Private Laboratory Testing

Resources for Private Laboratory Testing

Import Alert Resources | LAAF Resources | Compliance Programs | Other Resources | Contact Us

This page provides supplementary sampling, method information and sample preparation information to assist private laboratories who are analyzing products being held under Detention Without Physical Examination (DWPE) as part of an Import Alert. The goal is to assist private laboratories submit scientifically sound Private Lab Analytical Packages (PLAPs) as testimony pursuant to FD&C Act section 801 (21 U.S.C. § 381) and 21 CFR § 1.94. FDA does not endorse any private laboratory firms, nor requires specific methods to be used for PLAPs. Methods link herein are provided as a courtesy, but private laboratories are not required to use them. The collected sample(s) should be analyzed using appropriate methods that have been properly validated. The PLAP should cite the method(s) used and deviations from official methods should be explained and validated. Please refer to the current ORA Laboratory Manual, Volume III, Section 7, "Private Laboratory Guidance," (/media/73540/download?attachment) for more comprehensive information about private laboratory package contents and the review process.

- Food Laboratory Methods (/food/science-research-food/laboratory-methods-food-safety)
- Method Validation Guidelines (/science-research/field-science-and-laboratories/method-validation-guidelines)
- Laboratory Information Bulletins (/science-research/field-science-and-laboratories/laboratory-information-bulletins)
- Additional information on the Private Laboratory Analytical Package Program and PLAP submissions (/media/73540/download?attachment)
- Additional Chemistry and Microbiology Resources Used by the Foods Program (/food/laboratory-methods-food/additional-chemistry-and-microbiology-resources-used-foods-program)
- Memo to Industry for Private Laboratories currently performing filth analyses for products on DWPE (/media/168511/download?attachment)

Import Alert Resources

View Import Alerts: Specific Method/Preparation Recommendations (/science-research/private-laboratory-testing/import-alerts-specific-methodprepar

Import alerts inform FDA staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of FDA laws and regulations. These violations could be related to the product, manufacturer, shipper and/or other information. If a product is detained without physical examination, importers have the right to provide evidence to FDA in an attempt to overcome the appearance of the violation. Depending on the type of issue covered by the import alert, submitting private laboratory analytical reports may be useful as evidence to overcome the appearance of the violation.

Under the FD&C Act section 801, FDA is authorized to refuse admission of FDA-regulated articles offered for import that appear to violate certain provisions of the FD&C Act, implementing regulations, and/or other laws enforced by FDA. FDA-regulated articles that appear to violate the FD&C Act are detained and therefore may be subject to refusal of admission by FDA. The importer is informed of the nature of the violation and of the importer's right to introduce testimony regarding the admissibility of the article (see FD&C Act section 801 [21 U.S.C. § 381] and 21 CFR § 1.94).

LAAF Resources

The Laboratory Accreditation for Analyses of Foods (LAAF) Program establishes a laboratory accreditation program for the testing of food in certain circumstances.

- Laboratory Accreditation for Analyses of Foods (LAAF) Program & Final Rule (/food/food-safety-modernization-act-fsma/laboratory-accreditation-analyses-foods-laaf-program-final-rule)
- Laboratory Accreditation for Analyses of Foods Program Dashboard (https://datadashboard.fda.gov/ora/fd/laaf.htm)

Compliance Programs

FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.

- Compliance Programs- Human Foods and related programs (/food/compliance-enforcement/food-compliance-programs)
- Compliance Programs- Animal food and related programs (/animal-veterinary/compliance-enforcement/cvm-compliance-programs)
- Compliance Programs for all FDA Program Areas (/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-manual)

Other Resources

- Investigations Operations Manual (IOM) (/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual)
- RPM Chapter 9-8 Detention without Physical Examination (DWPE) (/media/71776/download#page=36)

Contact FDA

If you have additional questions regarding sample preparation or analytical methodology for products being held under DWPE under an Import Alert, please contact the ORA/Office of Regulatory Science @ oraorsprivatelabimportalerts@fda.hhs.gov (mailto:oraorsprivatelabimportalerts@fda.hhs.gov)