FDA Manufacturer and FDA Shipper
Data Transmission Requirements

The FDA Manufacturer and FDA Shipper are two of the FDA data elements currently used for automated entry screening in FDA's Operational and Administrative System for Import Support (OASIS). Every effort must be made to provide the actual FDA Manufacturer and FDA Shipper as defined below.

FDA Manufacturer: The FDA Manufacturer is the site-specific location where the product is manufactured, produced, or grown.

FDA Shipper: The FDA Shipper is the actual shipper of the product identified on freight bills or bills of lading and is often the same as the USCS invoicing party.

Many FDA regulated products, e.g., Low Acid Canned Foods (not limited to those products packed in metal "cans"), Medical Devices, Human and Veterinary Drugs, and Biologics ALWAYS require evidence they were produced in a facility which has registered, licensed and/or listed its products with FDA. For these products, the site-specific location must be submitted as the FDA Manufacturer. The name and address of a corporate headquarters, "trading company", or other intermediate supplier is not acceptable. [1]

Some food products (including raw agricultural, aquacultural, or fishery products) do not have mandatory registration, listing, or licensing requirements. If the actual site-specific manufacturer (or manufacturers in a multi-source lot) is (are) identified on the entry documents that information MUST be transmitted to OASIS. Often the manufacturer and shipper information provided on an invoice is not the same as information provided on the bill of lading. Care should be taken to provide the most accurate information available.

Agricultural co-ops and other consolidators are often transmitted as the FDA Manufacturer and FDA Shipper. These firms may be appropriately used to identify the FDA Shipper. They should only be transmitted as the FDA Manufacturer when entry documents do not identify the actual FDA Manufacturer (manufacturer/producer/grower) and the filer has made an unsuccessful good faith effort to determine the actual FDA Manufacturer. When detained shipments are identified with a consolidator as the FDA Manufacturer, the entire shipment will be detained, regardless of the actual FDA Manufacturer(s). If the consolidator is put on Detention Without Physical Exam, related shipments from that firm, regardless of the FDA Manufacturer(s) involved, will be placed on Detention Without Physical Exam.

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Summary

1) If the FDA registration/licensing/listing requirement applies to an imported product and/or its manufacturer, the actual site-specific FDA Manufacturer must be supplied. If a given invoice line contains the same product from several manufacturers, the line must be broken out into separate FDA lines and the FDA data elements must be submitted separately for each FDA line.

2) If there is no FDA registration, listing, or licensing requirement, but the actual site-specific FDA Manufacturer information is readily available to the filer (from the entry papers or otherwise) it must be submitted. [1]

3) If a product (such as a raw agricultural commodity) does not require registration, listing, or licensing, and the actual site-specific FDA Manufacturer information is not available, after making a good faith effort to determine same, the filer may instead transmit the FDA Shipper in lieu of the FDA Manufacturer. NOTE: In this case the FDA Country of Origin remains the country where the actual site-specific FDA Manufacturer is located; the filer may be able to determine this from the invoice "Product of ---" statement. If, after due diligence, the filer cannot determine the FDA Country of Origin, the Customs Country of Origin may be substituted in its place.

4) While it is technically permissible to transmit the shipper or consolidator under the situations described in example three above, every effort must be taken to provide the actual FDA Manufacturer. Failure to do so may result in the wrong firm being added to an FDA Import Alert and future shipments could be subject to Detention Without Physical Exam when another firm is actually responsible for the violation.

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[1] The only exception to this data requirement is where a valid MOU or other binding agreement between FDA and a foreign governmental agency directs otherwise.