The U.S. Food and Drug Administration's Food Safety Modernization Act: Current & Future Requirements

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Seminar Overview

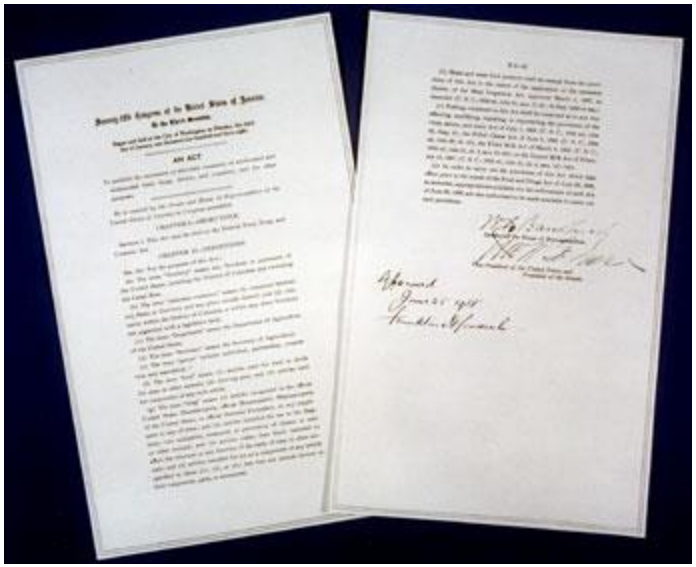
- Background of Food Safety Modernization Act (FSMA)
- Motivation and Concept
- Proposed Rules and Timeframes
- Questions & Answers

FDA Food Safety Modernization Act: Facts

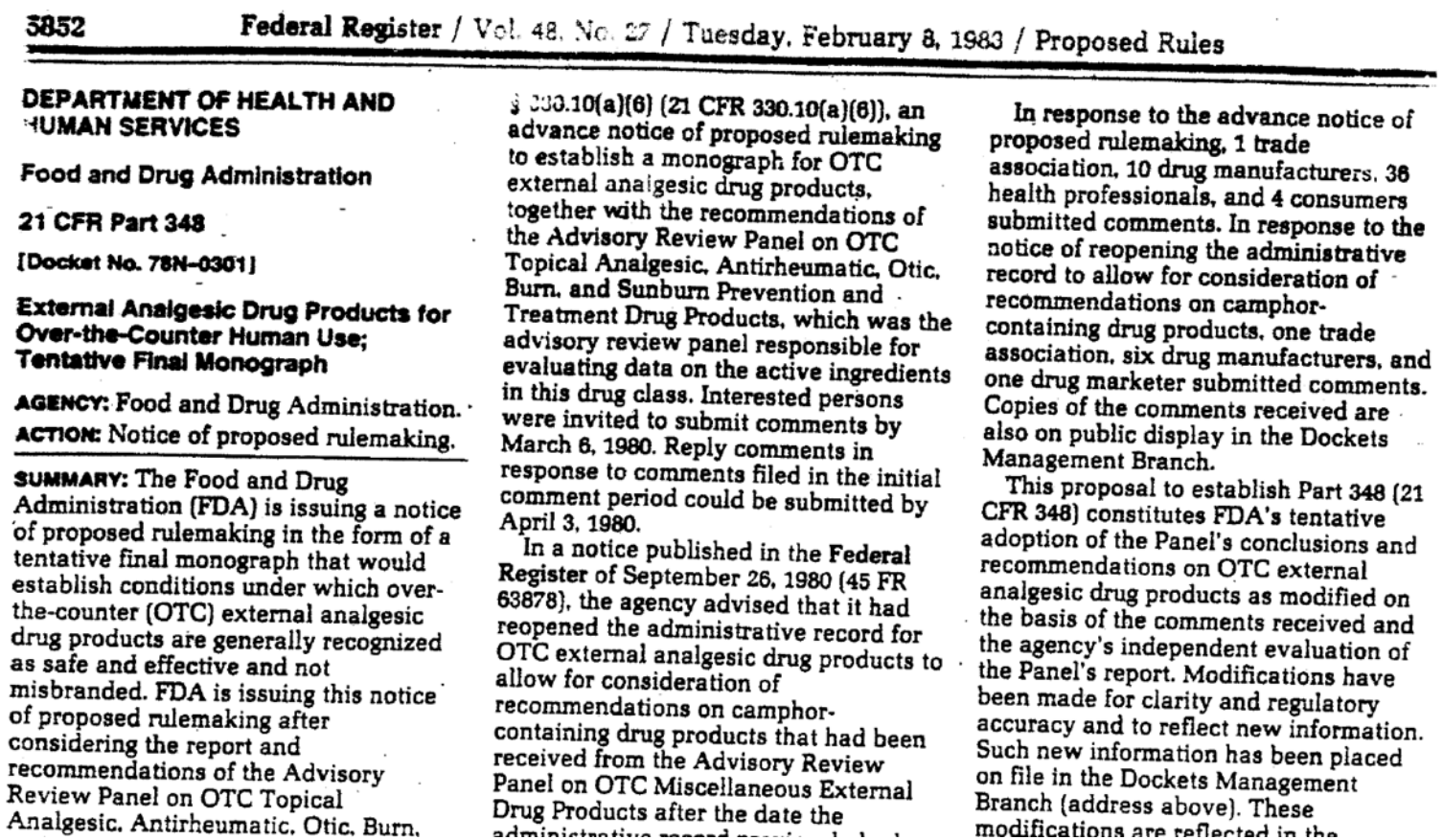
1938

2011

U.S. Regulation Overview



Federal Register Citation



5852 Federal Register / Vol. 48, No. 27 / Tuesday, February 8, 1983 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

External Analgesic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) external analgesic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn,

§ 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC external analgesic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by March 6, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by April 3, 1980.

In a notice published in the Federal Register of September 26, 1980 (45 FR 63878), the agency advised that it had reopened the administrative record for OTC external analgesic drug products to allow for consideration of recommendations on camphor-containing drug products that had been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products after the date the

In response to the advance notice of proposed rulemaking, 1 trade association, 10 drug manufacturers, 36 health professionals, and 4 consumers submitted comments. In response to the notice of reopening the administrative record to allow for consideration of recommendations on camphor-containing drug products, one trade association, six drug manufacturers, and one drug marketer submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

This proposal to establish Part 348 (21 CFR 348) constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC external analgesic drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the

Code of Federal Regulations

- The Food, Drug, and Cosmetic Act is detailed in what we call the Code of Federal Regulations or “CFR”
- The CFR is a codification of the general and permanent rules published in the “Federal Register”

Code of Federal Regulations

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL

PART 1 GENERAL ENFORCEMENT REGULATIONS

Subpart A--General Provisions
- § 1.1 - General.
- § 1.3 - Definitions.
- § 1.4 - Authority citations.

Subpart B--General Labeling Requirements
- § 1.20 - Presence of mandatory label information.
- § 1.21 - Failure to reveal material facts.
- § 1.23 - Procedures for requesting variations and exemptions from required label statements.
- § 1.24 - Exemptions from required label statements.

Subparts C-D [Reserved]

Subpart E--Imports and Exports
- § 1.83 - Definitions.
- § 1.90 - Notice of sampling.
- § 1.91 - Payment for samples.
- § 1.94 - Hearing on refusal of admission.
- § 1.95 - Application for authorization to relabel and recondition.
- § 1.96 - Granting of authorization to relabel and recondition.
- § 1.97 - Bonds.
- § 1.99 - Costs chargeable in connection with relabeling and reconditioning inadmissible imports.
- § 1.101 - Notification and recordkeeping.

Subparts F-G [Reserved]

Subpart H--Registration of Food Facilities

General Provisions
- § 1.225 - Who must register under this subpart?
- § 1.226 - Who does not have to register under this subpart?
- § 1.227 - What definitions apply to this subpart?

Procedures for Registration of Food Facilities
- § 1.230 - When must you register?
- § 1.231 - How and where do you register?
- § 1.232 - What information is required in the registration?
- § 1.233 - What optional items are included in the registration form?
- § 1.234 - How and when do you update your facility's registration information?

FDA Food Safety Modernization Act: Facts

Motivators for FSMA: Facts

48,000,000 Americans get sick

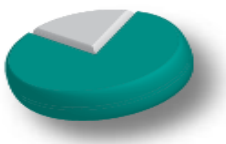
128,000 are hospitalized

3,000 die

High Profile Cases

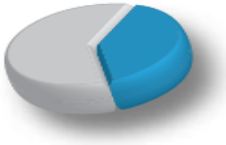
Imports in the spotlight over past decade:

Imports on the Rise



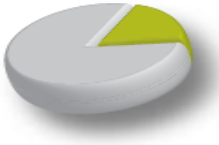
80 percent of active pharmaceutical ingredients

80 percent of seafood



40 percent of finished dosage drugs

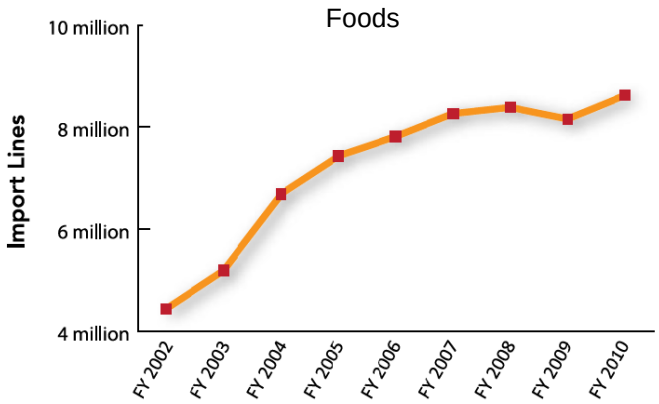
Approximately 50 percent of fresh fruit



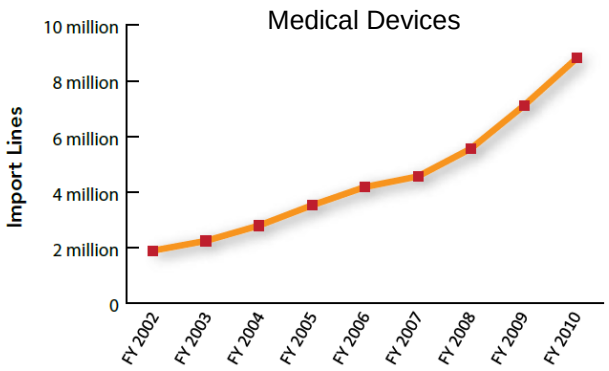
Approximately 20 percent of fresh vegetables

Sources: Hamburg, M. 2011. *Food and Drugs: Can Safety Be Ensured In a Time of Increased Globalization?* Presented at the Council of Foreign Relations New York Symposium, January 31.

Import Statistics



Source: Veneziano, D. 2011. *Import Stats FY 2002-2010.* U.S. FDA, Division of Import Operations and Policy, Office of Regulatory Affairs, Washington, DC.



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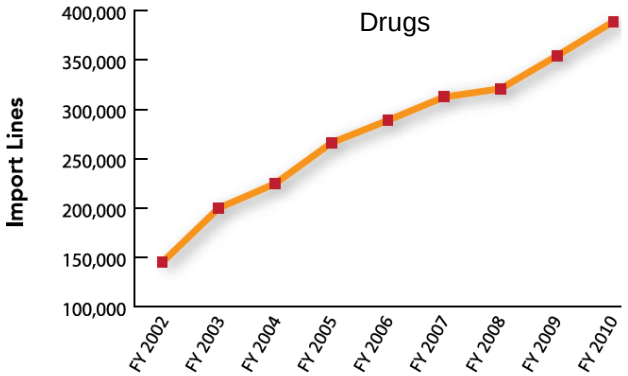
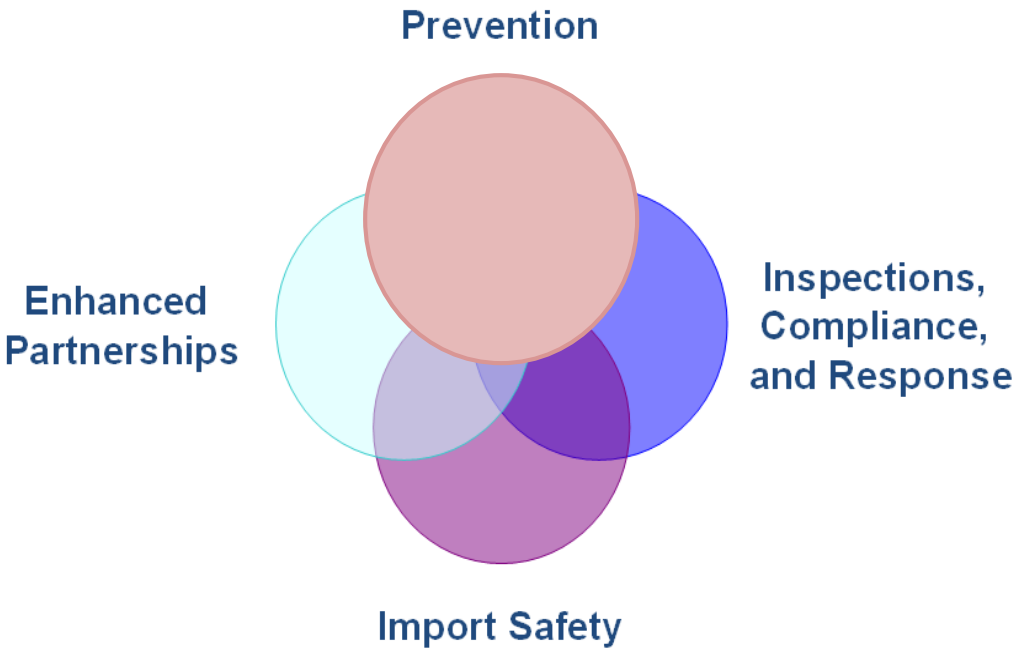


Source: Veneziano, D. 2011. *Import Stats FY 2002-2010.* U.S. FDA, Division of Import Operations and Policy, Office of Regulatory Affairs, Washington, DC.

FSMA Places Burden on Importers and Foreign Manufacturers

Increase in exports to the U.S.; too many ports; not enough FDA inspectors.

Vision of FSMA: Prevention



Key Components

Prevention

Prevention

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - New Proposed Rule Released September 19, 2014
  - Final Rule must be issued on or before August 30, 2015
- Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption
  - New Proposed Rule Released September 19, 2014
  - Final Rule must be issued on or before October 31, 2015

Mandatory Preventative Controls for Food 8/30/2015

Prevention

- New provisions requiring Hazard Analysis and Risk-based Preventative Controls
- Affects all firms required to register under the Bioterrorism Act, with exemptions

Hazard Analysis and Risk-based Preventative Controls

Prevention

- Science and risk-based to prevent hazards to public health
- Flexible in that firms develop these to fit their products and operations in order to significantly minimize or prevent all food safety hazards reasonably likely to occur
- Similar to HACCP currently required by FDA for seafood and juice and is common practice in many companies worldwide

Food Safety Plan

Prevention

- Requires development & implementation of "Food Safety Plan":
  - Conduct a Hazard Analysis
  - Establish Preventative Controls
  - Monitoring
  - Corrective Actions
  - Verification Activities
  - Recordkeeping

Food Safety Plan

Prevention

- Must be prepared by a “Qualified Individual”
  - “Qualified Individual” has training in standardized curriculum, or be otherwise qualified through job experience to develop and apply a food safety system
  - Prepares plan, develops hazard analysis, validates preventative controls, reviews records, and conducts reanalysis of food safety plan

Mandatory Produce Safety Standards 10/31/2015

Prevention

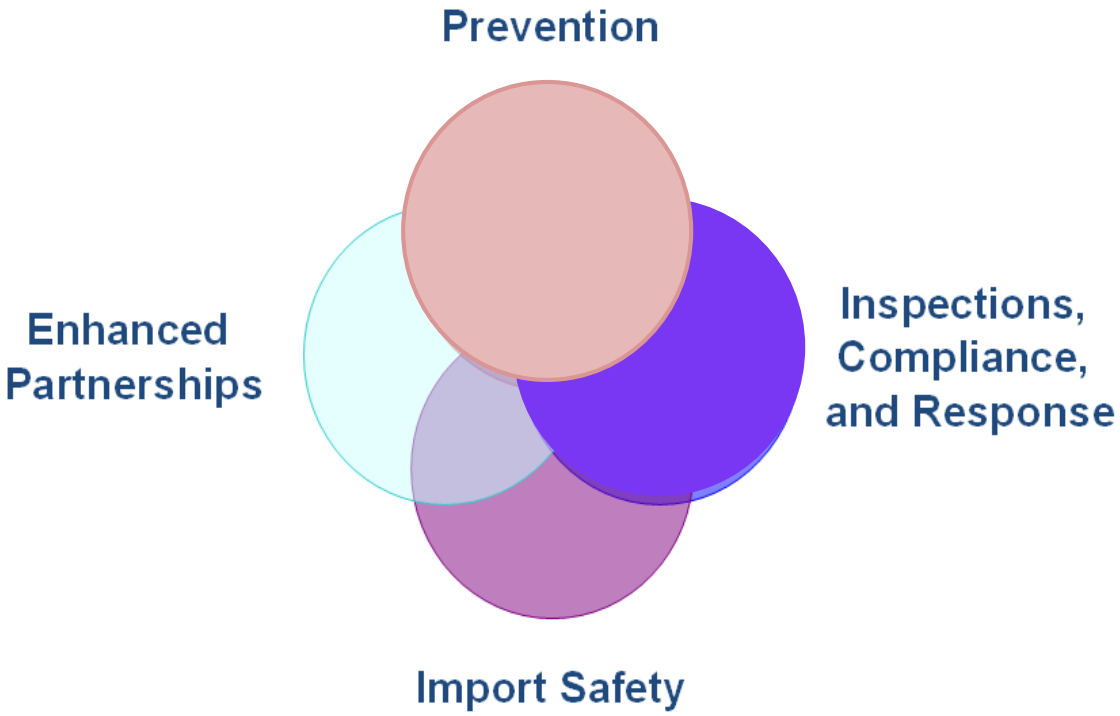
- Establishes science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms
- Identifies routes of microbial contamination
  - Agricultural water;
  - biological soil amendments of animal origin;
  - health and hygiene;
  - animals in the growing area;
  - equipment, tools, and buildings

Mandatory Produce Safety Standards – What's Covered?

Prevention

- Covers fruits and vegetables in raw or natural (unprocessed) state
- Exemptions include agricultural commodities rarely consumed raw and products that will be commercially processed (such as canned)

Vision of FSMA: Inspections, Compliance and Response



Key Components

Inspections, Compliance, & Response

Inspections, Compliance, and Response

- Mandated Inspection Frequency - **Immediate**
- Records Access – **Immediate**
- Registration Renewal: Each food facility must renew its U.S. FDA registration every two years -- **October 2014 – December 2014**
- Mandatory Recall – **Immediate**

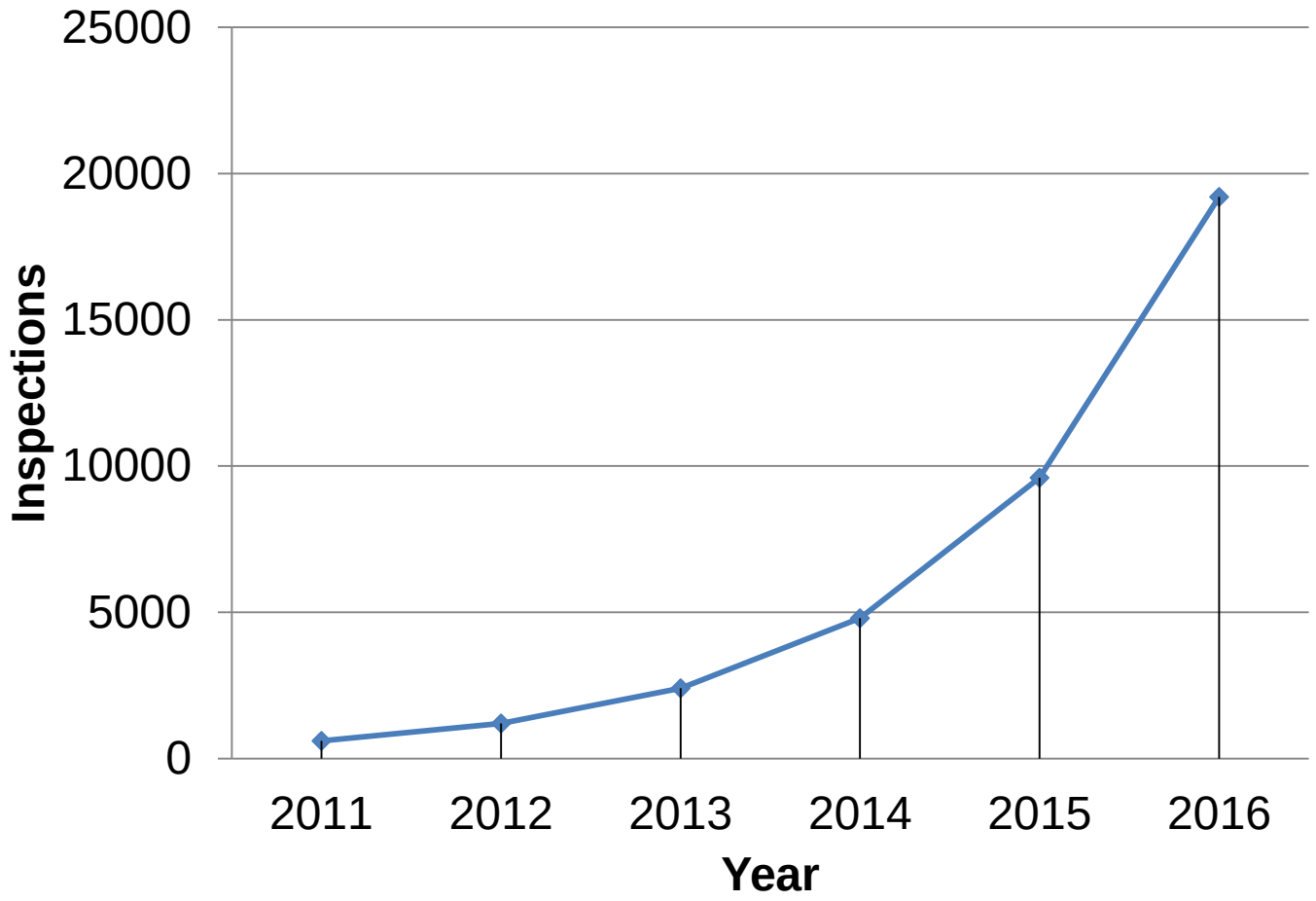
Mandated Inspection Frequency

Inspections, Compliance, & Response

- Based on risk, numbers to increase
- Foreign facilities: within one year of the bill's signing, FDA is to increase inspections of foreign facilities, and then double that number every year for five years.

Foreign Facility Inspection Schedule

Inspections, Compliance, & Response



Records Access

Inspections, Compliance, & Response

- Certain Hazard Analysis and Risk-Based Preventative Control Records must be kept for 2 years.
- FDA may access records if it believes that there is a *reasonable probability* that the use of or exposure to the article of food will cause serious adverse health consequences or death to humans or animal ("SAHCODHA")

Registration Renewal

Inspections, Compliance, & Response

- Required for both domestic and foreign facilities
  - "Facility" is a location that manufactures, processes, packs, or warehouses food or beverages for human or animal consumption
- Required between October 1st and December 31st of 2014 and every even year thereafter

Registration Renewal

Inspections, Compliance, & Response

- Facilities that fail to renew in 2014 will need to re-register
- A new 11-digit food facility registration number will issued
- Failure to renew will prevent issuance of a Prior Notice Confirmation Number, therefore preventing the submission (the FFRM and PNSI are linked)

Mandatory Recall

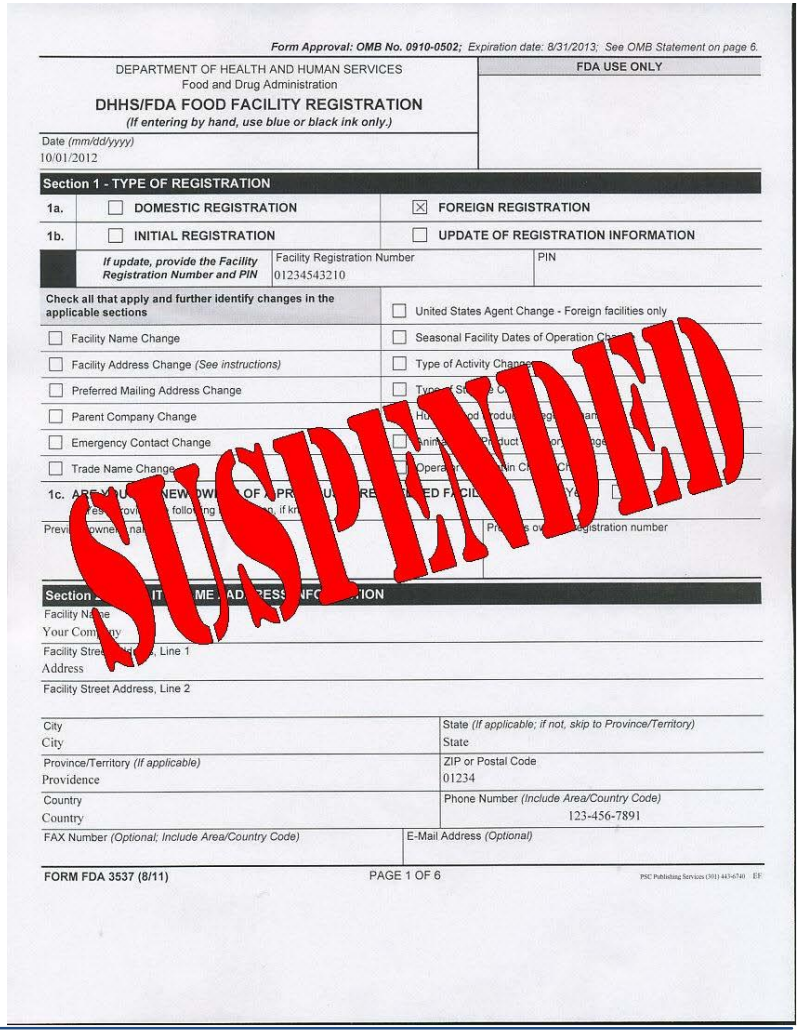
Inspections, Compliance, & Response

- FDA anticipates that mandatory recall authority will be used in rare instances. Companies will be provided with an opportunity for an informal hearing before an order to require recall is made.
- Prior to FSMA, a company would determine if they should recall a product; FDA could force a recall only through a court order

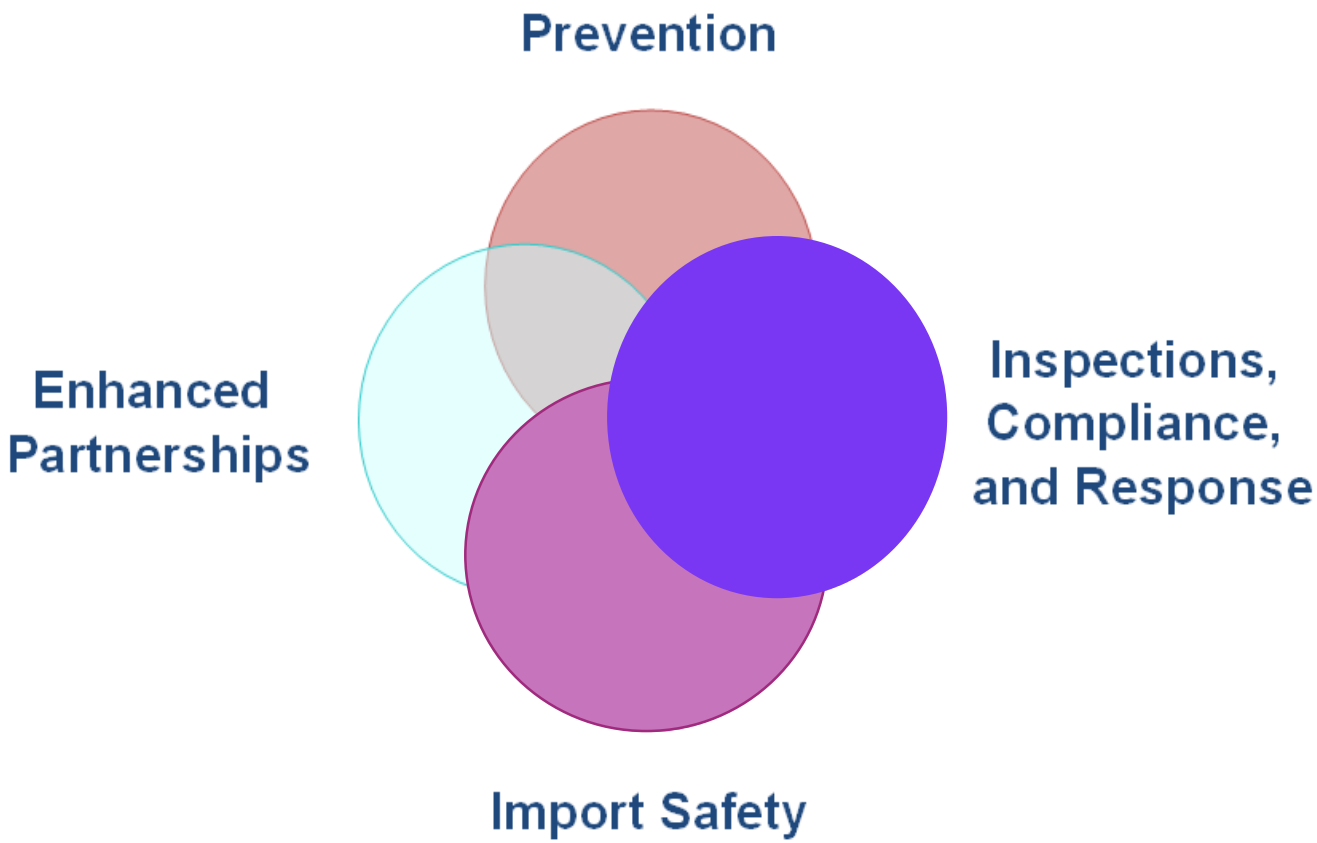
Suspension of Registration

Inspections, Compliance, & Response

- FDA may by order suspend the registration of a facility
  - reasonable probability of causing serious adverse health consequences or death to humans or animals
- If the registration of a facility is suspended
  - no person can import or export food into the United States from that facility



Vision of FSMA: Import Safety



Key Components

Import Safety

Import Safety

- Voluntary Qualified Importer Program
  - Guidance Document Not Yet Released
- Foreign Supplier Verification Program
  - New Proposed Rule Released 09/19/14
  - Final Rule to be issued on or before 10/31/15

Voluntary Qualified Importer Program (VQIP)

Import Safety

- FDA to establish a Voluntary Qualified Importer Program (VQIP) to expedite entry into the United States of imported food from eligible, qualified importers.
- FDA will qualify eligible importers to participate in VQIP based on risk considerations.
- FDA will charge a User Fee for importers wishing to enroll in the program

Foreign Supplier Verification Program for Importers of Food

Import Safety

- Final Rule to be issued by 10/31/2015
- All importers must establish, maintain, and follow a FSVP

Foreign Supplier Verification Program for Importers of Food

Import Safety

- Proposed regulations vary based on type of food (processed, produce, dietary supplements)
- Important: the obligations are placed on the importer, which in turn will place *some* obligations on the foreign manufacturer

Foreign Supplier Verification Program for Importers of Food

Import Safety

Key components:

- Conduct hazard analysis through verification activities, including a compliance status review (Warning Letters and Import Alerts)
- Conduct investigative & corrective actions (as needed)
- Reassess FSVP periodically
- Maintain Records

Hazard Analysis

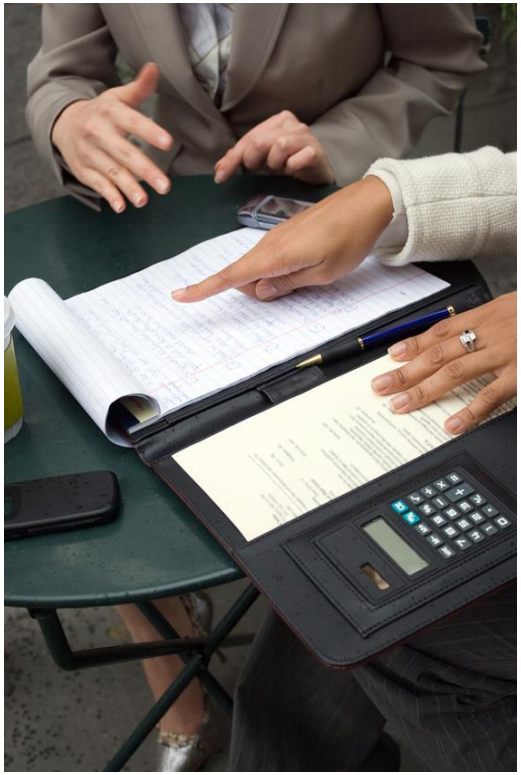
Import Safety

- Importers required to analyze the hazards associated with each food they import
  - Identify hazards reasonably likely to occur
  - Evaluate severity of the illness or injury if hazard were to occur

Hazard Analysis

Import Safety

- What does this mean for you?
  - Importers will be asking you to conduct hazard analysis through verification activities
- How?
  - Depending on risk level of the hazard:
    - Initial onsite audits (and then annually?)
    - Sampling and testing
    - Review of your records



Audits

Import Safety

- Who can conduct the audit?
  - Could be your customer
  - Could be 3rd party auditor not accredited by FDA
  - Could be 3rd party auditor accredited by FDA (but must be turned in to FDA if "serious adverse health consequences or death to humans or animals ("SAHCODHA")

    are identified.

Audits

Import Safety

- Are you required to have a 3rd party FDA-accredited audit?
  - Not unless your importer is enrolled under VQIP
  - As an option in certain circumstances based on level of risk

Control of Hazards

Import Safety

- Flexible, risk-based approach
- The proposed requirements vary based on several factors
  - The type of food produced (such as processed foods, produce, and dietary supplements)
  - The category of company (e.g., provisions for very small importers, very small foreign suppliers)
  - The nature of the hazard identified as likely to occur in the food, and
  - Who along the supply chain will be controlling the hazard.

Control of Hazards

Import Safety

- In determining which verification activities are needed and how often they should be conducted, the importer would need to consider:
  - The risk presented by the hazard
  - The probability that exposure to the hazard would result in serious harm
  - The food and foreign supplier’s compliance status.

Corrective Actions

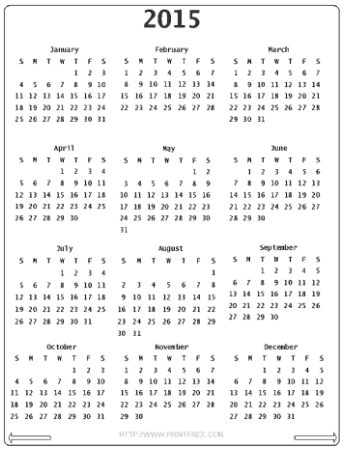
Import Safety

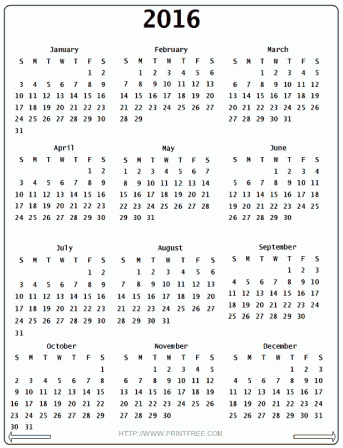
- Importers required to review complaints, investigate the cause(s) of adulteration or misbranding, and take corrective action
- How does that affect you?
  - If there are problems, you will hear from your importer

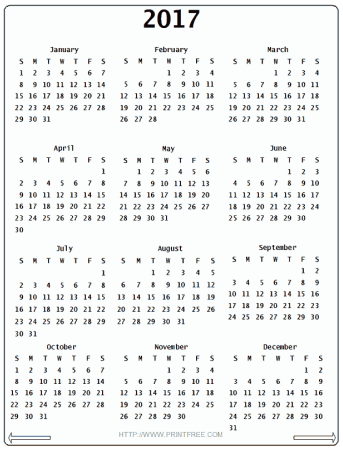
Periodic Reassessment of the FSVP

Import Safety

- Importers required to reassess their FSVP within three years of establishing the plan
  - Sooner if they become aware of new information about potential hazards associated with the food
- How does that affect you? Importers will look to you for updated information on hazards







Importer Identification

Import Safety

- Importers required to obtain a DUNS Number
  - DUNS Number will be required at time of entry with Customs and Border Protection
- DUNS Number currently required for drug establishments and coming soon for medical device establishments
- DUNS Number associated with a specific location

Recordkeeping

Import Safety

- Importers required to keep certain records
  - Hazard analyses
  - Foreign supplier verification activities
  - Investigations
  - Corrective actions
  - FSVP reassessments

Modified FSVP Requirements

Import Safety

- Dietary supplements and dietary supplement components
- Food imported by a very small importer or from a very small foreign supplier
- Food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent

Modified FSVP Requirements

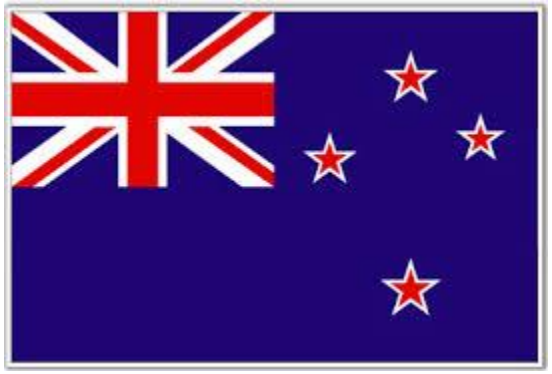
Import Safety

- Proposed rule defines “very small importer” and “very small foreign supplier” as having annual food sales of no more than $1,000,000 USD
- Document annually internally, and importers would have to obtain written assurances every 2 years that their suppliers are complying

Modified FSVP Requirements

Import Safety

- Food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent
  - New Zealand has been recognized
  - Perhaps the European Union and Canada next?



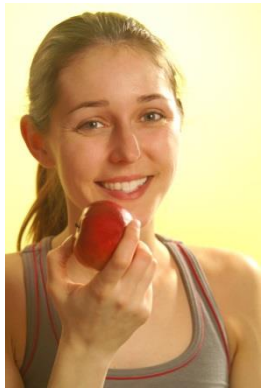
Modified FSVP Requirements

Import Safety

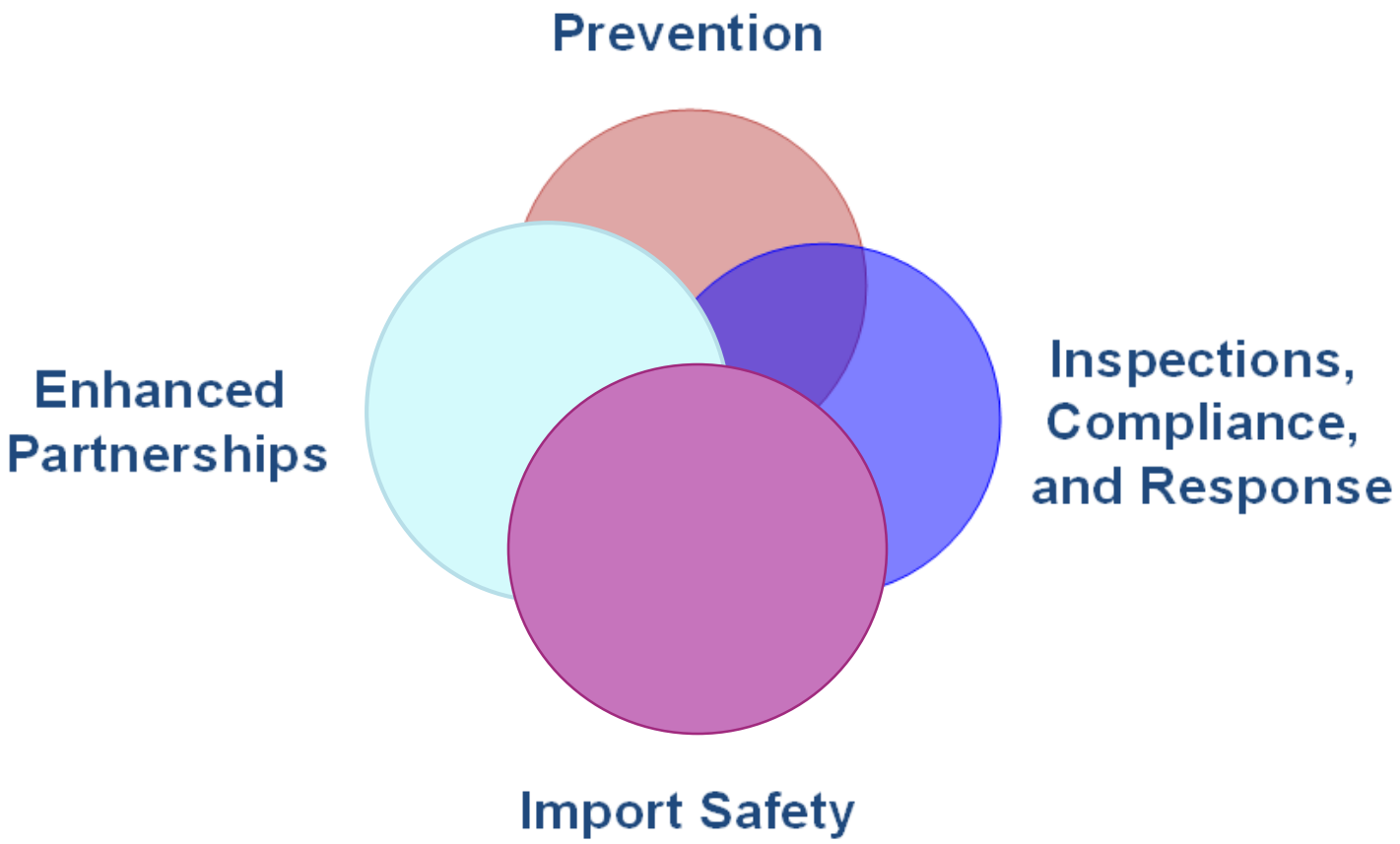
- Modified FSVP requirements for
  - Juice and seafood from facilities compliant with HACCP
  - Alcoholic beverages
  - Food imported for research or evaluation purposes;
  - Food imported for personal consumption; and
  - Food that is transshipped or imported for further processing and export.








Vision of FSMA: Enhanced Partnerships



Key Components

Enhanced Partnerships

Enhanced Partnerships

- Third Party Audits
  - Proposed Rule Released July 26, 2013
  - Final Rule to be issued on or before October 31, 2015
- Capacity Building
  - Outreach through training
  - Establishment of overseas offices

Third Party Audit Concept

Enhanced Partnerships

- Allows FDA to leverage industry audits
- Audits could be used to help facilitate entry of certain imported foods under VQIP
- A comprehensive third-party program will create a new path for working with industry and foreign governments

Third-Party Audits

Enhanced Partnerships

- Proposed Rule covers development of a program to establish Accreditation Bodies and Third Party Auditors seeking recognition by FDA.

Accreditation Bodies / Third Party Audits

Enhanced Partnerships

- Accreditation Bodies and Third Party Auditors could include:
  - Foreign Governments
  - Foreign Cooperatives
  - Private companies

Capacity Building

Enhanced Partnerships

- FSMA directs FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries

New User Fees under FSMA

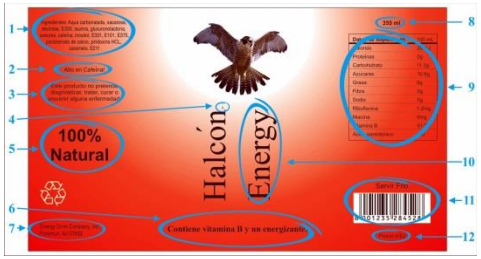
Enhanced Partnerships

- New FDA User Fees: Effective October 1, 2011
- FDA Hourly Rates for Fiscal Year 2015:
  - $217 per hour, domestic
  - $305 per hour, foreign activities
- May be charged for Re-Inspections

New User Fees under FSMA

Enhanced Partnerships

- Re-inspection Fees are calculated for:
  - Traveling to and from the facility
  - Preparing reports
  - Analyzing samples
  - Examining labels



- Thus far, FDA has not issued re-inspection fees
  - Guidance document pending

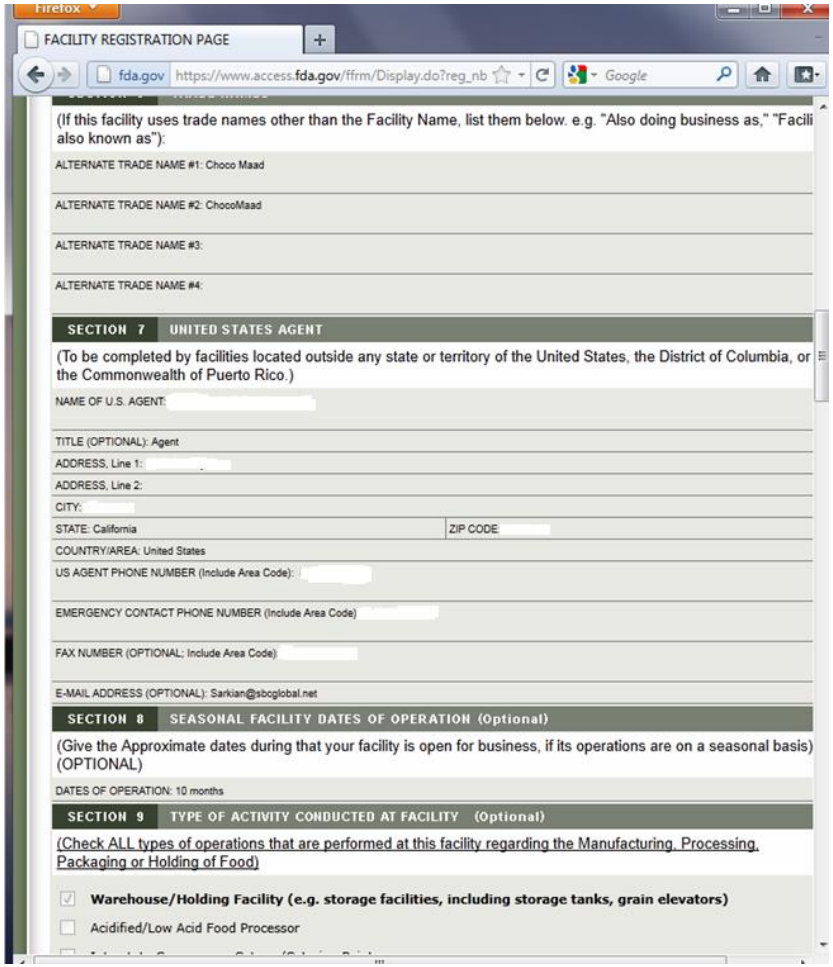
New User Fees under FSMA

Enhanced Partnerships

- Re-inspection Fees
  - Will be charged to the facility's U.S. Agent listed in Section 7 of the food facility registration module
  - An importer who was listed as the U.S. Agent in a foreign registration may be liable even if they were listed in 2003 and no longer conduct business with the foreign facility

U.S. Agent Responsibilities

Enhanced Partnerships



- US Agent is designated in Section 7, FFRM
- US Agent must:
  - Reside in USA
  - Be available 24/7
  - Answer questions as though they are answering for registrant
  - Should know how to deal with FDA.

Takeaways…

- Numerous “Final Rules” due in 2015
- Final Rules may differ from proposed rules
- Many of the rules will apply to importers, but they in turn will require foreign manufacturers to be in compliance
- Small businesses (less than $1,000,000 USD in annual food sales) may be exempt from some parts of the law
- Once finalized, rules will be phased in during 2015/2016/2017.

In Summary…

- U.S. remains a market of volume and high value
- Dedicate resources now to food safety to avoid expensive problems later
- Once final rules are released, Registrar Corp will offer a range of services to help foreign manufacturers comply with FSMA.

Questions?

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