Compliance Policy Guide
Sec. 150.200 Compliance Review of Private Laboratory Analytical Packages (PLAPs)

Guidance for FDA Staff

Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number of this Compliance Policy Guide: FDA-2016-D-3338.

For questions regarding this document contact the Director of the Division of Import Operations with the Office of Regulatory Affairs (DIO/ORA) at 301-796-0356.

U.S. Department of Health and Human Services
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This guidance represents 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 FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this document is to provide guidance for FDA staff when receiving and reviewing private laboratory analytical packages (PLAPs). Importers typically submit PLAPs to FDA to provide information regarding the admissibility of articles that are held under detention without physical examination (DWPE) due to the appearance of a violation. The policy described in this document applies to: 1) FDA compliance personnel review of the non-technical aspects of a PLAP; and 2) FDA compliance personnel determination of admissibility after the technical review of a PLAP is completed by an ORA Field Laboratory.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency'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 Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Section 801 of the Federal Food Drug & Cosmetic Act (FD&C Act) authorizes FDA to refuse admission of imported articles if it appears from the examination of such samples or otherwise that the article is in violation of applicable provisions of the FD&C Act. To carry out the provisions of section 801(a), FDA may detain articles that appear violative and inform the importer of the nature of the violation and the right to introduce testimony regarding the admissibility of the article (see 21 CFR 1.94). Depending on the information submitted by the importer, the article may either be permitted or refused entry into the United States.

FDA utilizes detention without physical examination (DWPE) when information indicates that future shipments of a product or products offered for entry appear violative within the meaning of section 801(a).

Section 801 provides the importer with the right to introduce testimony bearing on the admissibility of the articles. When an importer submits evidence to FDA to demonstrate admissibility, it is often in the form of private laboratory reports, known as Private Laboratory Analytical Packages (PLAPs), often prepared by third-party laboratories.

The Agency evaluates the PLAPs to determine whether and how the PLAPs bear on the admissibility of an article. This evaluation consists of two parts: (1) a non-technical review, to ensure the PLAP is complete, to verify sample integrity and relevance to the detained shipment, to assess if sound sample collection methods have been used, and to verify that the reported results indicate that there is no apparent violation; and (2) a technical review, to ensure that the analytical result is scientifically valid. The policy stated below applies to FDA compliance personnel review of the non-technical aspects of a PLAP. The determination of admissibility is typically made after the technical review of a PLAP is completed by an ORA Field Laboratory or other designated scientific authority within the agency. PLAPs reporting clearly violative results do not require a technical review. If the results are not clearly violative, the PLAPs can be sent for technical review.

III. Policy:

A. Non-Technical Review of PLAPs by Compliance Personnel

When FDA receives a PLAP, FDA compliance personnel conduct a review of the non-technical aspects of the package. FDA compliance personnel utilize a checklist to determine if the package is complete and if the package follows the sampling recommendations described in ORA Laboratory Manual, Section 7 – Private Laboratory Guidance. The checklist consists of the questions listed below.

If the answer to any of the questions is "No," compliance personnel may determine that it is appropriate to relay this information to the importer. If that occurs, compliance personnel will provide the importer an opportunity to address the identified issue(s), which can include providing a rationale for why the items in the checklist are not applicable or why an alternative approach is warranted. If the issue(s) cannot be resolved, the PLAP may be considered unacceptable.

i. Initial Questions:
   a. Does the lab analysis address the reason for the detention?
   b. Does the lab analysis demonstrate that the articles are non-violative? PLAPs reporting clearly violative results do not require a technical review.

ii. Questions to determine if the PLAP is complete:
   a. Are the entry number and, if applicable, line number correct in the report?
   b. Is the private lab sample number consistent throughout the report?
   c. Are the dated signatures included in the final report for the importer and the private lab?
   d. If there was a prior analysis, was the prior analysis field filled out within the private lab's statement?
   e. If there was a prior analysis, was the previous report submitted with the current report?
   f. Where included, are photos and labels legible?
   g. Are the raw analytical data and worksheets provided in the report?

iii. Questions to determine if the sample was collected appropriately and relevant to the detained product:
   a. Are the sample collector and his/her organization identified on the collection report?
   b. Is the product collected and analyzed the same as the product detained?
   c. Is the product description consistent throughout the report?
   d. Is the actual quantity available for sampling reported on the collection report consistent with the entry documents and declaration for the indicated product(s)?
   e. Is the collection date indicated in the collection report?
   f. Is the sequence of dates for sampling and analysis consistent, e.g., was the analysis conducted after the sample was collected?
   g. Is the sample collection appropriate? Factors to consider include, but are not limited to: (1) Is the sample representative of the detained product?; (2) Were a sufficient number of sub-samples collected based on the size of the lot? Consult ORA Laboratory Manual, Section 7 – Private Laboratory Guidance, for additional factors to consider. If additional information is required to make this determination, contact the private lab.

If the package is found to be acceptable for the non-technical portion, the package is generally forwarded to an ORA Laboratory or other specified entity for review of the technical portion of the PLAP. If the district is unable to determine if the PLAP non-technical review is acceptable or unacceptable, the district should refer the issue to DIO who will consult with the appropriate Center as needed.

B. District Assessment of PLAPs after Technical Review

ORA Field Laboratories typically conduct the technical reviews of the PLAPs. The results of the review of the technical portion of the package are reported to the appropriate district compliance personnel.

If the technical review conducted by the FDA reviewing entity classifies the PLAP as "unacceptable", then FDA will inform the importer of the unacceptable nature of the PLAP, and will provide the importer an opportunity to respond. Depending upon the

nature of the deficiencies noted, FDA may provide the importer an opportunity to correct the deficiencies and submit the PLAP for re-evaluation. Some deficiencies may not be correctable.

FDA will review requests to reanalyze products on a case-by-case basis. There is no automatic right to reanalyze products after they have been analyzed and the results submitted to FDA as part of testimony regarding the admissibility of an article.

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