FDA Prior Notice Requirements for Importation of Food and Food Ingredients

The Bioterrorism Preparedness and Response Act of 2002, implemented in December of 2003, is intended to protect the health and safety of United States citizens and residents from a terrorist attack on the nation's food supply. This piece of legislation included the **Prior Notice** requirement mandating that the FDA must receive electronic notification for all food, and food ingredients imported into the United States, including nutritional supplements, and animal and pet food before arrival of the goods into the U.S.

The Prior Notice data can be transmitted to the FDA by any person or entity having the information required to make a full and accurate submission. Importers, foreign shippers (or their U.S. agent), freight forwarders, and customs brokers, can all transmit prior notice data on behalf of the importer of record if they are in possession of the necessary data elements. Customs brokers would typically transmit prior notice data via the Automated Broker Interface (ABI), but other parties may also transmit data via the FDA's Prior Notice System Interface (PNSI) at http://www.access.fda.gov/

If the Prior Notice data is transmitted via FDA's PNSI, the prior notice Confirmation Number must be provided to the FDA on arrival. The transmitter should keep a screen-print showing the Confirmation Number for this purpose. For mail shipments, it must appear on the parcel itself. If you or your shipper are transmitting Prior Notice, your Customs Broker will also need this Confirmation Number to transmit to FDA along with the Customs entry transmission.

Prior Notice Exemptions

Exemptions to the Prior Notice requirements exist for meat products, poultry products, and egg products that fall under the jurisdiction of the USDA at the time of import. Also exempted are homemade goods shipped as gifts, food accompanying a traveler for their personal use, food in diplomatic bags and pouches covered by the terms of The Vienna Convention on Diplomatic Relations (1961), and foods that are immediately exported from the port of arrival.

Timeframes

The required timeframes for filing the prior notice vary depending on the mode of transport:

Data must be transmitted before the food arrives at the 1st port of arrival:

- 8 hours for food arriving by water
- 4 hours for food arriving by air or land/rail
- 2 hours for food arriving by land/road

Required Data Elements

The Prior Notice data transmission must include the following:

1. Product description, FDA product code, and quantity. The product code is assembled using the FDA Office of Regulatory Affairs (ORA) product code builder, which can be found at http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm. As your customs broker we can assist you in compiling the product code, but will rely on you for important details about the product itself. Depending on the particular product, the FDA product code might need to include data elements that reflect the packaging that comes in contact with the product itself, or the manufacturing process used to

make the product. Certain commodities, such as low acid canned foods and infant formula will also require lot or code numbers.

2. Submitter – the name, address, contact person, phone number, and e-mail address for the party submitting prior notice data. If a second party is actually transmitting data on behalf of the submitter, the same information must also be reported for the Transmitter.

3. Manufacturer/Shipper/Grower – the name, address, and **FDA registration number** for this party must be included in the prior notice transmission. A Grower would specifically be reported for food imported in its natural state, along with the growing location. Often the manufacturer or Grower will also be the Shipper, but if they are not, names and addresses must be reported for the Shipper as well. Separate facilities owned by the same Manufacturer or Grower are expected to have their own FDA registration number, unless it is obvious that several buildings are on the same lot, and are therefore a single facility.

4. Importer/Owner/ Ultimate Consignee – sometimes all of these parties will be the same, but if they are not, names and addresses must be reported for each. FDA is interested in the actual "deliver to" of the goods. When the ultimate consignee is different from the importer, **a Food Establishment Identifier Code (FEI)** must be reported so that the FDA will know the physical delivery address of the merchandise after importation.

5. The FDA country of production, using the two-letter code for the country.

6. Country from which the food or food ingredient is shipped, reported using the two-letter code for that country.

7. Anticipated 1st port of arrival.

8. Anticipated date and time of arrival at 1st port.

9. The entry type, such as "01" for Consumption entries valued at $2500 or more, or "11" for informal entries valued at less than $2500. Other entry types exist for merchandise subject to quota, merchandise subject to anti-dumping or countervailing duties, and for other specific circumstances.

10. Carrier (reported using the specific carrier code) and mode of transport

11. Shipment information such as the ocean bill of lading and container number, or the air waybill

The FDA Food Facility Registration Number

All domestic and foreign facilities that manufacture, process, pack, or hold food must register with the FDA. According to industry guidance issued by the FDA, this requirement is intended to help FDA to "determine the location and source of a potential bioterrorism incident or an outbreak of food-borne illness", and to help the FDA to "quickly notify facilities that may be affected". There is no fee for registration, and it can be done on-line at:

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm

It is specifically the registration number of the Manufacturer or Grower (or in some cases, Consolidator) that is reported as part of the FDA prior notice. FDA defines Manufacturer as the last facility that manufactured/processed the food. Activities such as labeling or storing the food are not taken into account when determining which party to report as the manufacturer. FDA gives the example of wine

produced and bottled at winery “X”, sent to winery “B” for labeling, sent to facility “S” for storage, and finally transferred to freight forwarder “F” for storage and consolidation with other freight for shipment to the U.S. For prior notice purposes, winery “X” is the manufacturer.

All FDA registration numbers must be renewed every other year during the period beginning on October 1 and ending on December 31 of each even-numbered year. If a foreign manufacturer fails to renew their registration, any FDA prior notice that includes their registration number will be rejected and it will be impossible to obtain an FDA release until they have re-registered and the prior notice has been re-transmitted.

Foreign food facilities must appoint a U.S. agent to serve as the contact party for any communications or requests for information from that agency. Customs brokers are usually reluctant to act as the U.S. agent for foreign facilities because of concerns that they will be held liable for FDA re-inspection fees that can be incurred when agents are sent to the foreign facility; however there are law firms and FDA consultants who will act as U.S. agent, if the importer-of-record does not want to assume this role.

As your Customs Broker, M.E. Dey & Co. can assist you in navigating through the FDA requirements. We can provide additional tools and resources to assure you are importing food and food related products in full compliance.

Contact our Import Division for additional information.