

Mandatory requirements

(a) FDA Registration

Exporters need to register their manufacturing/ packing/ distributor facility (which shall be exporting to USA) as a Food establishment with FDA through a US based FDA agent.

(b) Product Labeling

Product labels should be as per FDA guidelines. These guidelines provide directions on claims on the product, ingredients, artwork and other specifications as present on labels.

(c) Category Wise Certification

Exporters of Food products from India will require certifications from Indian regulatory departments for exporting out of the country such as:-

- **Raw Unprocessed/Agricultural Products (Honey, Flour, Ghee etc.):** Require RCMC certificate from the Agricultural and Processed Food Products Export Development Authority India (APEDA).

(d) Prior Intimation Notice

Prior intimation of the food shipment is required to be filed with FDA through registered FDA agent for every shipment being Imported into US.

(e) FSSAI Central Registration

Exporters are required to have central license from **The Food Safety and Standards Authority of India (FSSAI)** in order to make them eligible for exports via the e-commerce platforms.

(f) FDA Approval (If required)

If the product being imported into the United States has a colour additive/ingredient/claim which requires approval/certification from FDA prior to the selling of the product then the same has to be done as per the FDA guidelines.

FAQs:

1. When are the compliance requirements needed?

All requirements are to be completed before exporting the products to USA

2. How often are the requirements needed?

- FDA registration of Food Category shall be renewed every even numbered year.
- Product Labeling as per the FDA guidelines is required once for every product unless there is a change in the regulations.
- Category Wise Certification shall be renewed at regular intervals as per the timelines given by the governing authority.
- Prior Intimation Notice is required to be filed once for every food shipment being imported into US.

Disclaimer: This is to state that information provided in the document is subject to product specification and applicable regulation at the time of sending the shipment into the destination country. We hereby declare that P&A or its officials, employees, partners do not hold any responsibility for the use of the information as provided in the document, and hence it is advised to the exporter to take legal advice before relying upon any information shared in the document or refer to the applicable provisions w.r.t. to the product of the seller.

- (e) FSSAI Central registration shall be renewed at regular intervals as per the timelines given by the governing authority.
- (f) FDA Approval is required once for every color additive batch/ingredient/claim unless there is a change in the regulations.

3. Links for reference:

- (a) FDA registration: <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>
- (b) Product Labeling: <https://www.fda.gov/food/food-labeling-nutrition>
- (c) Agricultural and Processed Food Products Export Development Authority India (APEDA): <https://apeda.gov.in/apedawebsite/index.html>
- (d) The Food Safety and Standards Authority of India (FSSAI): <https://fssai.gov.in/>