

# FDA National Entry Review (NER) Trade Communications Guide

## Detailed Contact Protocols and Special Shipment Procedures

### FDA's Nationalized Entry Review Program (NER)

Effective August 4, 2025, FDA is launching the Nationalized Entry Review Program (NER) to revolutionize import operations through a standardized, efficient, technology-driven approach. This program transitions from port-by-port reviews to a nationwide system that utilizes staff across multiple time zones, explores automation opportunities, and optimizes resources to focus on higher-risk products.

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## General Contact Protocols

### Direct Contact

When you need to contact the NER program about a specific shipment, this communication guide ensures your correspondence reaches the correct team promptly with the necessary information for quick response.

### Key Points of Contact

- Use [ITACS](#) to query real-time status, upload documents, submit locations for exam, and obtain Notices of FDA Action. **ITACS is the preferred method for status inquiries and submitting entry information or documents.**
- Entry-Specific Status Inquiries
  - Under initial review (pending review, documents requested, etc.): [NERInquiry@fda.hhs.gov](mailto:NERInquiry@fda.hhs.gov)
  - Under field review (pending exam/sampling, detained, refused, etc.), contact the division who cover the port of entry: [FDA Import Offices and Ports of Entry](#)
- For all other inquiries, see [Contact the FDA Program](#)

## Communication Procedures

### Contacting the FDA NER Team

When emailing the [NERInquiry@fda.hhs.gov](mailto:NERInquiry@fda.hhs.gov) mailbox,

- Do not email multiple FDA mailboxes.
- Only use this mailbox for:
  - Checking the status of entries under initial review (e.g., pending FDA review, documents requested, documents submitted, etc.); or
  - Providing entry documents (first preference is via [ITACS](#)).
- Use the proper subject line formatting.

### Subject Line Format

- Entry number (one entry number per email)
- Space
- Commodity type:
- Commodity type: Animal Foods/Feeds, Animal Drugs/Devices/Medicated Feed, Biologics, Cosmetics, Dietary Supplements, Food Related Products, Human Drugs, Human Foods, Infant Formula, Medical Devices, Rad Health Products, Tobacco, Multiple
- Space
- Port code

### *Examples of properly formatted subject lines:*

- 000-1234567-8 Food 2704
- 987-7654321-0 Multiple 4601

## Hot Shipments Handling

On occasion, there may be specific situations for which trade needs to contact FDA regarding certain types of shipments.

### *Urgent Situation Types for Hot Shipments: (Tier 1)*

- **Shipments of nuclear medicaments/medical devices** – These urgent, time-sensitive products may be unstable or perishable and often require same-day patient use. Nuclear products must be FDA-approved and transmitted with accurate data elements, including applicable affirmations of compliance (AOC). With FDA Import Division consent, importers may move shipments to destination

pending the admissibility decision.

- **Emergency personal medicaments/medical devices** – Urgent or emergency personal medication and medical device shipments (e.g., needed for surgery) that satisfy FDA's personal import requirements. Entries must include accurate data elements with applicable affirmations of compliance (AOC) and all supporting personal importation records uploaded into ITACS.

#### *Perishable Shipment Types: (Tier 2)*

- **Perishable** – Products whose integrity would be compromised by delivery delays (e.g., fresh fish, fruits/vegetables, live lobsters, fresh truffles). Entries must include accurate data elements with applicable affirmations of compliance (AOC).

***Note:** Tier 1 shipments receive priority over Tier 2 due to urgent human health and safety concerns. Tier 2 shipments are handled expeditiously like other perishable FDA-regulated products.*

### **Hot Shipment Communications Procedures**

Only if your shipment meets the criteria above, you may contact the FDA's Hot Shipment Team at: [OIIOICourierNotification@fda.hhs.gov](mailto:OIIOICourierNotification@fda.hhs.gov)

When emailing this mailbox,

- Do not email multiple FDA mailboxes.
- Only use this mailbox for:
  - Shipments that meet the criteria above
- Use the proper subject line formatting.

#### **Subject Line Format**

- Entry number (one entry number per email)
- Space
- Commodity type: Animal Foods/Feeds, Animal Drugs/Devices/Medicated Feed, Biologics, Cosmetics, Dietary Supplements, Food Related Products, Human Drugs, Human Foods, Infant Formula, Medical Devices, Rad Health Products, Tobacco, Multiple
- Space
- Port code
- Space
- HOT SHIPMENT

#### *Examples of properly formatted subject lines:*

- 000-1234567-8 Food 2704 HOT SHIPMENT
- 987-7654321-0 Multiple 4601 HOT SHIPMENT

## Hot Shipment Email Body/Message

Within the body of the email, for each product provide:

- Products/product names
- Manufacturer name
- Entry number and its associated air waybill number if applicable.
- Attach all relevant documentation.

## Frequently Asked Questions

- Q: What if my shipment doesn't meet hot shipment criteria but is time-sensitive?  
A: Contact [NERInquiry@fda.hhs.gov](mailto:NERInquiry@fda.hhs.gov) with proper subject line formatting. Include "TIME SENSITIVE" in the email body and explain the circumstances.
  - Q: Can I call instead of emailing?  
A: For most inquiries, email is preferred for proper documentation and tracking. Phone support is available only for prior notice inquiries at 866-521-2297.
  - Q: What if I need to update information after submitting an inquiry?  
A: Send a new email with the same subject line format and reference your previous inquiry. Include "UPDATE" in the email body.
  - Q: How long should I wait for a response?  
A: Response times vary based on inquiry type and complexity. Hot shipments receive priority processing. Check ITACS for status updates between inquiries.
- Q: What if my entry involves multiple commodity types?  
A: Use "Multiple" as the commodity type in your subject line and list all relevant commodities in the email body.

## Additional Resources

- [FDA Import Offices and Ports of Entry](#)
- [ITACS Resources](#)
- [Entry Submission](#)