to meet program requirements or evaluate a participant's ability to continually meet program requirements.

If there are no USDA-approved laboratories for the specific commodity and test, then that industry may lose access to a market. The Aflatoxin Program is a component of the US control system in place to control aflatoxin contamination in almonds and

pistachios intended for export to the European Union (EU). If the LAP was not administered, it would result in additional time and cost for exporters to have product sampled and tested at the maximum rate instead of reduced rates at the port of entry. For the Export Program, only through lengthy negotiations with foreign countries is the U.S. government able to arrange for the export of meat and poultry products. Key to these negotiations was the development of the LAP to verify these products, destined for export, meet country specific requirements (e.g., chemical residues, microorganisms, and parasites). Without this LAP, industries exporting these products to countries such as the EU, China, and Russia would not meet the negotiated country specific requirements.

7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:

- **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**

For the continued participation process, submission of analytical proficiency information may be required more often than quarterly. Currently, one program, Dairy Program, requires a monthly submission of analytical proficiency information. The Dairy Grading Branch requested Laboratory Approval and Testing Division to administer their proficiency test program.

- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**

- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**

- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**

- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**

- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**

- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE**

OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY P OLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR

- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES TO PROTECT THE INFORMATION'S CONFIDENTIALITY TO THE EXTENT PERMITTED BY LAW.**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 7 CFR Parts 90-91.

8. **IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY"S NOTICE, REQUIRED BY 5 CFR 1320.8(D), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.**

On DATE OF PUBLICATION (May 26, 2020), Vol. No. 85, pages 31432 to 31433, the agency published the notice of information collection and request for comments in the Federal Register. No comments were received.

DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED OR REPORTED.

The Laboratory Approval and Testing Division consults with interested industries or other agencies on the programs' requirements, including information collected. Once a program is developed, the protocol is sent to representatives of the industry and/or agency requesting its development. The industry and/or agency representatives are required to review the protocol and accept or reject the program.

Industry/agency representatives contacted:

Director, FSIS, Import/Export Coordination & Policy Development Staff; (202) 720-0082

Deputy Administrator, FAS, Office of Agreements and Scientific Affairs; (202) 720-4434

Vice President, Global Technical & Regulatory Affairs, Almond Board of California; (209) 549-8262

Peanut Standards Board, AMS, Marketing Orders and Agreements Division; (863) 324-3375

President, American Peanut Council; (703) 838-9500

Manager, Administrative Committee for Pistachios; (559) 255-6480, ext. 103

Director, AMS, Commodity Procurement; (202) 720-4517

Deputy Administrator, AMS, Livestock and Poultry; (202) 720-5705

Deputy Administrator, AMS, Dairy Program; 202-720-7392

CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS—EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFI SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.

Consultation with applicants and participants occurs at least annually.

9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.

No payments or gifts are provided to respondents.

10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.

The confidentiality of the collected information is maintained in accordance with the Privacy Act of 1974 and subsequent amendments. The Laboratory Approval and Testing Division (LATD) staff works as a U.S. Government entity under the laws and subsequent regulations specified in 7 CFR Parts 90-91. The confidentiality of information is conducted in a manner consistent with the guidelines in 7 CFR Part 91.30(d).

11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FORM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO OBTAIN THEIR CONSENT.

Questions of a sensitive nature are not found in this information collection.

12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION.

THE STATEMENT SHOULD:

- **INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DISIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSOMARY AND USUAL BUSINESS PRACTICES.**

- **IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN ITEM 13 OF OMB FORM 83-I.**

- **PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

The number of respondents, frequency of response, and annual burden for each information collection requirement, as well as totals, are shown in AMS Form 71.

There are 60 participants in the laboratory approval programs (LAP) administered. It is estimated that four new applicants will apply for approval into a LAP (one per LAP) and one scope expansion request annually.

The respondents' estimated annual cost of providing information to AMS for laboratory approval programs is approximately $54,622.66. This total has been estimated based on:

(19-1010) Agricultural and Food Scientists:
All applicants and participants would be from this occupation

Total annual responses	Hourly Wages	Benefits & Compensation cost per hour (31.7 percent)	Total Wage plus benefits & compensation per respondent	Total Hrs. of burden for this group	Total Cost
538	$34.88	$11.06	$45.94 hr.	1189.00	$54,622.66
SUB-TOTAL					$54,622.66
TOTAL					**$54,622.66**

Data for computation of these hourly wages were obtained from the U.S. Department of Labor Statistics publication, "May 2019 National Occupational Employment and Wage Estimates. This publication can also be found at the following Website: https://www.bls.gov/oes/current/oes_nat.htm.

13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMTION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.

The Federal Government recovers all costs thru a fee for service for these laboratory approval programs.

15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-1.

The information collected has not changed. Laboratory Approval Service (LAS) has made significant improvements to laboratory approval programs (LAPs) administrative processes by better defining the processes and functions for implementing application, continual participation, and withdrawal/suspension in a consistent way. As a result, the approach to estimating burden changed. The estimation of burden hours has decreased. The decrease is due to; 1) using data from records maintained since the last approval of the collection, and 2) reduction of participants and applicants because of changes in the market.

In this information collect package, descriptions are given as processes and functions that apply uniformly across all LAPs rather than approaching each LAP individually as before. There have been decreases and increases in respondents for individual LAPs. Overall, the number of respondents increased from 57 to 60; the number of burden hours decreased from 4,157 to 1204; and the number of annual responses increased from 380 to 538 because approach to estimating burden changed due to use of data collected since last estimation. The explanation for the number changes for individual LAPs are described in Attachment #1.

16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PURBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJET, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.

Customer/business information used to contact a laboratory approved into a laboratory approval program (LAP) is published on LAP webpage. No other materials may be published without permission of the respondent.

17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.

Laboratory Approval Service is seeking approval to not display the OMB expiration date associated with this information collection because there are no forms, surveys, or questionnaires associated.

18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK RESUCTION AT SUBMISSIONS," OF OMB FORM 83-1.

The agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection does not employ statistical methods.