Overview of U.S. FDA Regulations for Manufacturers and Exporters of Food & Beverages

Beatrice Moreau
Senior Regulatory Advisor
Registrar Corp
144 Research Drive
Hampton, VA 23666

Registrar Corp

Seminar Overview

- U.S. FDA and the Import Process
- Key FDA Regulations: Food, Drug, and Cosmetic Act
- FDA Food Safety Modernization Act
- FDA Inspections & Detentions
- Questions & Answers

FDA Structure

Office of the Commissioner

Office of Foods

Office of Regulatory Affairs

Center for Food Safety & Applied Nutrition

Center for Veterinary Medicine

Center for Devices & Radiological Health

Center for Drug Evaluation & Research

Center for Biologics Evaluation & Research

Center for Tobacco Products

National Center for Toxicological Research

Food, Drug, and Cosmetic Act

- President Franklin D. Roosevelt signed into law the Food, Drug, Cosmetic Act in 1938.
- Remains today the principal law regulating all food, beverages, drugs, cosmetics, and medical devices in the USA
- Amended over the years to reflect changes in scientific knowledge and global trade.

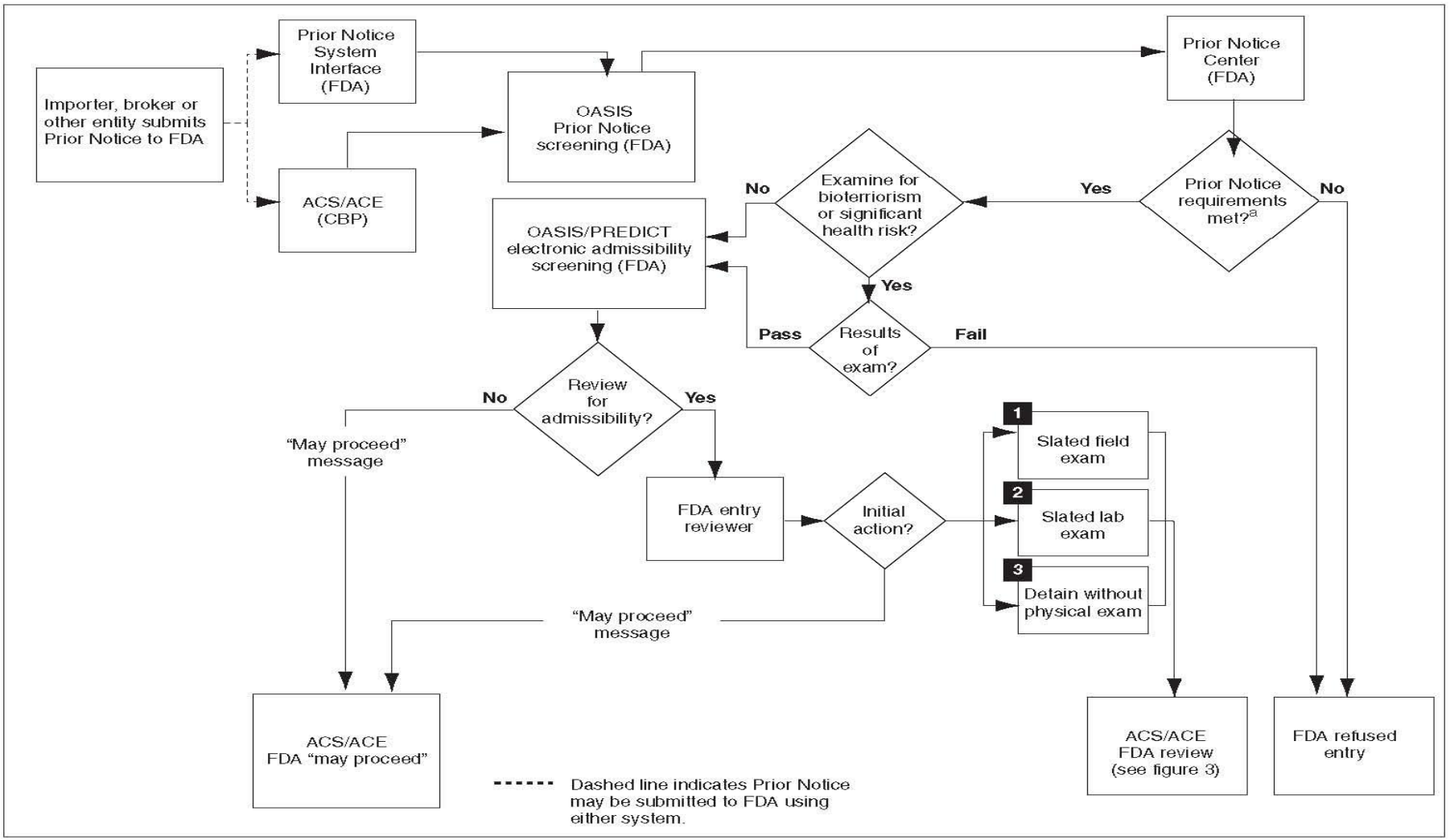
Food, Beverages, & Supplements

- **C**enter for **F**ood **S**afety and **A**pplied **N**utrition ("CFSAN")
  - Jurisdiction encompasses most food products (other than meat and poultry)

The Import Process

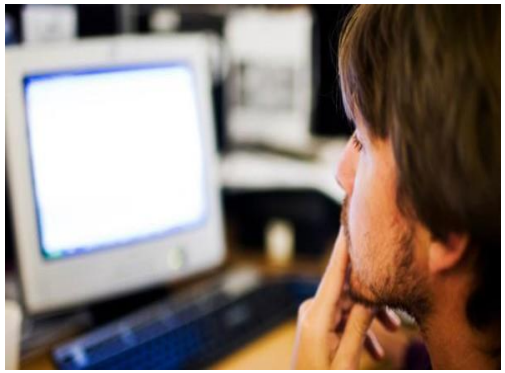
- Manufacturer / Exporter find a U.S. Importer
- U.S. Importer purchases the goods and must hire a Customs Broker licensed by Customs and Border Protection (CBP)
- Once shipped, product information is submitted to CBP by the licensed Customs Broker
- If an FDA-regulated product, then FDA is notified during the submission to CBP
- CBP defers to FDA on admissibility

U.S. FDA's Entry Process



FDA Review of Entry

- What U.S. FDA does depends on:
  - The **history** of the manufacturer, importer *(have they had other violations*?), and even the country
  - The **risk level** of the product: type (seafood?) and presentation (fresh?)



PREDICT

- PREDICT establishes a risk score by analyzing importer's shipment information using sets of FDA-developed risk criteria.
- Allows FDA to better use limited resources by targeting import inspections

FDA Options at time of Entry

- Product is cleared, ready to be removed from the port of entry by importer
- FDA detains product for further review
- FDA detains product for testing
- FDA refuses entry of product

Reasons for Detentions in Port of Entry

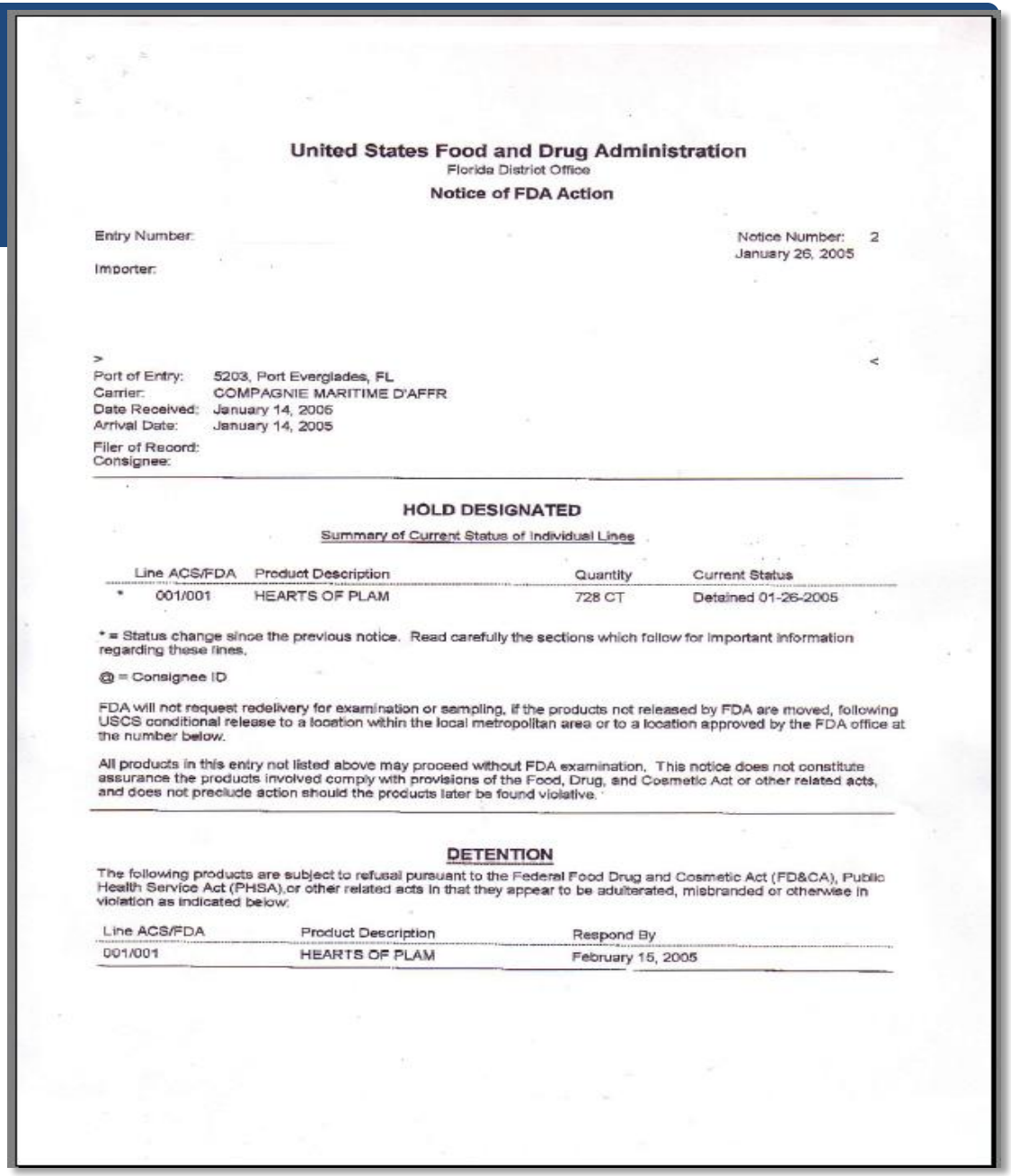
- "Adulteration"= filth, e.coli, salmonella, etc.
- "Misbranding"=improper label or claims
- Failure to make required electronic filings
  - Failure to have renewed your Facility Registration in 2012
  - Lack of Process Filings for each size product required to have an SID
  - Failure to file Prior Notice

"Notice of FDA Action"

Issued by FDA and sent to two parties:

1. Importer of Record
2. Customs Broker

Time sensitive with a respond by deadline



United States Food and Drug Administration
Florida District Office
Notice of FDA Action

Entry Number:
Notice Number: 2
January 26, 2005
Importer:

>
Port of Entry: 5203, Port Everglades, FL
Carrier: COMPAGNIE MARITIME D'AFFR
Date Received: January 14, 2005
Arrival Date: January 14, 2005
Filer of Record:
Consignee:
<

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	HEARTS OF PLAM	728 CT	Detained 01-26-2005

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	HEARTS OF PLAM	February 15, 2005

Key Food Regulations

Requirements

Food, Drug, and Cosmetic Act

- Bioterrorism Act
  - Registration, U.S. Agent, Prior Notice
- Labeling & Ingredients
- LACF = Low-Acid Canned Food
- GMPs = Good Manufacturing Practices
- Future requirements: FDA FOOD SAFETY MODERNIZATION ACT

Bioterrorism Act of 2002

- Effective starting in October 2003
- Requires companies to register if they "manufacture, process, pack, or store"
- Requires designation of a U.S. Agent for FDA communications
- Require companies to file Prior Notice

Food Facility Registration

- Registration of "Facility", not a company or product
- Must select product categories and provide facility details
- FDA issues an 11-digit number for each facility
- Registrar Corp issues a Certificate you can provide to prospects, buyers, etc.

CERTIFICATE OF REGISTRATION

This certifies that:

Company Name
Address
City, Province, Postal Code
Country

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Registrar Corp.

U.S. FDA Registration No.: **12345678901**

U.S. Agent for FDA Communications: **Registrar Corp**
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2012 unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

Russell K. Statman
Executive Director
Registrar Corp
Dated:

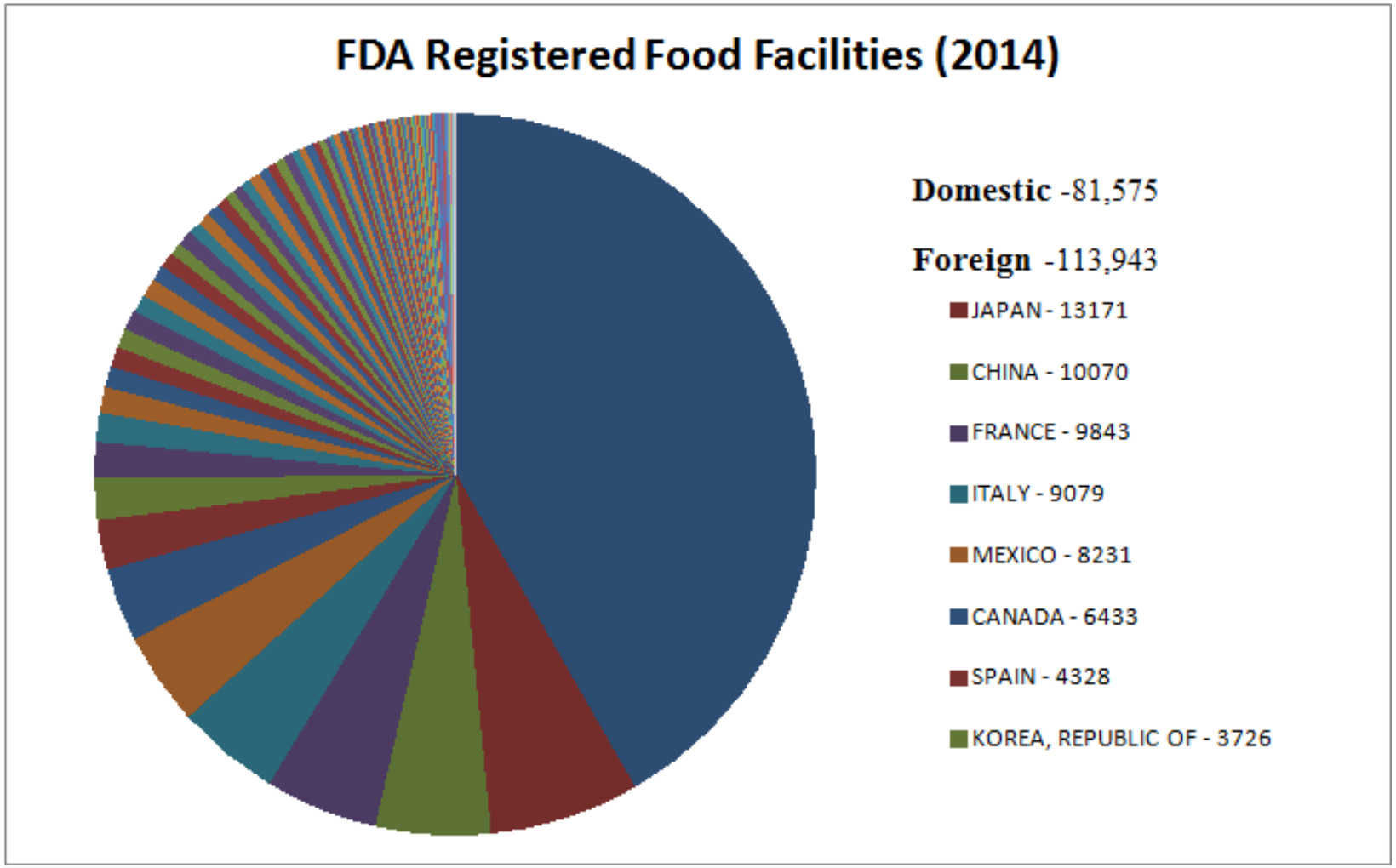
Registration

- Some companies own multiple facilities (factory in one city, warehouse in another city). Each must be registered and receive their own registration number
- Registration is one time, but must be renewed every even year (2014, 2016, etc)
- If any data changes, registration must be updated within 60 days

U.S. Agent for FDA communications

- U.S. Agent for FDA communications must be designated in Section 7 of the Registration
- The U.S. Agent:
  - Must be physically located in the U.S.
  - Must be available for FDA calls 24/7
  - Is responsible for assisting FDA schedule inspections, answer questions, etc.

Registration Statistics



Prior Notice

- Notify FDA before shipments arrive in U.S. instead of after arrival
- Allows FDA to better target imports before they arrive in a U.S. port
- Best use of limited resources
- Less than 2% actually inspected

PRIOR NOTICE SYSTEM INTERFACE
UNITED STATES FOOD AND DRUG ADMINISTRATION

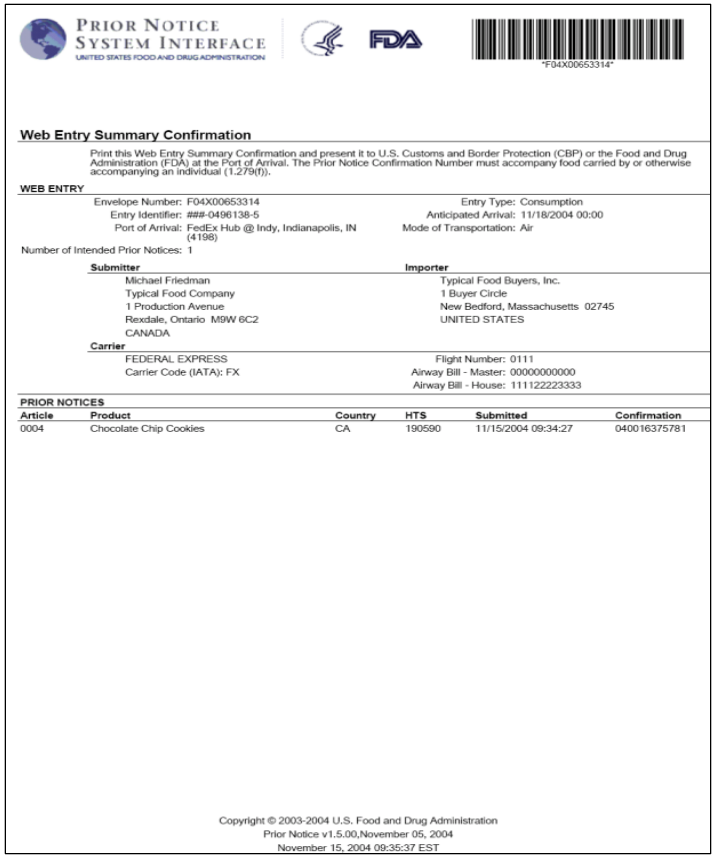
FDA

Prior Notice

- Must be filed for all shipments: Sea, Air Cargo, Express Mail or Land
- Samples for customers or for trade shows must obtain a Prior Notice
- Samples not for consumption (testing) do not require a Prior Notice
- May be filed by anyone with knowledge of the shipment (usually you or your importer, depending on mode of transport)

Prior Notice Confirmation

- Prior Notice is NOT an "approval" (FDA could still inspect)
- Bar-coded confirmation number issued for each product



PRIOR NOTICE SYSTEM INTERFACE
UNITED STATES FOOD AND DRUG ADMINISTRATION

FDA

F04X00653314

Web Entry Summary Confirmation

Print 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 (1.279(f)).

WEB ENTRY

Envelope Number: F04X00653314
Entry Identifier: ###-0496138-5
Port of Arrival: FedEx Hub @ Indy, Indianapolis, IN (4198)
Entry Type: Consumption
Anticipated Arrival: 11/18/2004 00:00
Mode of Transportation: Air
Number of Intended Prior Notices: 1

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

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

Carrier
FEDERAL EXPRESS
Carrier Code (IATA): FX
Flight Number: 0111
Airway Bill - Master: 00000000000
Airway Bill - House: 111122223333

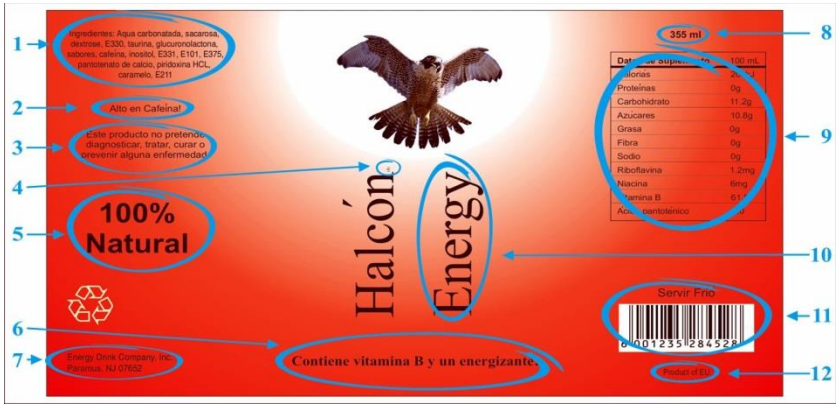
PRIOR NOTICES

Article	Product	Country	HTS	Submitted	Confirmation
0004	Chocolate Chip Cookies	CA	190590	11/15/2004 09:34:27	040016375781

Prior Notice v1.5.00,November 05, 2004
November 15, 2004 09:35:37 EST

Food Labeling & Ingredients

- A top reason product is detained: Incorrect labeling, unapproved ingredients, prohibited health claims
- Common errors in trying to avoid problems:
  - Copy other wrong labels
  - Only follow part of the regulations
  - Nutrition Facts Chart formatting is critical



Examples of Products Detained due to Labeling Violations

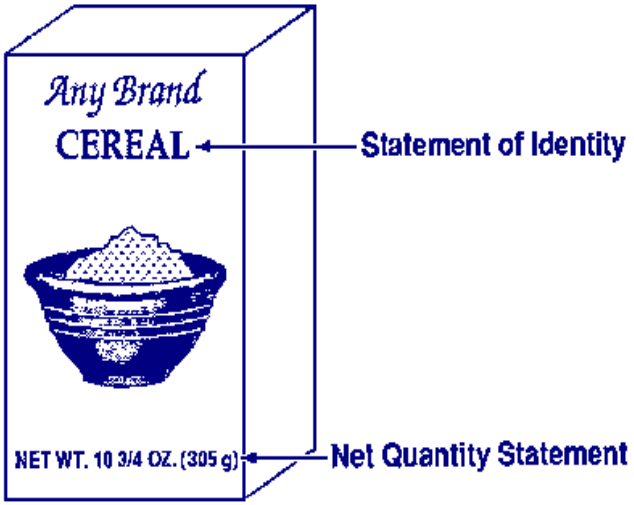
- Cookies
- Noodles
- Sauces
- Canned Seafood
- Energy Drinks
- Dried Seafood

Labels for Retail

- Will consumers see your product label?
- If so, retail labeling rules apply
- Basic Panels
  - Principal Display Panel
  - Information Panel

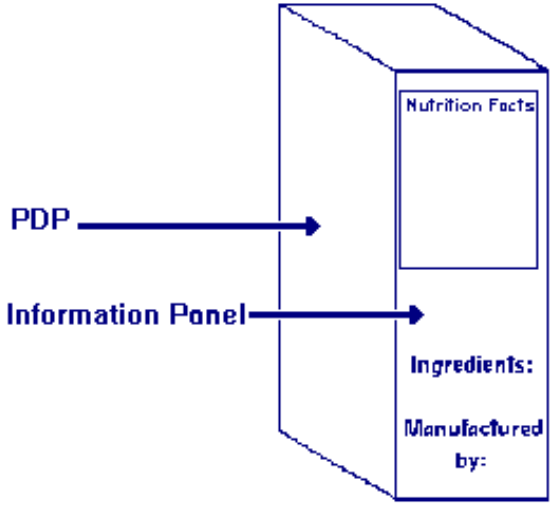
Principal Display Panel

- Two required elements
  - Statement of Identity (name of food)
  - Net Contents Declaration

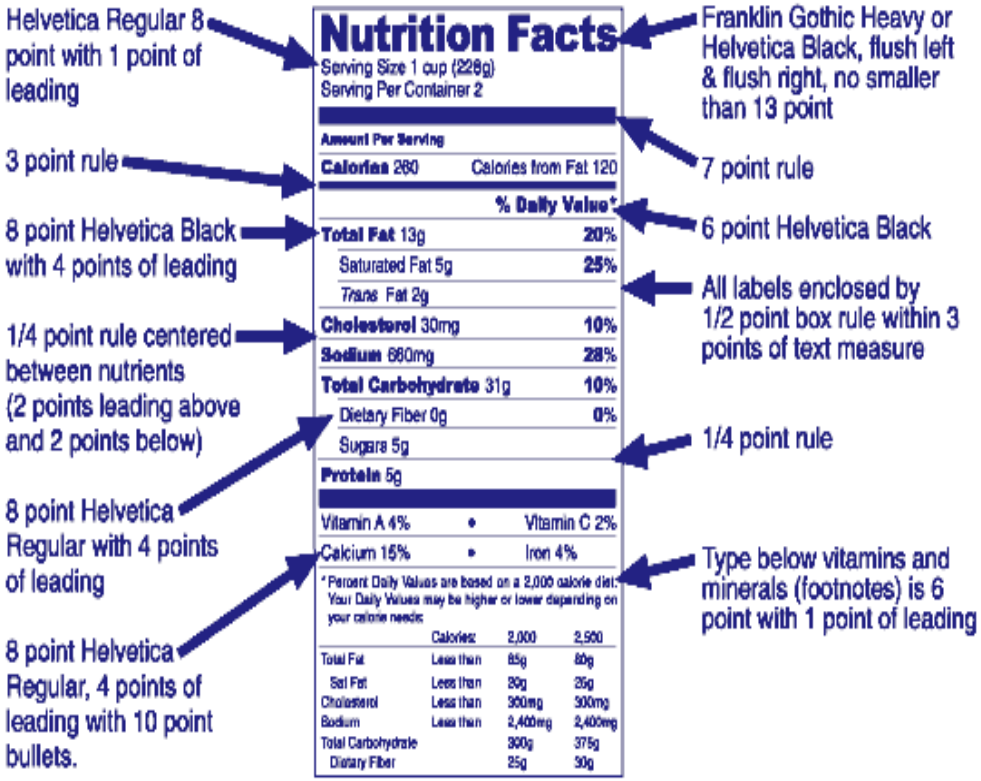


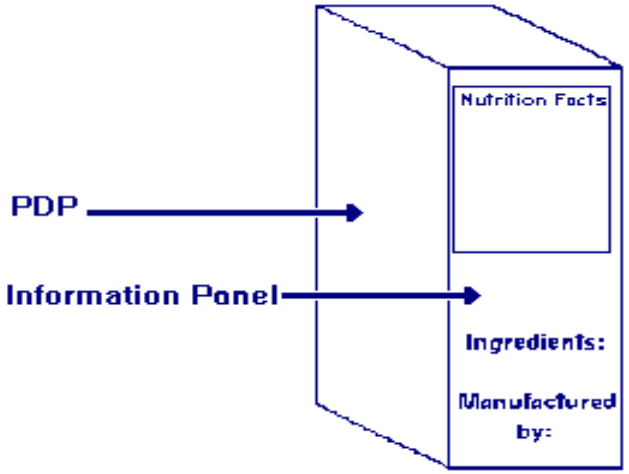
Information Panel (IP)

- Three required elements
  - Nutrition Facts Chart
  - Ingredients List
  - Manufacturer Identity



Nutrition Facts Chart





Examples of Other Formats

Nutrition Facts
Serving Size 1 can

Amount Per Serving

Calories 140

% Daily Value

Total Fat 0g — **0%**

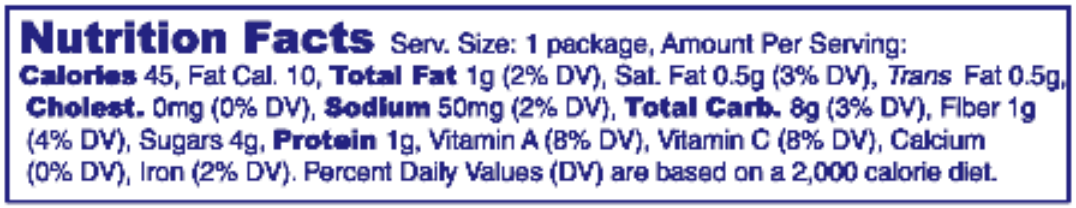
Sodium 20mg — **1%**

Total Carbohydrate 36g — **12%**

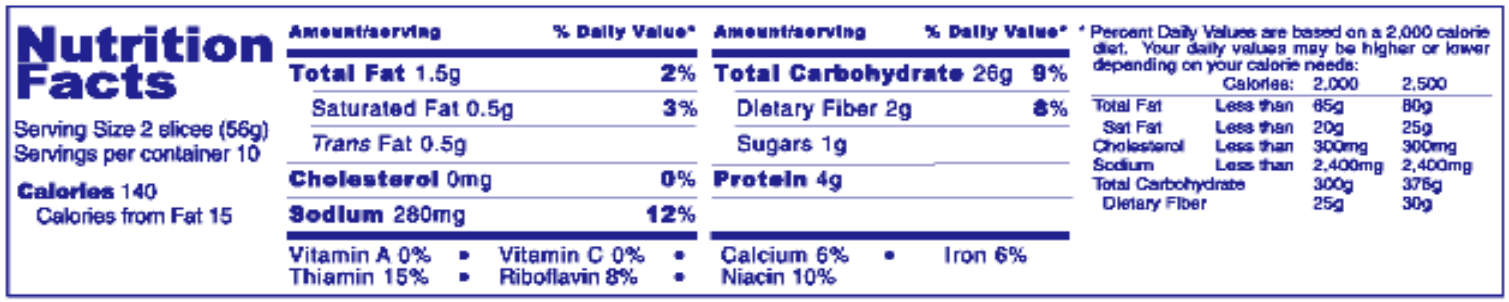
Sugars 36g

Protein 0g

*Percent Daily Values are based on a 2,000 calorie diet.



Nutrition Facts Serv. Size: 1 package, Amount Per Serving:
Calories 45, Fat Cal. 10, **Total Fat** 1g (2% DV), Sat. Fat 0.5g (3% DV), *Trans* Fat 0.5g, **Cholest.** 0mg (0% DV), **Sodium** 50mg (2% DV), **Total Carb.** 8g (3% DV), Fiber 1g (4% DV), Sugars 4g, **Protein** 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium (0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.



Nutrition Facts
Serving Size 2 slices (56g)
Servings per container 10

Calories 140
Calories from Fat 15

Amount/serving	% Daily Value*
Total Fat 1.5g	2%
Saturated Fat 0.5g	3%
Trans Fat 0.5g	
Cholesterol 0mg	0%
Sodium 280mg	12%

Amount/serving	% Daily Value*
Total Carbohydrate 26g	9%
Dietary Fiber 2g	8%
Sugars 1g	
Protein 4g	

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 6%
Thiamin 15% • Riboflavin 8% • Niacin 10%

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

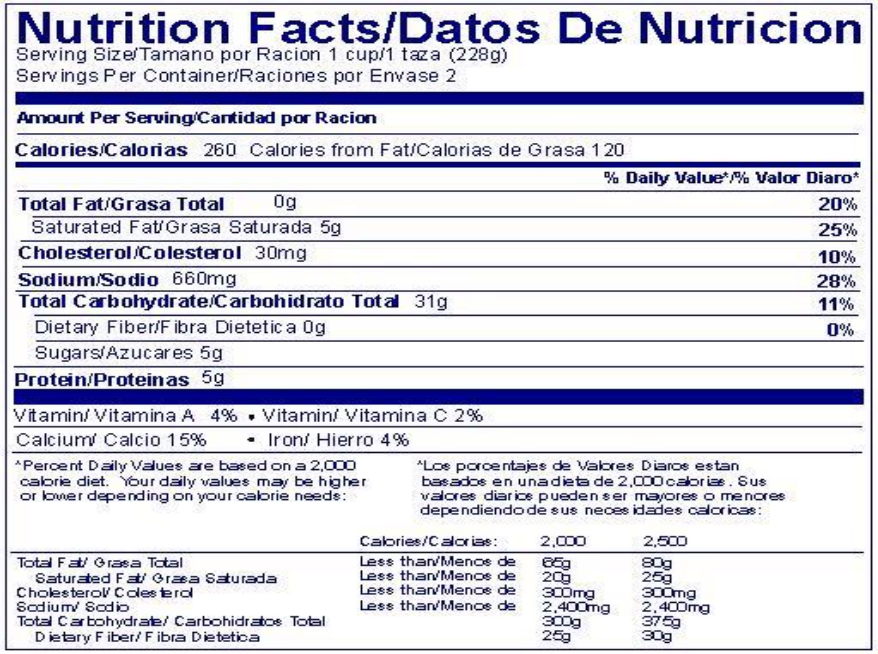
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Other Regulated Elements

- Serving Sizes
- Ingredients and the list format
- Trans fat & allergens
- Manufacturers identity
- Country of Origin
- Web site and marketing materials

Bilingual Labeling

- All labels must be in English but may also be in additional languages



Nutrition Facts/Datos De Nutricion

Serving Size/Tamano por Racion 1 cup/1 taza (228g)
Servings Per Container/Raciones por Envase 2

Amount Per Serving/Cantidad por Racion

Calories/Calorias 260 Calories from Fat/Calorias de Grasa 120

	% Daily Value*/% Valor Diaro*
Total Fat/Grasa Total 0g	**20%**
Saturated Fat/Grasa Saturada 5g	**25%**
Cholesterol/Colesterol 30mg	**10%**
Sodium/Sodio 660mg	**28%**
Total Carbohydrate/Carbohidrato Total 31g	**11%**
Dietary Fiber/Fibra Dietetica 0g	**0%**
Sugars/Azucares 5g	
Protein/Proteinas 5g	

Vitamin/ Vitamina A 4% • Vitamin/ Vitamina C 2%
Calcium/ Calcio 15% • Iron/ Hierro 4%

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

*Los porcentajes de Valores Diarios estan basados en una dieta de 2,000 calorias. Sus valores diarios pueden ser mayores o menores dependiendo de sus necesidades caloricas:

	Calories/Calorias:	2,000	2,500
Total Fat/ Grasa Total	Less than/Menos de	65g	80g
Saturated Fat/ Grasa Saturada	Less than/Menos de	20g	25g
Cholesterol/ Colesterol	Less than/Menos de	300mg	300mg
Sodium/ Sodio	Less than/Menos de	2,400mg	2,400mg
Total Carbohydrate/ Carbohidratos Total		300g	375g
Dietary Fiber/ Fibra Dietetica		25g	30g

Product Claims

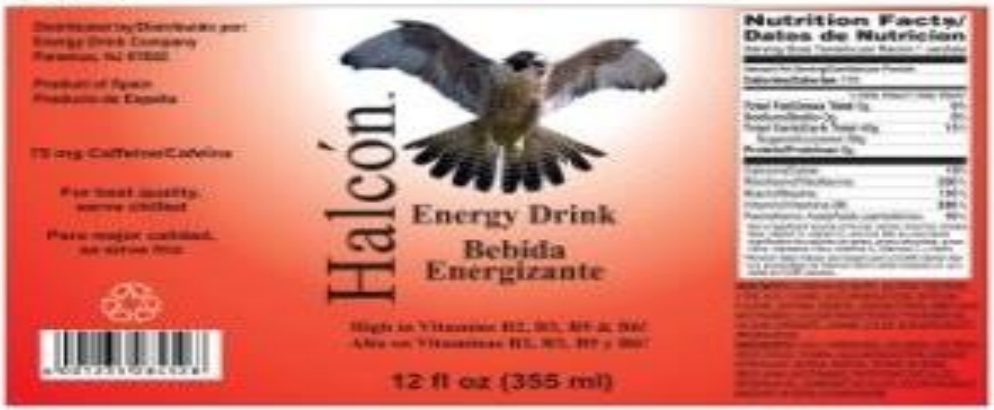
- FDA regulates four types
  - Nutrient claims
  - Relative Claims
  - Structure/Function Claims
  - Health Claims

- Unapproved new drug or dietary supplement?
  - Exporters of dietary supplements often encounter claim-related detentions

Before & After

Before:

After:



Low-Acid Canned Food

- Low-Acid, Acidified, Thermally Processed Foods
- Typically produced in Cans, Bottles, Jars, or Tetra Paks
- Food Canning Establishment ("FCE") Registration required
- Process Filings (Submission Identifies or "SID") for each product, each size
- Important factors are pH and Water Activity

Low-Acid Canned Food

- Low-acid foods = any food, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85
- Acidified foods = low-acid food to which acid(s) or acid food(s) are added and which have a water activity (aw) greater than 0.85 and a finished equilibrium pH of 4.6 or below.

HACCP

- Focuses on the prevention of hazards
- Can be applied throughout the food chain ("from farm to table")
- Currently required for
  - Seafood (21 *CFR* 123)
  - Juice (21 *CFR* 120)

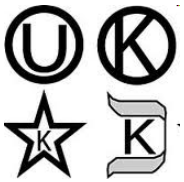
Current Good Manufacturing Practices (cGMPs)

- Guidelines and conditions which must be met by every food facility to ensure production of safe and wholesome foods.
- GMPs required for all food and beverages are found in 21 CFR Part 110
- GMPs required for dietary supplements are found in 21 CFR Part 111

cGMP – 21 CFR Part 110

- GMP requirements include:
  - Sanitation
  - Employee hygiene and hygienic practices
  - Pest Control
  - Equipment construction, maintenance and calibration
  - Facility construction
  - Water quality

Voluntary Certifications



How can you prepare?

- Be sure your Registration is Valid:
  - Renewal is required between October 1, 2014 and December 31, 2014
  - If you do not renew, your registration will be cancelled, and your exports to the U.S. could be blocked

How can you prepare?

- Be certain your or your importer files a Prior Notice for each and every shipment
- Verify that your product labeling and ingredients meet FDA requirements (including claims, website, etc.)
- If producing a canned/bottled food, obtain an FCE number and submit Process Filings
- Prepare for FDA inspections

Questions?

Registrar Corp's Office in Europe
16 Rue Jean Marie Barre – Auray -France

Phone: +33-(0)-2-97-56-60-65
Fax: +33-(0)-2-72-68-57-24
Email: europe@registrarcorp.com

Web: www.registrarcorp.com