

How to Resolve Your FDA Hold or Detention

Getting an FDA hold lifted takes coordination, precision, and the right legal support. An FDA lawyer reviews the detention notice, identifies what caused the issue, and prepares documentation to prove compliance. You can also apply for reconditioning to make your products compliant.

Have you ever thought about how one stalled shipment could disrupt your entire supply chain? Working with an **FDA lawyer** to resolve an FDA hold or detention helps you clear shipments faster and maintain business continuity.

Overcoming an FDA detention is a process that demands experience and strategy. Understanding how the system works and where an attorney fits in protects your business from recurring holds and costly disruptions.

What Triggers an FDA Hold?

An FDA hold happens when ***imported products fail to meet U.S. safety and regulatory standards***. The agency pauses clearance until the issue is reviewed and corrected. A shipment under hold cannot move forward until the importer shows proof of compliance.

Common triggers for an FDA hold include:

- Incomplete or incorrect product labeling
- Inaccurate documentation
- Suspected contamination or quality control concerns
- Products from unregistered or unapproved facilities
- Misrepresentation of ingredients or country of origin

A [regulatory compliance lawyer](#) helps you gather proper records and communicate with the FDA to release your goods and avoid costly delays.

How Long Can the FDA Hold a Shipment?

An FDA hold usually lasts as long as it takes for you to respond to the detention notice and clear the issue. The agency gives 10 business days to submit your testimony, but most notices list **20 calendar days** from the detention date to cover weekends, holidays, and mailing time. Quick action helps prevent the shipment from being refused.

What Is an FDA Import Refusal?

An [FDA import refusal](#) happens when the agency decides your product cannot enter the United States. A refusal often follows issues such as:

- Failed inspection or sample testing
- Failure to respond to notices
- Incomplete or inaccurate documentation

After refusal, you must work with the FDA and U.S. Customs and Border Protection to **destroy or export the product within 90 days**.

Resolving the Hold or Detention

Getting an [FDA hold](#) lifted takes careful coordination, accurate records, and clear communication with the agency. You can move your shipment forward through the following steps:

Identify the Exact Cause of the FDA Hold

An FDA hold begins when the agency flags [imported products](#) for possible violations. An FDA lawyer reviews the **Notice of Detention and Hearing**, which lists the specific laws or regulations that you violated. Knowing the root cause allows for precise communication with the agency and faster clearance.

Respond to the FDA's Documentation Requests Quickly and Accurately

When the FDA issues a Notice of FDA Action, the agency often requests documents that show how the product meets U.S. standards. A lawyer can review the detention notice and **prepare evidence to confirm product safety and traceability**. Evidence may include:

- Supplier declarations
- Lab test reports
- Proof of facility registration

Your lawyer ensures the submission is complete and consistent, reducing the chance of further review and helping the shipment move toward release.

Submit a Reconditioning Plan

A reconditioning plan gives importers a chance to correct noncompliant products instead of facing outright refusal. An FDA lawyer can prepare **Form FDA 766** outlining the steps that you'll follow to ensure the products meet import standards. The agency reviews the proposal and approves or denies it based on the quality of evidence submitted.

Common reconditioning actions include:

- Relabeling to meet FDA [packaging rules](#)
- Cleaning or repackaging to remove contamination concerns
- Supplying missing lab reports or certifications

FDA Reinspection

After your reconditioning plan gets approved, the FDA reinspects the goods to confirm compliance. Inspectors **review labeling, packaging, and product quality** to verify that corrections meet U.S. import standards.

Successful reconditioning allows the FDA to release the shipment once it meets all requirements, completing the FDA detention resolution process. If there are still unresolved issues, it leads to a continued hold or refusal.

Understanding and Avoiding FDA Import Alerts

FDA import alerts flag products or companies that have shown repeated noncompliance, allowing the agency to place shipments under **Detention Without Physical Examination (DWPE)**. Under DWPE, the burden shifts to the importer to prove the product meets U.S. standards before release.

Unresolved detentions can trigger [FDA import alerts](#) and block future entries at the border. Other reasons for being placed on an alert include:

- Repeated labeling or contamination issues
- Unregistered manufacturing facilities
- False or missing compliance records

An attorney examines your import record to identify what led to the alert, then prepares the documentation needed to request removal.

How an FDA Lawyer Helps Resolve a Hold or Detention

A food and drug administration legal expert acts as your authorized representative before the agency. A lawyer will **handle all communication** with compliance officers to prevent delays or missteps. Attorneys understand complex FDA regulations and can clearly explain the basis of the hold or detention.

Beyond interpretations, an **FDA lawyer** also plays a key role in preparing a strong response strategy backed by accurate data and documentation. To demonstrate full compliance, lawyers help you coordinate:

- Testing
- [Label reviews](#)
- Reconditioning plans

Preventing Future FDA Holds

Steering clear of FDA holds protects your supply chain, reduces financial loss, and strengthens trust with regulators. You can reduce the risk of another detention when you:

Build a Compliance Program

A strong compliance program helps you **stay aligned with FDA rules before products reach inspection**. To ensure each shipment meets import standards, organize the following:

- Supplier records
- Lab reports

- Labeling details

Regular audits within the program catch potential issues early and prevent them from turning into costly detentions.

Train Staff on FDA Requirements

Staff who understand FDA import rules help prevent compliance mistakes that cause delays. Training should cover how to:

- Prepare documentation
- Recognize labeling errors
- Maintain traceable supply records

When everyone involved in import operations knows the standards, your business runs smoothly and avoids repeat detentions.

Work With Legal Counsel Proactively

Partnering with an experienced **FDA lawyer** helps you spot issues before they reach inspection. Legal counsel can help you ensure compliance with current regulations by reviewing:

- Import practices
- Product classifications
- Supplier documentation

Early involvement protects shipments from unnecessary holds and strengthens your position if the agency raises concerns later.

Frequently Asked Questions

What Is the Process of FDA Customs Clearance?

FDA clearance starts when importers file Prior Notice before the shipment arrives, giving the agency time to review product details in advance. Once the goods reach entry, the FDA checks documentation, facility registration, and labeling for compliance. If everything meets U.S. standards, a "May Proceed" notice authorizes Customs to release the shipment.

Do Importers Need to Register With the FDA?

The need for FDA registration depends on the type of product you import. Importers of drugs, medical devices, and some food items must complete registration.

In other cases, only the manufacturing or storage facility is required to register. Some products fall outside registration rules altogether, depending on FDA classification.

How Many Days Can the FDA Detain Food Under Administrative Detention?

The FDA can hold food for up to **20 calendar days** under administrative detention. The period allows the agency to determine if the product poses a safety risk or violates U.S. food laws.

If more time is needed, the detention may be extended for an additional 10 calendar days with written approval. During that time, the food cannot be distributed, moved, or sold until the issue is resolved.

How Do You Choose an FDA Lawyer?

Find a lawyer with **deep experience in regulatory and import law**. The best fit understands how FDA and Customs interact and has a record of resolving holds, refusals, or import alerts.

Key things to look for include:

- Proven success with FDA detentions
- Experience communicating with compliance officers
- Strong knowledge of product classification and labeling rules

An attorney with these skills can navigate complex regulations and protect your business from long-term compliance issues.

Can You Appeal an FDA Import Refusal?

An FDA import refusal **is usually a final decision**, and the agency rarely reconsiders it. Only in cases where the refusal was issued in error can the importer request a review. Once a refusal stands, you must export or destroy the product under FDA and Customs supervision.

How Long Does It Take to Get Off an FDA Import Alert?

The time it takes to be removed from an FDA import alert *depends on how quickly you can prove compliance*. The FDA must review your petition, evaluate supporting evidence, and confirm that recent shipments meet all requirements. The process can take several months, depending on case complexity and agency workload.

Work With an FDA Lawyer to Overcome a Hold or Detention

Getting through an FDA hold takes clear communication and expert guidance. An **FDA lawyer** identifies the cause of the detention, prepares accurate documentation, and handles communication with compliance officers. They also help you build stronger systems that prevent future delays and import alerts.

At MyFDALawyers, *we have over 35 years of combined experience helping importers resolve FDA detentions*. Our firm has helped over 1,000 clients navigate complex FDA procedures, earning a strong record of satisfied clients. [Contact us](#) to resolve your FDA hold and keep your business moving forward.