Food & Drug

E-ALERT

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Draft FDA Guidance on Submission and Expedited Review of Abbreviated Laboratory Packages From Accredited Laboratories

On January 16, 2009, the Food and Drug Administration (FDA) published a draft guidance describing FDA's proposal to begin accepting abbreviated data packages submitted by accredited laboratories for detained imported products.[1] Acceptance of abbreviated data packages could significantly expedite FDA review of the test data and help speed release of detained products.

According to the draft, laboratories wishing to submit abbreviated packages must follow the accreditation and administrative procedures described in the guidance.[2] The proposed expedited review process for abbreviated packages is expected to be particularly useful for importers of goods subject to import alerts under which every entry of imported goods must be tested and the test results cleared by FDA prior to release of the products. Although comments on a draft guidance may be submitted anytime, FDA encourages submission by **April 16, 2009** so that comments can be considered prior to FDA beginning work on the final version of the guidance.

Background

In 2004, FDA issued a proposed rule setting requirements for sampling services and private laboratories in connection with imported food.[3] Since the rule was proposed, significant changes have taken place. In late 2007, the President's Interagency Working Group on Import Safety presented its Import Safety Action Plan to the President, which contains short- and long-term recommendations for continuing to improve the safety of imports entering the United States.[4] One recommendation in that Plan was for FDA to issue guidance that "would set standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved." In light of this recommendation and the evolution of laboratory accreditation, FDA elected to issue the draft guidance instead finalizing the 2004 proposed rule.

[1] 74 Fed. Reg. 3056 (Jan. 16, 2009); the full text of the draft guidance can be found at http://www.fda.gov/oc/guidance/labpackages.html.

[2] Accreditation is voluntary and non-accredited laboratories may continue to submit full laboratory packages (containing complete data sets and all raw data) for review by FDA analysts and compliance officers. Non-accredited laboratories submitting full data packages should continue to refer to FDA's laboratory manual, "ORA Laboratory Manual, Section 7 - Private Laboratory Guidance," available at http://www.fda.gov/ora/science_ref/lm/pdf/volumes/vol3_07.pdf.

[3] 69 Fed. Reg. 23460 (Apr. 29, 2004).

[4] The Action Plan for Import Safety can be found at http://www.importsafety.gov/report/actionplan.pdf.

Process for Filing Abbreviated Laboratory Packages

Laboratory Accreditations

"Accreditation" is defined in the draft guidance to mean "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." The guidance recommends that laboratories be accredited for the specific test method(s) they use to generate the test results they submit to FDA and provides extensive recommendations regarding how laboratories can obtain voluntary accreditation that would be acceptable to FDA.[5]

Sampling

The draft guidance recommends that before a sample is collected, the importer should notify the FDA District Office reviewing the entry of the importer's intent to use a particular accredited laboratory and to submit an abbreviated laboratory package. The notice should include the name, address, and contact information for each laboratory, a description of the product, the entry number, and the expected test method(s) to be performed. The guidance notes that FDA will generally not consider to be appropriate the submission of an abbreviated package by a laboratory for which such notice has not been provided.

Under the provisions of the draft guidance, either the accredited laboratory or an independent third party under contract to the laboratory may collect the sample, but the accredited laboratory remains responsible for ensuring the integrity of the sample it analyzes and that the sample is representative of the lot being tested. 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.[6] When feasible, import alerts will contain links to recommended sampling methods.

The identification information listed in the draft guidance to be submitted for each sample includes: U.S. Customs and Border Protection entry number; FDA entry line number (if applicable or available); location where the product was sampled (including warehouse or cold storage lot number); and any marks noted by the sample collector on the containers from which samples are collected. The sample collection report should include, *inter alia*, the identity of the sample collecting entity and individual; the sample collection date; lot size and identification number; and observations by the sample collector about the condition of the lot, containers or other circumstances that could affect the sample's integrity. The sample collection report should also describe the chain of custody of the sample collection process and provide a detailed product description with identifiers such as those contained in Attachment 4 of ORA Laboratory Manual, Section 7 - Private Laboratory Guidance.

According to the draft guidance, the sample should include original labels or labeling, or, if unavailable, pictures thereof. The accredited laboratory should maintain copies of any such labels, labeling, and/or pictures for at least five years after sample collection for possible later review by FDA. The laboratory or its subcontractor should also retain a reserve sample until the laboratory completes its analysis.

[5] The draft guidance provides a list of the laboratory methods and procedures the assessment body should consider in reviewing a laboratory for accreditation.

[6] Available at http://www.fda.gov/ora/inspect_ref/iom/pdf/chapter4.pdf.

Test Methods

Accredited laboratories can either use: 1) any method that is validated for its intended application and for which the laboratory is accredited; or 2) that FDA otherwise identifies as suitable.[7] The draft guidance anticipates that the applicable import alert will refer to the method FDA used to identify the violation for which an entry is detained.

Contents of An Abbreviated Laboratory Package

The draft guidance recommends that an abbreviated laboratory package consist of:

- A commercial invoice or bill of lading listing the goods that were sampled.
- A Summary of Analysis that contains the information listed in the Appendix to the draft guidance.
- A signed and dated affirmation by the laboratory director that:
  - affirms the accuracy of the submission;
  - affirms that the client has not influenced or interfered with the manner in and the process by which samples were collected and analyzed;
  - affirms that the package contains all test results conducted by the laboratory under the laboratory director's control and identifies any known analyses run by other laboratories; and
  - contains a statement acknowledging the applicability of the False Statements Act (18 U.S.C. § 1001) to any statements made to FDA.

FDA recommends in the draft guidance that the accredited laboratories submit directly to FDA all test results on the articles. This submission should be made electronically to the FDA office reviewing the entry.

Implications

If laboratories are able to gain accreditations per the draft guidance for particular test methodologies and are therefore in a position to file FDA-acceptable abbreviated laboratory packages, this proposed system could make significant inroads in alleviating the delays currently experienced by importers when awaiting FDA-review of submitted laboratory packages for detained imported goods. Under the present system, complete laboratory packages are submitted to the field office associated with the port at which the products are held. These frequently voluminous data packages are then forwarded to the FDA laboratory, where they routinely remain for weeks or longer until their review can be completed. The detained goods continue to be held during this interval. These delay times become much longer in periods of crisis within FDA, such as in 2007 during the pet food melamine contamination issue and more recently throughout the events surrounding the *Salmonella* contamination of certain peanut products. During these periods, FDA laboratories are inundated with samples to test and become bottlenecks in the import clearance process.

Routine acceptance of abbreviated packages from accredited laboratories could significantly improve the processing times for this data and, thus, the amount of time

[7] After FDA has made an admissibility decision based on the submitted abbreviated package, the agency may on occasion collect an audit sample to test in FDA's laboratories. The draft guidance states that if audit samples yield test results different from those in the abbreviated laboratory package, FDA may take regulatory action regarding the product, including potentially requesting a recall. Such a situation might warrant the submission of a full laboratory package and FDA will report its concerns about its audit sample to the private laboratory and its accreditation body for investigation.

products remain on hold. Although the draft guidance describes FDA's ability to collect audit samples and compare the results of testing those samples against test results in the abbreviated package, FDA has always had the ability to collect and test audit samples and we have seen the agency exercise that authority on a number of occasions. The audit sample procedure outlined in the draft guidance therefore does not represent a departure from FDA's existing practices.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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