

2008 SUPPORTING STATEMENT

Laboratory Approval Programs OMB NO. 0581-NEW

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), AMS provides analytical testing services that facilitate marketing and allow products to obtain grade designations or meet marketing or quality standards. Pursuant to this authority, AMS develops and maintains laboratory certification and approval programs (7CFR parts 90-91) as needed by the agricultural industry, to support domestic and international marketing of U.S. products. Previously, laboratories requesting certification numbered 6 or less. However, changes in the import requirements of foreign countries and proposed regulatory changes make it likely that requests for laboratory certification will increase and need to comply with the Paperwork Reduction Act requirements. The laboratory certification and approval programs will remain voluntary, fee for service, and for admission into one of these programs a laboratory must have a client who requires the specific testing.

To ensure that a laboratory is capable of accurately performing the specified analyses, it must adhere to certain good laboratory practices and show technical proficiency in the required areas. Forms have been developed that ask the laboratory for information concerning the physical facility and employees, and their training. They are also asked to respond positively or negatively to the performance of activities deemed necessary for a highly responsible and competent laboratory. These questions also serve as a reminder to the laboratory of those elements that will be examined and verified during an on-site audit of their laboratory. AMS will not approve a laboratory unless we are sure that the laboratory is capable of performing accurate analyses. A sloppy laboratory could produce faulty results and cause a foreign country to reject thousands of pounds of U.S. product or even reject that product from all U.S. producers. This is particularly important if the offending product causes disease. Consequently, it is absolutely necessary to collect and require a laboratory to attest to the performance elements necessary to determine the credibility of the laboratory. To do less would be a disservice to the agricultural community we are here to serve.

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 information is collected by degreed scientists in the Technical Services Branch (TSB) of Science & Technology Programs, Agricultural Marketing Service, USDA. Individual scientists are responsible for specific laboratory approval programs. The scientists are assigned programs in response to their technical expertise. The scientists set up files and billing accounts for each applicant.

The information collection processes are as follows:

- a. The scientists review the information submitted by the laboratory on the initial letter requesting entrance, checklists, and/or standard operating procedures (SOPs).
- b. If the laboratory paperwork shows that the laboratory follows good laboratory practices, appears to understand how to perform the required analyses, agrees to use the methods specified in the program protocol, and provides method validation documentation; then the test samples are sent to the applicant laboratory.
- c. The laboratory provides the analytical results of the test samples via FAX or letter. If the analyses performed produce the appropriate results, the scientist, responsible for the program, will visit the laboratory and verify the analytical activities being performed.
- d. Except for the Poultry Exported to Russia Program, the scientists conduct an initial on-site laboratory review. This is done by observation, conversation and review of written documentation. If the laboratory has deficiencies, they must correct them, and provide a written statement to AMS that they have done so.
- e. At this time, the laboratory may be accepted into the program. To remain in the program the laboratory must perform analyses on proficiency test samples at spaced intervals, and provide AMS with their analytical results. They must also submit to yearly on-site laboratory reviews and provide the Agency with updates if they change their methods or their personnel.

Above gathered information has been used to examine laboratories for entrance into and maintaining the following programs:

1. Analyst and Laboratory Certification Program for the Detection of Trichinae in Pork [export program requested by Food Safety and Inspection Service and U.S. Pork Producers Association];
2. Laboratory Verification Program for Poultry Exported From the United States to Russia [export program requested by Food Safety and Inspection Service];

3. Aflatoxin in Pistachios Program [exporting pistachios to European Union requested by California Pistachio Committee and the domestic program identified in the Pistachio Marketing Order (7CFR Part 983)];
4. Aflatoxin in Peanuts Program (7 CFR Part 996); and
5. Aflatoxin in Almonds Program [requested by the Almond Board of California].

The information collection involved in these programs is necessary to maintain the credibility of the USDA. If we are not rigorous in our demands for entrance into our programs, then foreign governments will not be willing to accept the results generated by these laboratories.

Each laboratory is billed for the services. The Alternate Payment Form (ST-212), which will be processed through the www.pay.gov, may be used by the laboratory as an option of paying the service.

Since much of the information requires a signature of a responsible person attesting to the truth of the statements, most of the information must be provided as a hard copy. This may change if or when e-mail signatures become legally binding.

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.

Science and Technology has redesigned its web site. There has been a complete overhaul which provides the user with extensive additional information, and direct access to laboratory approval information. Upon approval of this collection by OMB, these forms will be placed in the appropriate program area on the web site, and will be accessible by anyone with a computer. Initially, the completed forms will not be submitted electronically since the technology required to provide adequate security to the information that will be sent is not in place. A Secure Socket Layer (SSL) would have to be set up on the server and the laboratory would have to be given instructions on how to access that server. Since these laboratory approval programs are required by law to be self-sustaining, the cost of this secure system would have to be added to the cost of the various laboratory approval programs. This would require an increase in the fees that we charge. Most private business would prefer to send in hard copies of documents rather than pay extra for the convenience of electronic submission. In addition, signatures of the responsible persons will be required to attest to the

truthfulness of the provided information. Once the security issue is resolved and guidance from USDA regarding e-authentication of signatures is received and implemented, the laboratories will then be able to submit the forms electronically.

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.

Our laboratory approvals are unique to the Government in that they are specific to enhance the marketing of U.S. agricultural products. Other Federal government entities capable of this type of work deal with regulatory issues will not consider involvement in a program where the need is a marketing issue. Since our programs are so specific to a commodity and to a test or tests, the likelihood of any other government agency having these data is remote. It is possible that a laboratory may have ISO 17025 accreditation for one or more of the analyses, but that information would be held by an accrediting body from outside Government that will not share it with us. In addition, our programs frequently require specifications that are unique to export to a specific country. These would not be required in an ISO 17025 accreditation situation. In some instances such as the pre-export certification program authorized by the European Union (EU), the EU requirement is that laboratories have both ISO 17025 accreditation and an approval by a government agency.

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 have estimated the number of respondents for this collection is 82, and we estimate that 30 are considered small businesses.

However, the information collected from small laboratories is the same as that collected from large laboratories. There is no additional burden placed on small laboratories to participate. In fact, the only reason a laboratory would participate in one of the programs is to provide additional service to its clients. The laboratory would probably charge an additional fee to its clients for the analyses it performs under the approval program, and in this way recover the cost involved in becoming approved as a business expense.

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 OBSTACLES TO REDUCING BURDEN.

If the information is not collected, the agency cannot determine if the laboratory is capable of performing the required analyses in a manner which meets good laboratory practices and/or the requirements specified by a foreign government. Therefore, the agency cannot approve the laboratory. If there are no approved laboratories for the specific commodity and test, then that industry loses a market for its product. Any reduction in the quantity of data collected could result in the purchaser determining that the program is not stringent enough, and therefore they might reject the results produced by the laboratory and lose any confidence they may have had in the USDA approval process. In the case of the Aflatoxin in Almonds program, without the approved laboratory program, **every lot** of almonds shipped to the EU would be tested for aflatoxin in an EU laboratory before being accepted for importation. This would cause considerable expense to the almond growers since they would have to pay for storage of the product, the laboratory analysis, and any penalty for delay in delivery required. With the program in place, only 5% of the lots will be held and retested by the EU. Without the Trichina program in place, the EU, Russia, Chile, and Singapore will not accept U.S. pork unless every lot is held frozen for 30 days or more prior to shipment. This freezing and holding causes considerable expense to the processor and reduces the marketability of the product since customers prefer fresh (not frozen) product. In regards to the Russian program, only through lengthy negotiations was the U.S. government able to arrange for the export of poultry to Russia. Key to those negotiations was the development of a USDA laboratory verification program to test product for a list of microorganisms and chemical residues determined by Russia. In short, when a foreign government reviews the USDA approved laboratories, if they are not convinced that the approval process was stringent enough to protect their citizens, they will no longer accept the U.S. product.

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;**

Proficiency sample results for some commodity tests may be required more often than quarterly since they frequently parallel the growing and testing season. There are then gaps in the year when proficiency sampling does not occur. In addition, for some programs which are quantitative, the number of the proficiency tests pre year will not be exactly the same for all laboratories. A data analysis of the proficiency sample results must be performed to determine if the laboratory is meeting the performance criteria. More than four analyses per year are needed, since the number of laboratories in each program tends to be quite small.

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

Due to the biological nature of some proficiency samples, it is necessary for the analyses to be performed as quickly as possible upon receipt of the samples. If they are held for 30 days, the organisms may die or the toxins degrade, and the laboratory will be unable to isolate the appropriate culture or detect the appropriate amount of toxin. This could be the basis for removal of the laboratory from the program. The laboratories are informed prior to shipment that the samples are coming. Marking the results on the sample response sheet takes 30 seconds and it is to the laboratories advantage to submit the results quickly so they know if they have a problem in their laboratory and must repeat the analysis.

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

There are no special circumstances that would require respondents to submit more than and 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;**

There are no special circumstances that would require respondents to retain records more than three 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;**

The data collected is not designed to be generalized to the universe of study. It is designed to determine if the specific laboratory is capable of determining the expected outcome of the proficiency sample analysis. The statistical calculations performed are to determine if the specific laboratory's results vary significantly different from that obtained by other laboratories in the program. These results are called "outliers" and are an indication that the laboratory is not conducting the analysis correctly.

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

The statistical methods used in some of these programs are specifically for scientific data. At present, the Cusum analysis is used to detect a bias in the analysis, and the Grubb analysis is used to detect "outliers". These statistical methods are routinely used in the scientific community.

- **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**

There are no pledges of confidentiality given that are not supported by authority established in statue or regulation.

- **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.**

The confidentiality of the collected information is maintained in accordance with the Privacy Act of 1974 and subsequent amendments. The TSB works as a U.S. Government entity under the laws and subsequent regulations specified in 7 CFR Parts 1.110-1.123.

- 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.**

A 60-day notice concerning this information collection was published in the Federal Register on December 12, 2007 (Vol. 72, No. 238, page 70564-70565), which invited comments from interested persons through February 11, 2008.

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 TSB has consulted with interested industries or other agency on the programs' requirements. Once a program is developed, the protocol is sent to representatives of the industry requesting its development. The industry representatives are required to review the protocol and accept or reject the program.

Individuals contacted:

Rick Harries (USDA/FSIS/IEPS)	Phone: 202-720-6508
James H. Sumner (USA Poultry & Egg Export Council)	Phone: 770-413-0006
George Watts (National Chicken Council)	Phone: 202-296-2622
Stuart Proctor (National Turkey Federation)	Phone: 202-898-0100
Howard Valentine (Peanut Administrative Committee)	Phone: 706-579-1755
Bob Klein (Administrative Committee for Pistachios)	Phone: 559-255-6480
Julie Adams (Almond Board of California)	Phone: 209-343-3238

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.

The program managers are in constant contact with the laboratories in the programs.

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 Technical Services Branch works as a U.S. Government entity under the laws and subsequent regulations specified in 7 CFR Parts 1.110-1.123.

The privacy act advisory statement, on the ST-212 form, stated as “The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with the request for information solicited on the Alternate Payment Form (ST-212). Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the authority for the collection of this information is 15 U.S.C. § 1113 or 35 U.S.C. § 41 and 37 CFR 1.16-1.28, 1.492, or 2.6-2.7; (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the Science and Technology Programs (S&T) is to charge the appropriate fee amount to the appropriate credit card account. Each laboratory is billed for the services. The Alternate Payment Form (ST-212), which will be processed through the www.pay.gov, may be used by the laboratory as an option of paying the service. If you do not furnish the requested information, S&T may not be able to charge the fee to the credit card or the credit card institution may refuse to accept the charge, either of which will result in the fee being treated as not having been paid.”

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 FROM 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 respondents' (82 laboratories) estimated annual cost of providing information to AMS for laboratory approval programs is approximately \$183,245. This total has been estimated based on:

(a) \$1,402 by multiplying 41 burden hours (an applicant spent about 30 minutes to prepare an initial letter requesting entrance) by \$34.21;

(b) \$181,785 by multiplying 5,649 burden hours (including the laboratory chemist completed checklist, SOP, training, method validation, test sample and proficiency test sample analyses, and was interviewed by the TBS program manager during an on-site laboratory review) by \$32.18;

(c) \$58 by multiplying 4 burden hours (a laboratory took about 3 minutes to complete the ST-212 Alternate Payment Form, if this payment is chosen by the laboratory) by \$14.44; and

(d) The average hourly earnings (e.g. \$32.18, \$34.21, and \$14.44) of professional, specialty and technical white-collar occupations, and executive, administrative, and managerial support white-collar occupations by worker and establishment characteristics and geographic (metropolitan). Data for computation of this hourly wage were obtained from the U.S. Department of Labor Statistics' publication, "National Compensation Survey: Occupational Wages in the United States, June 2005", published August 2006 (Bulletin 2581). This publication can also be found at the following website: <http://www.bls.gov/ncs/ocs/sp/ncb10832.pdf>.

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 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.

This is a new information collection.

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

The information collected will not be published. It is strictly to assess the quality of a laboratory seeking to perform certain work under a USDA approval. The only thing that will be available to the public is a list of the approved laboratories in each program.

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.

The forms that we use are not professionally printed. The laboratories in our programs are too few in number to warrant such an expense. Our Trichina program has only 10 laboratories, our peanut program has 12 laboratories, our poultry program has 36 laboratories, our pistachio export program has 5 laboratories and our domestic pistachio program has 7 laboratories, and our almond program has 12 applicants. New programs that come along always start small and some even are canceled when the marketing need disappears. We just make copies as needed, and may customize

them for a specific analysis as the technology changes. We therefore do not want to print an expiration date of OMB approval on these forms.

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

The agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-1.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection does not employ statistical methods.