

FDA Requirements for Exporting Food and Beverages to the U.S.

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Director

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Presentation Overview

- Registration, U.S. Agent, & Prior Notice
- Labeling
- Food Canning Establishment (FCE) Registration
- HACCP
- Food Safety Modernization Act (FSMA)
- Summary / Questions & Answers



Registration, U.S. Agent, & Prior Notice

Basic FDA Requirements



Registration

- Companies that handle human food:
 - Manufacture
 - Process
 - Pack
 - Hold
- Exemptions
 - Farms
 - Retail establishments
 - Restaurants



U.S. Agent

- Different than a commercial agent, food broker, or customs broker
- Must be available 24/7
- Responsibilities
 - Coordinate inspections
 - Fees for re-inspection
 - Answer questions about shipments
 - Recalls
 - General day-to-day communications

Prior Notice

- Notification to FDA
- NOTE: Required even for samples
- Detention in port if not filed
- Includes information about the shipment and the facility

PRIOR NOTICE SYSTEM INTERFACE
LATEST ENTRY TRACK AND DRUG ADMINISTRATION

FDA

1342363212

Web Entry Summary Confirmation
From this Web Entry Summary Confirmation and present it to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.2795).

WEB ENTRY

Enrollment Number: FD400003314
Entry Identifier: #08-0490138-5
Port of Arrival: FedEx Hub @ Indy, Indianapolis, IN (4156)
Number of Intended Prior Notices: 1

Entry Type: Consumption
Anticipated Arrival: 11/16/2004 00:00
Mode of Transportation: Air

Submitter
Michael Friedman
Typical Food Company
1 Production Avenue
Rexdale, Ontario M9W 6C2
CANADA

Importer
Typical Food Buyers, Inc.
1 Beaver Circle
New Bedford, Massachusetts 02745
UNITED STATES

Carrier
FEDERAL EXPRESS
Carrier Code (ATA): FX

Flight Number: 0111
Always BB - Master: 0000000000
Always BB - House: 111122223333

PRIOR NOTICES

| Article | Product | Country | HTS | Submitted | Confirmation |
|---------|------------------------|---------|--------|---------------------|--------------|
| 9506 | Chocolate Chip Cookies | CA | 190100 | 11/15/2004 09:34:27 | 040265375761 |

Copyright © 2003-2004 U.S. Food and Drug Administration
Prior Notice v1.5.00, November 05, 2004
November 15, 2004 09:35:37 EST



New changes for 2016.

Product Labeling



Labeling

- Definition of “Misbranded”
- Top reason for import issues
- Broad requirements
 - Principal display panel
 - Nutrition facts
 - Advertising (including online)
 - Health claims

| 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% |
| Trans Fat 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.

Labeling

Must be *largest* text (except Calories value) and at least 16-point **bold** or **extra-bold**.

At least 10 point.

At least 6-point **bold** or **extra-bold**.

Must be the *same size or smaller* than "Nutrition Facts" and at least 16-point **bold** or **extra-bold**.

At least 8 point. Nutrients that are not indented (Total Fat, Cholesterol, etc.) should be flush left and **bold** or **extra-bold**.

At least 8 point.

At least 10-point **bold** or **extra-bold**; *amount* must be right-justified.

At least 22-point **bold** or **extra-bold**.

At least 6 point **bold** or **extra-bold**.

At least 8-point **bold** or **extra-bold**.

At least 8-point.

| Nutrition Facts | |
|---------------------------|---------------------|
| 2 servings per container | |
| Serving size | 1 cup (140g) |
| Amount per serving | |
| Calories | 160 |
| | % Daily Value* |
| Total Fat 8g | 10% |
| Saturated Fat 3g | 15% |
| <i>Trans</i> Fat 0g | |
| Cholesterol 0mg | 0% |
| Sodium 60mg | 3% |
| Total Carbohydrate 21g | 8% |
| Dietary Fiber 3g | 11% |
| Total Sugars 15g | |
| Includes 5g Added Sugars | 10% |
| Protein 3g | |
| Vitamin D 5mcg | 25% |
| Calcium 20mg | 2% |
| Iron 1mg | 6% |
| Potassium 230mg | 4% |

An Additional Requirement

Food Canning Establishment (FCE) Registration

Food Canning Establishment

- Food Canning Establishment (FCE) – 5 digits
 - Different than regular registration
 - Requires a specific street number
- Submission Identifiers (SID)
 - Filings with FDA containing process information
 - Each product is assigned an SID number





For seafood and juice.



HACCP

HACCP

- Required for:
 - Juice (100%)
 - Seafood
- U.S. customs has specific regulations for importing HACCP-mandated products





The biggest change in 70 years...

Food Safety Modernization Act

Preventive Controls



Food Safety Plan

HACCP vs. HARPC

- Hazard Analysis and Critical Control Points
 - Hazard analysis
 - CCPs to control food hazards
 - Critical limits
 - Monitoring
 - Corrective actions
 - Verification
 - Records
- Hazard Analysis and Risk-based Preventive Controls
 - Hazard analysis
 - Preventive controls (PCs)
 - Monitoring
 - Corrective actions
 - Verification
 - Records

Certain Commodities – HARPC Modified/Exempt

- Commodities that need to be cooked before consumption - **Modified**
 - Coffee
 - Cocoa
 - Grains
- Raw agricultural commodities – **Exempt**
 - Produce
 - Packaged fruits and vegetables
 - No manufacturing or processing
- Commodities for alcohol - **Exempt**
 - “Hops,” “Must”

Preventive Controls

- Exemptions and modified requirements:
 - Retail establishments (restaurants and stores)
 - **Qualified facilities**
 - Juice and Seafood HACCP
 - Alcoholic beverages
 - Dietary supplements
 - USDA products
 - Farms
 - Unexposed, packaged food in warehouses

Preventive Controls

- Deadlines
- Food Safety Plan
 - Facilities with >500 full-time equivalent employees: **September 19th, 2016**
 - Small business (<500 employees): **September 18th, 2017**
- Qualified facility attestation
 - Qualified facilities and very small businesses: **September 2018**



FSMA Compliance Wizard

- Go to www.fsmawizard.com to assess your requirements under FSMA free.

Registrar Corp ★
FSMA Compliance Wizard



Registrar Corp's solutions.

Summary / Questions & Answers



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Registrar Corp's Solutions

- Registrar Corp provides a full range of fixed-fee compliance services:
 - Registration & U.S. Agent Service
 - Prior Notice Filings
 - Label, Ingredient, and Product Review
 - LACF and Food Safety Services (Mock FDA Inspections)
 - FSMA Compliance Services
 - Detention Assistance
 - DWPE Petition Submissions
 - FDA Compliance Monitor