

GUIDANCE FOR INDUSTRY:

Submission Of Laboratory Packages By Accredited Laboratories

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For questions on the content of this guidance, contact the Division of Field Science at 301-827-7605 or -7606.

**United States Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
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DRAFT GUIDANCE

Guidance for Industry Submission of Laboratory Packages by Accredited Laboratories¹

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This document is intended to provide guidance to industry about accreditation standards for laboratories and about the quality and type of test data and information that accredited laboratories should produce in support of test results submitted to FDA (we or us) pertaining to the admissibility of articles offered for import of all product types (i.e., biological products, drugs, devices, and food) that we regulate. In general, if a laboratory is accredited according to the procedures set forth in this document and the administrative processes described in this document are followed, submission of an abbreviated laboratory package (containing a Summary of Analysis, an affirmation, and import documents associated with the entry) from the laboratory will likely provide sufficient information for purposes of our review. Whether a laboratory seeks accreditation is completely voluntary. Non-accredited laboratories can continue to submit full laboratory packages containing complete data sets (including all raw data) and information for review by our analysts and compliance officers. Non-accredited laboratories should continue to refer to FDA's laboratory manual, entitled, "ORA Laboratory Manual, Section 7 – Private Laboratory Guidance."² In addition, both importers and accredited laboratories who wish to submit abbreviated laboratory packages should follow this guidance in its entirety, including provisions concerning notification, reporting, and administrative and technical operations (such as sampling and testing). If importers or accredited laboratories elect to use an approach other than that laid out in this guidance, we might ask that they submit full laboratory packages pursuant to ORA's Laboratory Manual.

This guidance applies to analyses by accredited private laboratories of all imported FDA-regulated products that have been detained and/or that are subject to an Import Alert.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

II. Background

On July 18, 2007, President Bush, through Executive Order 13439, established the Interagency Working Group on Import Safety (Working Group) to conduct a comprehensive review of the United States import system and identify ways to further increase the safety of imports entering the country. The Working Group was chaired by the Secretary of the Department of Health and Human Services and was comprised of 12 Federal departments and agencies. The Working Group presented its initial findings to the President on September 10, 2007 in a report titled, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety* (Strategic Framework). The Strategic Framework presents a new import safety strategy emphasizing a cost-effective, risk-based approach. It considers risks at the points they are most likely to occur, and then targets the application of controls to those critical

points to minimize the likelihood of unsafe products reaching American consumers. The Strategic Framework lists three "keystone" principles: (1) prevention of harm in the first place; (2) intervention when risks are identified; and (3) rapid response after harm has occurred. The "keystones" themselves are supported by six "building blocks:" (1) Advance a Common Vision; (2) Increase Accountability, Enforcement and Deterrence; (3) Focus on Risk Over the Life Cycle of an Imported Product; (4) Build Interoperable Systems; (5) Foster a Culture of Collaboration; and (6) Promote Technological Innovation and New Science. The "building block" concerning increased accountability is particularly relevant here, as the discussion noted, in part, that:

We can improve accountability by developing better tools for linking products to manufacturers, importers, distributors, and retailers, and verifying supplier and producer compliance with safety standards. This step would enable more timely investigations and interventions, help prevent potentially dangerous goods from entering the stream of commerce, and make possible stronger and more effective enforcement actions....

On November 6, 2007, the Working Group presented to the President its Import Safety Action Plan (Action Plan), which contains short- and long-term recommendations for continuing to improve the safety of imports entering the United States. The Action Plan contains 14 broad recommendations and 50 action steps that provide a road map for better protecting American consumers and enhancing the safety of the increasing volume of imports entering the United States. The Action Plan is the product of extensive coordination among Federal agencies, months of hands-on information-gathering, and feedback and suggestions from the private sector and the public. As stated in Appendix C of the Action Plan, one action would have FDA issue guidance that "would set standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data and information to FDA to assist in evaluating whether an appearance of a violation may be resolved."

More recently, on January 29, 2008, the Government Accountability Office (GAO) testified before the House Subcommittee on Oversight and Investigations. The GAO's testimony recommended, among other things, that FDA "consider accrediting private laboratories to test seafood" (see GAO, "Federal Oversight of Food Safety – FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical," GAO-08-435T, at page 7). The GAO stated that accreditation of private laboratories "could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe" (id.). When FDA-regulated articles are offered for import, we consider whether they comply with the Federal Food, Drug and Cosmetic Act (Act). We can refuse to admit articles appearing to be in violation of the Act, subject to the right of the importer to introduce evidence regarding admissibility. When FDA has sufficient information to refuse admission of future shipments of an imported article (i.e., when future shipments appear to be in violation), we can issue an Import Alert for Detention Without Physical Examination. Such an Import Alert advises our field personnel that they can detain those shipments without physical examination. When FDA detains a shipment, the importer can provide evidence showing that the goods meet FDA standards. Depending on the

nature of the violation, this might be done by having samples of shipments collected and tested in private laboratories and submission of those test data and information to us to prove that the goods comply with FDA's regulatory requirements. FDA laboratory and compliance personnel then review the data and information submitted by importers (known as "laboratory packages") to determine whether the particular shipment that was tested should be admitted into the United States.

As the volume of goods offered for import has continued to grow, we have considered how best to ensure the validity of the information and scientific data submitted to show that those goods meet FDA requirements. In 2004, we issued a proposed rule for persons who use sampling services (services that collect samples for other parties) and private laboratories in connection with imported food (see 69 FR 23460 (April 29, 2004)). The proposed rule was intended to help ensure the integrity and scientific validity of data and information submitted to FDA in connection with an enforcement action for food that is offered for import, and was also intended to deter manipulation, alteration or substitution of samples to be tested by a private laboratory or the selective reporting of private laboratory data and test results by importers. If finalized, the proposed rule would require samples to be properly identified, collected and maintained. Additionally, the proposed rule would require laboratories to use validated or recognized analytical methods and to submit test data and information directly to FDA.

Since the time we issued the proposed rule, significant changes in laboratory accreditation have occurred. For example, when we drafted the proposed rule, there was a trend towards the use of the International Organization for Standardization (ISO) standard ISO 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," but no firm consensus (see 69 FR at 23461). Additionally, when we drafted the proposed rule, parties disagreed as to the value of laboratory accreditation, and FDA's own laboratories were not accredited. Today, there is widespread agreement on ISO 17025, the laboratory industry favors accreditation, and FDA's own laboratories are accredited. Moreover, the Administration's Strategic Framework expressly seeks better ways to ensure compliance with safety standards, while the Action Plan and the GAO testimony reflect greater support for the use of accredited laboratories. Thus, given these and other developments and the Action Plan's recommendation to issue guidance, we have decided to issue this guidance document instead of proceeding with a final rule at this time.

Rigorous accreditation standards give us more confidence that accredited laboratories have the technical capability and trained personnel to perform the specific methods for which they are accredited. Our confidence in the accredited laboratories' abilities and, by extension, the laboratory packages which these accredited laboratories generate, is enhanced by the accreditation bodies' continuing oversight over these accredited laboratories and our plans to conduct, from time to time, onsite visits to accredited laboratories. Therefore, we have determined that abbreviated laboratory packages from accredited laboratories, when combined with the other recommendations in this document, can provide FDA with information and assurances comparable to those contained in full laboratory packages from non-accredited laboratories. FDA believes that

the contents of an abbreviated laboratory package from an accredited laboratory would provide appropriate information on which to make an admissibility determination.

With greater assurance about the information submitted by accredited laboratories, we could review the abbreviated laboratory packages they submit more quickly, and this will enable us to decide whether to admit these products into the United States more quickly than if we had to review full laboratory packages. While full laboratory packages include the details of any analyses performed and raw data, the abbreviated laboratory packages focus on the test results and could take less time to review. As a result, products meeting FDA standards should move more quickly into United States commerce. We also will be able to reallocate our own laboratory and field resources to ensuring the accuracy and reliability of data and information submitted by non-accredited laboratories about which we have less information or have specific concerns.

III. Accreditation For Fda Submissions

A. What Does "Accreditation" Mean?

For purposes of this document, accreditation refers to a rigorous assessment, conducted by an independent science-based organization, to assure the overall capability and competency of a laboratory and its Quality Management Systems. An accredited laboratory should have established standard operating procedures that are routinely followed and have quality systems in place for identifying and correcting deviations from those procedures. The independent organizations that accredit laboratories are known as "accreditation bodies."

We recommend that laboratories be accredited for the specific test method(s) that they use to generate the data and test results they submit to FDA. That is, in addition to a general assessment of the laboratory's operations, we are recommending that an accreditation body assess the specific sampling techniques and analytical capabilities of the laboratory, including equipment and personnel, that the laboratory uses to generate the data and prepare the report that it submits to us. A laboratory might be accredited for one method and not for another. Accreditation would indicate that the private laboratory is generally competent to perform a specific test method(s) within the scope of its accreditation.

B. How Should A Laboratory Become Accredited?

1. How Should a Laboratory Select an Accreditation Body?

There are several national and international accreditation bodies that can accredit laboratories for FDA submissions. Rather than endorse one or more accreditation bodies, we are recommending that a laboratory seeking to become accredited ascertain and rely upon both of the following factors in choosing an accreditation body:

- The accreditation of a testing laboratory should be issued by an accreditation body operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*.³ This would help ensure that the accreditation bodies are competent to accredit the laboratories.
- The accreditation body should be a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement. Signatories to this Arrangement agree to maintain conformity with the current version of ISO/IEC 17011 and also agree to ensure that all laboratories that they accredit comply with appropriate laboratory standards (see ILAC, "The ILAC Mutual Recognition Arrangement," accessed on the Internet at http://www.ilac.org/documents/ILAC_Mut_Rec_Arr_jun_2007.pdf on February 21, 2008). Having accreditation bodies be signatories to the ILAC Mutual Recognition Arrangement would result in consistent standards among accrediting bodies and accredited laboratories regardless of where these are located. This would enable us to have the same confidence in results from an accredited laboratory in a foreign country as we would have in results from an accredited laboratory located in the United States. One current laboratory standard, ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories," is discussed immediately below.

2. What Should the Accreditation Body Assess, and What Are FDA's Additional Recommendations?

An accreditation body should assess a laboratory's conformance to ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, and should assess whether the laboratory is qualified to use the specific method(s) producing the data and test results that are submitted to FDA. ISO/IEC 17025 is the most widely used laboratory standard for federal testing laboratories, including FDA's own laboratories, and ISO/IEC 17025 is internationally recognized and accepted world-wide. Accreditation in accordance with this guidance should be to specific methodologies used for testing FDA-regulated products. The methods should demonstrate suitable performance and be fit for the intended use.

An accreditation body should review a laboratory's sampling procedures and ensure that it has established adequate controls for ensuring the integrity of the samples it analyzes. Appropriate sampling protocols should ensure that sample integrity is maintained from the time of collection until the sample is delivered to the laboratory. Whether samples are collected by the laboratory itself or by a sampling service under contract to the laboratory, an accreditation body should evaluate whether the sampling protocol includes:

- Verifying the location, identity, and size of the lot to be sampled;
- Collecting samples following established procedures that ensure the sample's integrity, accuracy, and statistical representation, ensuring that it was collected randomly and from a sufficient number of containers (product distribution);

- Ensuring the integrity of the sample after the sample is collected by properly identifying samples, preventing contamination of the sample and the lot to be sampled, maintaining sterility or appropriate temperature controls, or taking other measures to ensure sample integrity;
- Sealing samples with tamper-evident systems;
- Identifying all containers from which samples are collected;
- Completing a detailed sample collection report;
- Preparing and shipping the sample, using appropriate precautions to maintain the sample's integrity or to maintain sterility or appropriate temperatures, and shipping or delivering the sample and collection report directly to the laboratory; and
- Examining the physical condition and integrity of the sampled lot and recording any unusual or objectionable conditions.

Accreditation bodies should also assess whether:

- The testing laboratory employs or contracts the services of personnel with appropriate skills and experience to collect and process samples in accordance with FDA sampling and chain of custody parameters as set out in FDA's laboratory manual entitled "ORA Laboratory Manual, Section 7 – Private Laboratory Guidance";
- The testing laboratory periodically audits the sampling procedures used by the sampling services it hires, if any;
- Calculations are clear, accurate and easy to follow;
- If data sheets contain analysts' initials, the official laboratory file contains a key that matches initials to analysts' names, titles, and positions;
- Complete files of all tests run on FDA-regulated products are maintained for 5 years; and
- Personnel files, containing employees' curricula vitae and training, are maintained for 5 years.

The accreditation body should accredit a laboratory to conduct specific test methods. It should be possible to maintain accreditation indefinitely so long as the laboratory continues to meet the standards to which the laboratory is accredited. The accreditation body should conduct periodic audits of the laboratory to ensure that the laboratory is consistently following accreditation standards. We recommend that all laboratories be audited at least once every 2 years, and that newly accredited laboratories, or accredited laboratories that add new methodologies to the scope of their accreditation, be audited more frequently. Accreditation bodies might conduct audits of the laboratory premises, the laboratory documents, or both.

In addition, FDA recommends that laboratories that are currently accredited for the specific methods used to test FDA-regulated products consider whether they need to modify their method standard operating procedures so that critical performance elements (quality control, sensitivity, accuracy, etc.) are adequate for FDA review purposes. Additionally, we recommend that laboratories incorporate in their implementation of

ISO/IEC 17025 the factors established in the AOAC International “Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025: 2005” which is available from AOAC International. This document provides a section-by-section interpretation of ISO/IEC 17025 as it pertains to food and pharmaceuticals. Use of the AOAC International guidelines would therefore offer additional assurance that the laboratory accreditation includes a sufficient level of detail for the laboratory’s implementation of ISO/IEC 17025 and for the testing that is the subject of this guidance.

3. How Should Accredited Laboratories and FDA Interact?

From time to time, we might conduct onsite visits to accredited laboratories. For example, periodically, we might choose to witness sample collection, examine worksheets on which a Summary of Analysis is based, visit accredited laboratories to assess their work, and conduct our own sample collection and analyses to verify the test results submitted in abbreviated laboratory packages. We might also request that a laboratory allow us to examine the reports of audits conducted by the accreditation body. While we have a high degree of confidence in work performed in accordance with the rigorous standards recommended in this guidance, we anticipate exercising a greater degree of oversight as we initially implement this guidance than we might exercise after we have gained experience with it. Generally, we would conduct these oversight activities after we have made an admissibility decision.

Accredited laboratories should give us the results of their audits and notify us if their accreditation is withdrawn or suspended. In addition, we intend to contact accreditation bodies to verify a laboratory’s accreditation status.

Laboratories should send a copy of the specific methods used, including the latest method revisions, with quality control measures and performance specifications, to us on a compact disc (CD) at Food and Drug Administration, Division of Field Sciences (HFC-141), Room 12-41, 5600 Fishers Lane, Rockville, MD 20857, Attn: Private Laboratory Guidance. We would keep this information on file to use in our assessment of the compliance status of a particular product that has been detained and/or is subject to an Import Alert.

IV. SAMPLING

A. Is Advance Notice to FDA Recommended?

Before the sample is collected, an importer should notify us that the importer intends to use a particular accredited laboratory and that an abbreviated laboratory package will be submitted pursuant to this guidance. Notice should be provided to the FDA District Office that is reviewing the entry, and should include the name, address, and contact information for each laboratory that the importer intends to use as well as a description of the product and the entry number. The notice also should identify and describe the test method(s) that each accredited laboratory is expected to perform. An importer can use

different laboratories to conduct different analyses or different parts of the analyses; for example, one laboratory might analyze a product for decomposition while another laboratory might analyze the same product for microbiological contamination. However, only those accredited laboratories identified by the importer before sampling should submit an abbreviated package for review. If we do not have advance notice that an importer intends to use the laboratory that submits an abbreviated package, we would generally not consider submission of an abbreviated package to be appropriate. Importers should maintain control of the lot from which the sample is collected until we notify them that the lot is released or other action can be taken on the lot.

By receiving advance notice of the laboratory to be used, we want to discourage importers from withholding bad test results, re-testing, or re-sampling. We might, from time to time, observe the sampling procedures used by accredited laboratories and collect an audit sample to test in our laboratories. The information provided in the advance notice will help us to manage our workload and to schedule our observation or audit of the sampling procedures, if warranted. To avoid delays associated with collecting and analyzing an audit sample prior to allowing entry into the United States, we will generally make an admissibility decision on the basis of data and information submitted by an accredited laboratory in the abbreviated laboratory package. Any audit samples will generally be collected after we have made the admissibility decision. Should our analyses of audit samples provide test results different from those reported in the abbreviated laboratory package, we might take regulatory action regarding the product in domestic commerce, including requesting that the product be recalled. Such a situation might also warrant the submission of full laboratory packages pursuant to FDA's laboratory manual entitled "ORA Laboratory Manual, Section 7 – Private Laboratory Guidance." Additionally, we intend to report any concerns about our audit sample to the private laboratory and its accreditation body for investigation.

B. Who Should Collect the Sample?

An accredited laboratory is responsible for ensuring the integrity of the sample it analyzes and that the sample is representative of the lot being tested. Either the accredited laboratory can collect the sample itself or the accredited laboratory can subcontract with an independent third party to collect the sample in accordance with the accredited laboratory's accreditation.

C. How Should a Sample be Collected?

The laboratory should have adequate controls for ensuring the integrity of the samples it analyzes. Appropriate sampling protocols should ensure that sample integrity is maintained from the time of collection until the sample is delivered to the laboratory. Whether samples are collected by the laboratory itself or by a sampling service under contract to the laboratory, the sampling protocol should include the features laid out in section III.B.2 of this document.

The laboratory director should attest to the integrity of the sample collected and that proper procedures and analytical methods were followed, as explained in section VI of this document.

Sampling should be conducted in accordance with the applicable compliance program or with sampling procedures described in FDA's Investigations Operations Manual, Chapter 4 – Sampling. When feasible, any Import Alert associated with the detained goods will contain a link to the recommended sampling method.

Identification of the sample should include the:

- U.S. Customs and Border Protection entry number;
- FDA entry line number, if applicable or available;
- Location where product was sampled, including warehouse or cold storage lot number; and
- Identity of the marks noted by the sample collector on the containers from which samples are collected.

The sample collection report should include information on the:

- Identity of the sample collecting entity, whether an accredited laboratory or a sampling service;
- Identity of the individual collecting the sample, whether employed by an accredited laboratory or a sampling service;
- Invoiced quantity that was made available for sample collection;
- Sample collection date;
- Sample collection method;
- Sample preparation techniques;
- Lot size and identification number;
- Production code;
- Sample size; and
- Observations by the sample collector about the condition of the lot, containers or other conditions that could affect the sample's integrity.

The sample collection report also should:

- Describe the chain of custody identifying each party and its role in collecting and delivering the sample to the lab, from the time the sample is collected to its receipt by the lab; and
- Provide a detailed product description with identifiers such as those contained in Attachment 4 of "ORA Laboratory Manual, Section 7 – Private Laboratory Guidance."

D. Should a Sample Include Labels or Pictures?

The person collecting the sample should ensure that original labels or labeling are collected and submitted along with the sample. If that is not possible, pictures of the labels or labeling should be collected and submitted instead. Both the labels and/or any pictures of the labels should be legible. An accredited laboratory should maintain copies of labels, labeling, and pictures for a minimum of 5 years after the sample was collected for later review by FDA, if appropriate.

E. Should the Laboratory Maintain a Reserve Sample?

The laboratory or its subcontractor that collected the sample (mentioned in part IV.B above) should retain a reserve sample until the laboratory completes its analysis.

V. TEST METHODS

In an abbreviated laboratory package from an accredited laboratory, we will likely find appropriate the use of any method that is validated and fit for its intended application and for which the laboratory is accredited, or that FDA otherwise identifies as suitable. We anticipate that any applicable Import Alert will reference the method that we used in identifying the violation for which an entry is detained, with a link to our website. In the event that only one method has been developed for the relevant analysis, we anticipate that any Import Alert will identify the specific method or set out the analytical figures of merit associated with an appropriate method, including linearity, accuracy, precision, limit of detection, limit of quantitation, selectivity, stability in matrix, process sample, stability, robustness, sensitivity, reproducibility, and linearity.

Accredited laboratories can use methods different from those that we used to identify the violation giving rise to an Import Alert. However, accredited laboratories should use validated methods which assure method performance, including sensitivity, as outlined in the previous paragraph. Sometimes, our regulatory methods are more rigorous than the methods that laboratories could use to show that a sample is within specifications. On the other hand, if an accredited laboratory uses the same method that FDA used and that is cited in the Import Alert, we will generally presume that that method is appropriate for analyzing the product.

VI. ABBREVIATED LABORATORY PACKAGE

We expect that laboratories that are accredited in accordance with this guidance will, to a significantly greater degree than unaccredited laboratories, be competent to conduct the testing methods for which they have been accredited and that their analyses generally conform to established standards. Moreover, as described above, we recognize that accreditation bodies have a continuing role in ensuring that accredited laboratories maintain the high standards to which they were accredited. Therefore, we would have confidence in reviewing abbreviated laboratory packages from accredited laboratories when the recommendations in this document have been observed. Such abbreviated laboratory packages should consist of: (1) documents identifying the entry from the

importer of record; (2) a Summary of Analysis; and (3) an affirmation by the laboratory director.

A. What Import Documents Should an Accredited Laboratory Include in an Abbreviated Laboratory Package?

The abbreviated laboratory package should include a commercial invoice or bill of lading listing the goods that were sampled.

B. What Information Should a Summary of Analysis Contain?

In the Appendix to this document, we have provided an example of the contents of a Summary of Analysis. The checklist reflects the information that we would generally find useful for assessing the test method performed by an accredited laboratory and for making an admissibility decision based at least in part on that analysis. If an accredited laboratory chooses not to use the checklist, the laboratory should ensure that its package contains the data and information elements and information reflected in the checklist.

C. What Sort of Affirmation Should Be Provided?

The laboratory director or similar responsible official should sign and date the submission, personally affirming the accuracy of its contents and that the client has not influenced or interfered with the manner in and the process by which samples were collected and analyzed. The laboratory director should also affirm that the package contains all test results conducted by the laboratory under the laboratory director's control and identify any laboratories or analyses run by other laboratories, if known by the laboratory director. Furthermore, the laboratory director should include a statement acknowledging that the knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to criminal sanctions according to the provisions of Title 18 of the United States Code, Section 1001.

D. How Should a Laboratory Submit an Abbreviated Laboratory Package?

Accredited laboratories should submit directly to FDA all test results on the articles. The laboratory can, at its discretion, explain whether any reported test results should not be considered in the evaluation of the tested article for entry. Accredited laboratories should use an electronic submission to provide an abbreviated laboratory package to the FDA Office that is reviewing the entry. The Notice of Detention for the articles detained and/or subject to an Import Alert will identify the appropriate e-mail address. If e-mail is not feasible, accredited laboratories should contact the Compliance Officer to discuss delivery alternatives.

VII. CONCLUSION

This guidance describes a process in which FDA expects an abbreviated laboratory package to be suitable for submission to FDA for review provided that the importer:

- Uses an accredited private laboratory for sampling and testing (as described in parts III through V of this document);
- Provides advance notice to FDA (as described in part IV.A of this document); and
- Requests that the accredited laboratory submit all test results directly to FDA (as described in part VI of this document and in the Appendix).

This guidance does not address situations where importers or the private laboratories the importers use decline to follow the recommendations in this guidance. In those situations, submission of a full laboratory package might be warranted.

APPENDIX

EXAMPLE

– SUMMARY OF ANALYSIS – SUBMITTED BY ACCREDITED LABORATORY

Product

Description: _____

Entry #: _____ **Lab Sample**
#: _____

Private Laboratory

Name: _____

Address: _____

Accredited by: Date accreditation expires: _____

Accreditation number:

Type of analysis: _____ **Import Alert #, if any:**

Name of Analyst Performing Analysis:

ANALYTICAL RESULTS

Composite Analysis (units)

Individual Subsample (units)

SAMPLE COLLECTION PERFORMED BY ACCREDITED LABORATORY _____ or INDEPENDENT THIRD PARTY SUBCONTRACTOR _____ (please check one)

Invoiced quantity was made available for sample collection

Sample was collected from the invoiced quantity of the detained article

Sample was received in condition fit for analysis

Collection report and commercial invoice are on file (see ORA Laboratory Manual Section 7, Attachment 1)

Sample was collected randomly and from sufficient number of containers (proper distribution)

Sample was collected according to (please check any of the following that are applicable to the sample):

Investigations Operations Manual

Import Alert

Compliance Program

Other, explanation attached

If composite sampling was conducted, each sub-sample consists of:

The following sizes: _____

The following production codes: _____

Legible copies of labeling &/or clear photographs are on file

SAMPLE PREPARATION (Complete Appropriate Section)

Composite Testing:

Number of subsamples composited _____

Weight of individual subsample in composite _____ g.

Individual Subsample Testing:

Number of subsamples tested _____

Weight of individual subsample tested _____ g.

ANALYTICAL METHOD

Method Title _____

SOP Revision Number/Tracking Number/Identification _____

Modifications to the method?

Yes

Attach modifications

Attach description of rationale for modifications, or reasons as to why the modifications are appropriate

No

All equipment is identified and traceable through applicable quality assurance records

Recovery data supports quantitation and demonstrates suitability that the methods are fit for use

Controls (spikes, duplicates, calibration verifications) are run at appropriate frequency and within established criteria for the method used

All analysts and their work are clearly identified

STANDARD DATA

Media and reagents are non-expired

Source and expiration date of each standard is cited; Certificate of Analysis is on file

For all standards, traceability to a stock source, including dates of preparation and dilutions, is included

For microbiological analysis, positive and negative culture controls(s) are used and give appropriate results

Controls are traceable to reference cultures and are run concurrently with sample analysis

INSTRUMENTATION

Instrumentation was operating within parameters determined by the method and in accordance with accredited quality assurance program.

Supplementary information attached

The information contained in this submission is accurate and complete. I have reported to FDA results of all tests run on this lot or product conducted by the laboratory under my direction. If I am aware of tests run by others, I have attached information identifying those tests and the laboratories that conducted them. If I have failed to check a box above, I have attached information explaining why.

I understand that the knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to criminal sanctions according to the provisions of Title 18 of the United States Code, Section 1001.

Laboratory Director

Signature &

Date: _____

Email address

Phone number:

Footnotes:

¹This guidance was prepared by the Office of Regulatory Affairs (ORA) in cooperation with the Office of Policy, Planning, and Preparedness of the Food and Drug Administration.

²Accredited laboratories can also refer to the ORA Laboratory Manual for guidance concerning submission of full laboratory packages.

³Also known as "ISO/IEC 17011:2004," with 2004 designating the date of the latest revision. According to an abstract on the ISO's website, "ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies." See International Organization for Standardization, "ISO/IEC 17011:2004," at "Abstract," accessed on the Internet at http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=29332 on February 21, 2008.

⁴The list of signatories to the Mutual Recognition Arrangement can be found on the ILAC website at http://www.ilac.org/documents/mra_signatories.pdf.

⁵Also known as "ISO/IEC 17025:2005," with 2005 designating the latest revision. According to an abstract on the ISO's website, "ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods." See International Organization for Standardization, "ISO/IEC 17011:2004," at "Abstract," accessed on the Internet at http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=39883 on February 21, 2008.

⁶An "admissibility decision" is a decision whether to admit the imported item into the United States.