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**TRADE &
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HUB**

Online Training Session for Cabo Verde Private Sector

FDA Compliance Issues for Food and Beverage Products

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OUTLINE



Overview of FDA



Food Facility Registration



Prior Notice Submission



Labelling Requirements

What does FDA regulate?

Foods, Drugs, Cosmetics, Tobacco products, etc...

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Live food animals
- Animal feeds and pet food
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum).

Food and Drug Administration (FDA)

The facilities that produce, store or otherwise handle the products are registered with FDA

Prior notice of incoming shipments is provided to FDA

Imported food products are subject to FDA inspection at U.S. ports of entry

FDA may detain products offered for import if they are not in compliance with U.S. requirements

FDA Food Facility Registration

Food Facility Registration User Guide: Step-by-Step Instructions

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Online Registration of Food Facilities

Return to Online Registration

En Español (Spanish)
 PDF - 836KB

Content current as of:
 10/30/2017

Regulated Product(s)
 Food & Beverages

- [Registration of Food Facilities Start](#)
- [Section 1 – Type of Registration](#)
- [Section 2 – Facility Name / Address Information](#)
- [Section 3 – Optional: Preferred Mailing Address Information](#)
- [Section 4 – Parent Company Name / Address Information](#)
- [Section 5 – Facility Emergency Contact Information](#)
- [Section 6 – Trade Names](#)
- [Section 7 – United States Agent](#)
- [Section 8 – Seasonal Facility Dates of Operation](#)
- [Section 9 – General Product Categories – Human/Animal/Both](#)
- [Section 9a – General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility](#)
- [Section 9b – General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility](#)
- [Section 10 – Owner, Operator, or Agent in Charge Information](#)
- [Section 11 – Inspection Statement](#)
- [Section 12 – Certification Statement](#)
- [Review - Registration Review](#)
- [Success - Registration Successful/View Complete Registration](#)
- [Save and Exit - Save a Partially Completed Registration](#)

FDA Industry Systems

System Status

- 09/19/2017 [FDA published the revised guidance, Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. Click here for details.](#)
- 09/12/2017 [Information regarding Tobacco Registration and Product Listing for manufacturers impacted by recent natural disasters. Click here for details.](#)

Login

Existing account holders, enter your account ID & password.

Account ID

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

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Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispayware software installed on your computer to help ensure the privacy of the information being entered.

If you are experiencing technical difficulties submitting your Tobacco Establishment Registration or Product List information, please email FDA at FURLSSupport@FDA.hhs.gov for further assistance. For compliance related questions regarding these requirements, please email FDA at CTPRegistrationandListing@fda.hhs.gov.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

Registration Submitted - Verification Pending

In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. agent. The U.S. agent that you have listed has been contacted and should respond to our confirmation request by 10/16/2016. Upon successful confirmation, the registration number and pin will be issued.

Once received, please keep the registration number and PIN for your records.

FDA Food Facility Registration Renewal

- ❑ Every 2 years, on even-numbered years
- ❑ Failure to renew results in a cancelled registration
- ❑ Beginning October 1st 2020, food facilities will need to provide UFI number as part of the registration and renewal process
- ❑ FDA recognize DUNS Number as acceptable UFI
- ❑ The D-U-N-S Number is a unique nine-digit number that identifies business entities on a location-specific basis. Assigned and maintained by Dun & Bradstreet (D&B), the D-U-N-S Number is widely used as a standard business identifier.



Prior Notice Submission

- ✓ Notification to FDA about all food, beverage, and supplements shipments, including samples.
- ✓ Shipments may be detained if not filled
- ✓ The prior notice includes information about the shipments and facility
- ✓ It can be filled by Exporter, Importer, or Third party
- ✓ It can be submitted via FDA's Prior Notice System Interface (PNSI)



2 hours before the arrival of shipments by **Road**



4 hours before the arrival of shipments by **Rail**



4 hours before the arrival of shipments by **Air**



8 hours before the arrival of shipments by **Sea**



Before the items are shipped by International **Mail**

HACCP Requirement

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

FDA HACCP Programs

- **Dairy**
- **Juice**
- **Seafood**
- **Meat**
- **Canned foods**

Retail packages and containers of food products sold in U.S. bear labels in English that include specific information

The identity of the product

The name, address and/or phone number of the responsible firm

A list of ingredients in descending order or predominance in the product

The net weight of contents

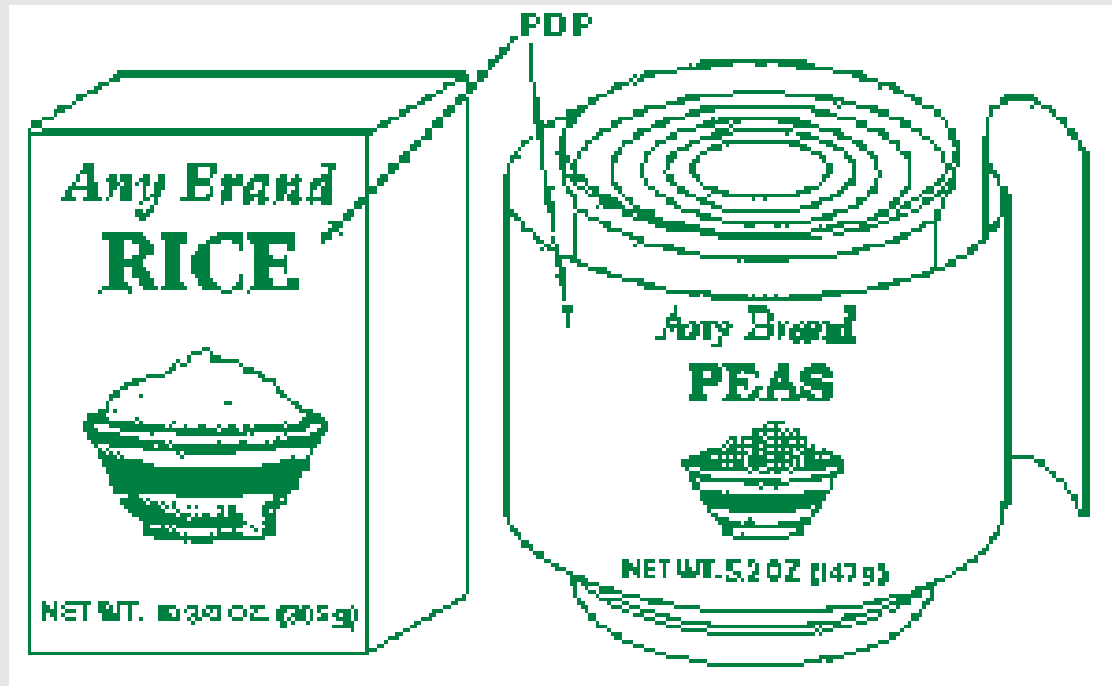
Nutritional information in most cases

Country of origin statement

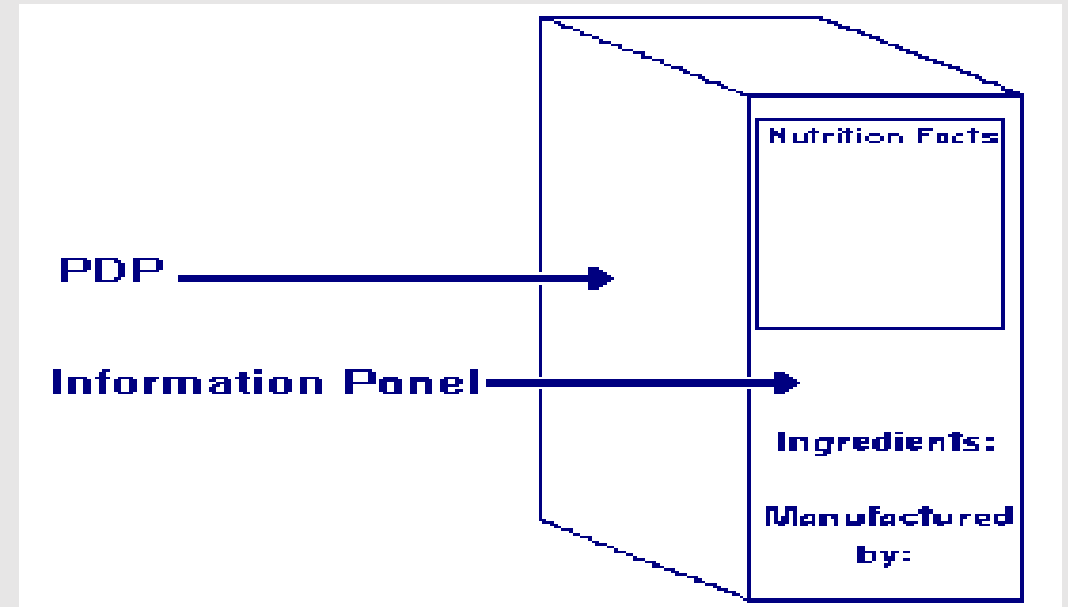
Explicit listing of allergenic ingredients



Principle Display Panel (PDP)



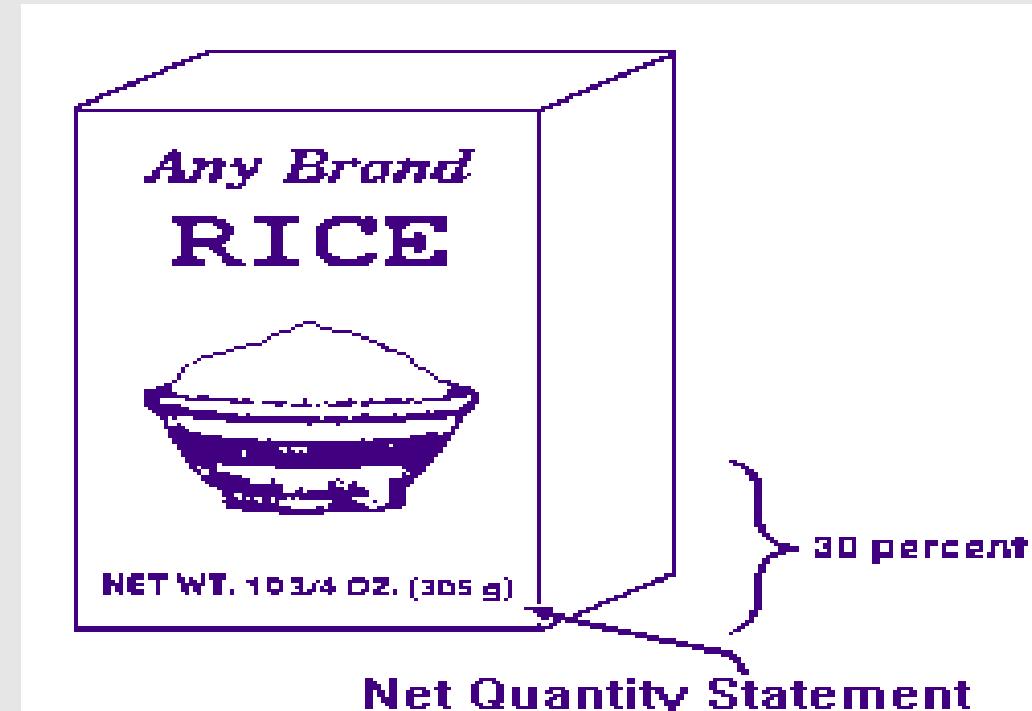
Information Panel (IP)

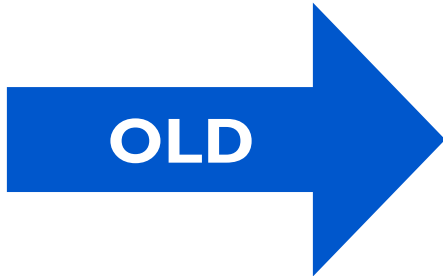


Net Quantity of Contents

The net quantity statement (net quantity of contents) is placed as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container.

Food labels printed must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms.





Nutrition Facts

Serving Size 2/3 cup (55g)
 Servings Per Container About 8

Amount Per Serving

Calories 230 **Calories from Fat** 72

	% Daily Value*
Total Fat 8g	12%
Saturated Fat 1g	5%
<i>Trans Fat</i> 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

Nutrition Facts

8 servings per container
Serving size 2/3 cup (55g)

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans Fat</i> 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



Nutrition Facts

Type Size for Certain Elements

- Serving Size information must also be bolded in at least 10-point type
- On Many labels, Calories must be bolded in 16 points type, while its value must be bolded in 22-point type.

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount Per Serving

Calories **230**

Nutrition Facts

Declaration for Added Sugars

Sugars added during food processing, sugars packaged with the intention of being added to food, and certain naturally-occurring sugars must be declared separately from Total Sugars.

Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%

Nutrition Facts

Nutrient Information

Quantities for Vitamin D, Calcium, Iron, and Potassium must be listed.

Quantities for these nutrients must be expressed in milligrams or micrograms.



Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

Daily values for nutrients like sodium, dietary fiber and Vitamin D are being updated based on newer scientific evidence (***2015-2020 Dietary Guidelines for Americans***).

Nutrition Facts

Change in Footnote

% Daily Value (DV) is now defined in the footnote.

Foods intended for children aged 1 to 3 years must substitute 2000 calories by 1000.



*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

For More Information

www.fda.gov

www.registrarcorp.com

<https://www.dnb.com/ca-fr/duns-number.html>

www.westafricatradehub.com



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