The Food and Drug Administration's Office of Inspections and Investigations (OII) Office of Import Operations (OIO) is implementing important changes to our import entry review process that will impact the way you engage with FDA import operations.

Effective, **August 4, 2025, OIO** will implement the **Nationalized Entry Review (NER)** program to address the increasing volume of imported FDA-regulated commodities driven by e-commerce growth, expanded trade volume, and supply chain complexities.

What's Changing

The NER program revolutionizes FDA's import operations by implementing a standardized, efficient, and technology-driven approach to entry reviews across all ports of entry. We are transitioning from our current geographic location model to a national-based review system that will:

- Conduct entry admissibility reviews on a national basis versus the current port-by-port entry review approach
- Utilize staff across multiple time zones for expanded coverage
- Explore automation opportunities to streamline processes
- Optimize resource allocation to focus on higher-risk products

What is NOT Changing

- **Review Processes and Standards**: Our established entry review procedures, quality standards, and regulatory requirements remain unchanged
- **Review Criteria**: The methods and standards we use to evaluate entries will continue as before

- **Public Health Protection**: Our commitment to identifying and addressing risks in imported products remains our top priority
- **All other processes and requirements remain the same.** As this is an internal operational enhancement, the NER program modernization requires only one change for industry: Modifying how you contact FDA regarding status of shipments under entry review that have not already gone to the Field for assigned

work using the NERInquiry@fda.hhs.gov email address. Contact Information (Effective August 4, 2025)

CRITICAL: New communication protocols have been established effective August 4, 2025,

Entry Status Inquiries

1. **Initial review status** (pending review, documents requested, etc.): NERInquiry@fda.hhs.gov
2. **Field review status** (pending exam/sampling, detained, refused, etc.): Contact the appropriate division at FDA Import Offices and Ports of Entry

General Import Questions

1. **General import operation questions**: imports@fda.hhs.gov or 301-796-0356
2. **Prior notice for food products**: notice@fda.hhs.gov or 866-521-2297
3. **ITACS issues**: ITACSSupport@fda.hhs.gov
4. **NER program questions**: NERInquiry@fda.hhs.gov
5. **For all other inquiries**, see Contact the FDA Program

Email Guidelines for NER Inquiries
When contacting NERInquiry@fda.hhs.gov:

- Use this mailbox only for checking status of entries under initial review or providing entry documents.
- Email only one FDA mailbox at a time (sending out to multiple boxes may delay your response)
- Use proper subject line formatting:

Subject Line Format Example

1. Entry number (one entry number per email)
2. Space
3. Commodity type:
4. Animal Foods, Animal Drugs, Animal Devices, Biologics, Cosmetics, Dietary Supplements, Food Related Products, Human Drugs, Human Foods, Infant Formula, Medical Devices, Medicated Feed, Rad Health Products, Tobacco, Multiple
5. Space
6. Port code

Examples of properly formatted subject lines:

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

Remember

- Check ITACS for real-time entry status before contacting the NER Team.
- Always provide accurate information.
- Use ITACS whenever possible for faster processing.

Thank you for your cooperation as we implement this enhanced program to better protect public health.

FDA NER Team
Office of Inspections and Investigations
Office of Import Operations
NERInquiry@fda.hhs.gov

For detailed procedures regarding urgent shipments and additional contact protocols, please refer to the FDA National Entry Review (NER) Trade Communications Guide