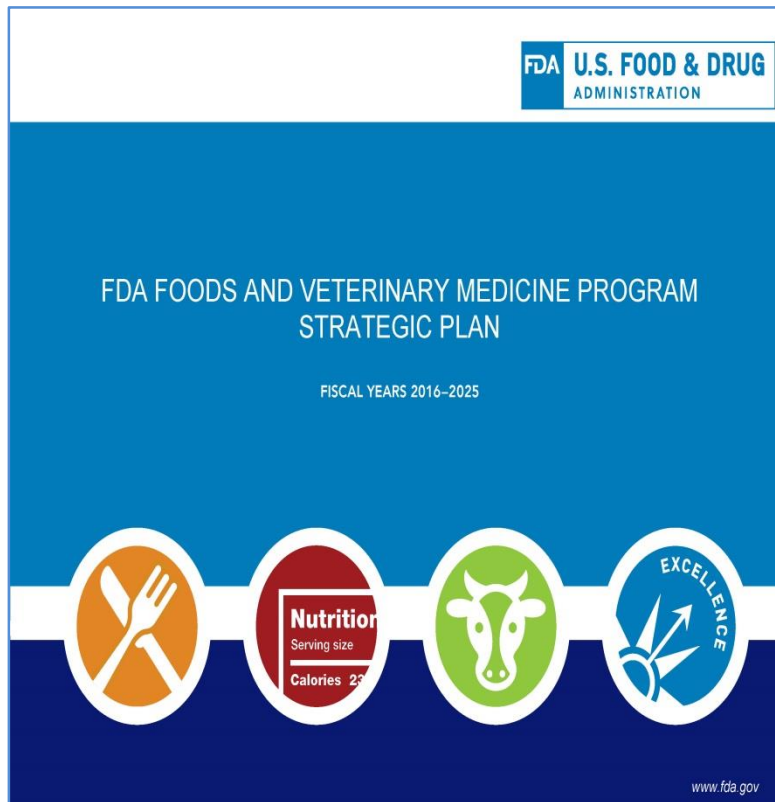


# Center for Food Safety & Applied Nutrition: Update

Comments by  
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Deputy Director for Regulatory Affairs  
FDA/Center for Food Safety and Applied Nutrition  
AFDO 2017 Annual Meeting  
June 20, 2017

# Foods and Veterinary Medicine



Issued July 2016  
Covers 2016-2025

10-year strategic plan  
priorities include three of  
critical importance to  
CFSAN:

- Food safety
- Nutrition
- Organizational excellence

# Strategic Priority: Food Safety

- Goal: Protect consumers from foreseeable hazards. Examples:
  - Implementation of FDA Food Safety Modernization Act (FSMA)
  - Food safety includes microbiological contaminants, but also chemical contaminants and substances added to foods (e.g., food additives)

# Preventive Approach to Food Safety

- Helping industry obtain compliance with preventive control standards rather than finding and responding to violations after an illness or outbreak has occurred
- Providing FDA technical expertise and capacity to support industry in implementing the new prevention standards
- Furthering federal, state, local, and territorial partnerships, and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide
- Using a variety of tools to increase oversight of imported food safety

# FSMA Implementation

- Seven FSMA rules finalized
- Developing guidance
- Establishing Produce Safety Network
- Establishing modernized approach to import activities



# FSMA Training

- **Food Safety Preventive Controls Alliance (FSPCA)**
  - Curricula to train those that manufacture, process, hold, and distribute human and animal food (since January 2016)
  - More than 2500 courses completed and 36,000 preventive controls certificates issued
- **Produce Safety Alliance (PSA)**
  - Curricula to train the farming community (since Fall 2016)
  - Trainers in all 50 states and collaborations to support international training
  - Issued ~ 2000 certificates
- **Sprout Safety Alliance (SSA)**
  - Training opportunities since August 2016
  - Thus far, trained about 100 members of the sprouting community
  - Collected information from ~200 sprout growers from 26 states; trained 22 sprout growers and 10 federal/state inspectors

# Current FSMA Initiatives

- Preventive controls for human food
  - Both modernized current good manufacturing practice inspections and full preventive control inspections are underway
  - Interactions with facilities on both types of inspections have been positive
- Produce safety
  - Sprouts guidance (draft) published 1/23/17
  - In process: implementation and compliance guide, updated good agricultural practices
  - FDA is considering how to simplify the agricultural water standards while still protecting public health

# Current Food Safety Initiatives

- Updated draft guidance on control of *Listeria monocytogenes* (*Lm*) in ready to eat foods – published on 1/17/17
  - Additional draft guidance on *Lm* -- i.e., compliance policy guide, classification of food as ready to eat
- Request for comments on gene editing in new plant varieties used for foods – published 1/19/17



# Strategic Priority: Safe and Nutritious Food

- Much of our work lies at the intersection of food safety and nutrition
  - Arsenic in rice
  - Methylmercury in fish



# Arsenic in Rice and Rice Products



<< [Arsenic Main Page](#)

Arsenic is an element in the Earth's crust, and is present in water, air, and soil. It exists in two forms, with the inorganic form considered to be the more toxic. The FDA has been monitoring the levels of arsenic in foods for decades and in 2011, after new methods to differentiate the forms of arsenic became available, the agency expanded its testing to help better understand and manage possible arsenic-related risks associated with food consumption in the United States.



Rice has higher levels of inorganic arsenic than other foods, in part because as rice plants grow, the plant and grain tend to absorb arsenic more readily than other food crops. In April 2016, the FDA proposed an action level, or limit, of 100 parts per billion (ppb) for inorganic arsenic in infant rice cereal. This level, which is based on the FDA's assessment of a large body of scientific information, seeks to reduce infant exposure to inorganic arsenic. The agency also has developed advice on rice consumption for pregnant women and the caregivers of infants.

# Advice About Eating Fish

## What Pregnant Women & Parents Should Know

Fish and other protein-rich foods have nutrients that can help your child's growth and development.

For women of childbearing age (about 16-49 years old), especially pregnant and breastfeeding women, and for parents and caregivers of young children.

- Eat 2 to 3 servings of fish a week from the "Best Choices" list OR 1 serving from the "Good Choices" list.
- Eat a variety of fish.
- Serve 1 to 2 servings of fish a week to children, starting at age 2.
- If you eat fish caught by family or friends, check for fish advisories. If there is no advisory, eat only one serving and no other fish that week.\*

### Use this chart!

You can use this chart to help you choose which fish to eat, and how often to eat them, based on their mercury levels. The "Best Choices" have the lowest levels of mercury.

### What is a serving?



To find out, use the palm of your hand!

For an adult  
4 ounces

For children, ages 4 to 7  
2 ounces

Best Choices <small>EAT 2 TO 3 SERVINGS A WEEK</small>			OR	Good Choices <small>EAT 1 SERVING A WEEK</small>		
Anchovy	Herring	Scallop		Bluefish	Monkfish	Tilefish (Atlantic Ocean)
Atlantic croaker	Lobster, American and spiny	Shad		Buffalofish	Rockfish	
Atlantic mackerel		Shrimp		Carp	Sablefish	Tuna, albacore/white tuna, canned and fresh/frozen
Black sea bass	Mullet	Skate		Chilean sea bass/Patagonian toothfish	Sheepshead	Tuna, yellowfin
Butterfish	Oyster	Smelt		Grouper	Snapper	Weakfish/seatrout
Catfish	Pacific chub mackerel	Sole		Halibut	Spanish mackerel	White croaker/Pacific croaker
Clam	Perch, freshwater and ocean	Squid		Mahi mahi/dolphinfish	Striped bass (ocean)	
Cod	Pickering	Tilapia				
Crab		Trout, freshwater				
Crawfish	Plaice	Tuna, canned light (includes skipjack)				
Flounder	Pollock	Whitefish				
Haddock	Salmon	Whiting				
Hake	Sardine					
<b>Choices to Avoid</b> <small>HIGHEST MERCURY LEVELS</small>						
				King mackerel	Shark	Tilefish (Gulf of Mexico)
				Marlin	Swordfish	Tuna, bigeye
				Orange roughy		

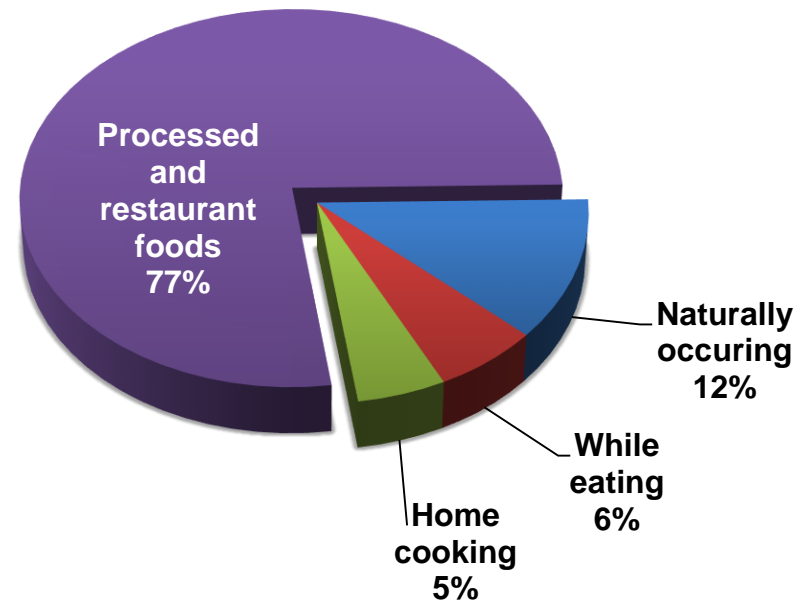
\*Some fish caught by family and friends, such as larger carp, catfish, trout and perch, are more likely to have fish advisories due to mercury or other contaminants. State advisories will tell you how often you can safely eat those fish.

# Strategic Priority: Nutrition

- Goal: Foster an environment to promote healthy and safe food choices. Examples:
  - Voluntary sodium reduction targets
  - Updating the Nutrition Facts label
  - Menu and vending machine labeling

# Why are Sodium Reduction Targets Needed?

- Most sodium comes from salt added to processed and restaurant foods
- It is difficult to meet recommended sodium intake with current food supply
- Overall sodium content of the food supply remains high, despite industry efforts
- Variability in sodium across similar foods in the food supply shows that reductions are possible



Mattes and Donnelly, 1991



## Overview of FDA Announcement

- Draft, voluntary guidance on sodium reduction targets
  - Gradual approach
  - Targets for 150 categories of food
  - Applies to food manufacturers, restaurants and food service operations
- Draft targets serve as a basis for continued dialogue



# Voluntary Sodium Reduction Targets

- Public comment periods closed on October 17, 2016 (2-year targets) and Dec 2, 2016 (10-year targets)
  - Many comments related to targets and food categories received
  - Public health groups and some in industry supportive
- Current activities
  - Reviewing comments; considerations:
    - Feedback regarding certain targets and categories
    - Technical role of sodium in foods



# SIDE-BY-SIDE COMPARISON

## Original Label

### Nutrition Facts

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

**Amount Per Serving**

**Calories** 230      Calories from Fat 72

**% Daily Value\***

<b>Total Fat</b> 8g	<b>12%</b>
Saturated Fat 1g	<b>5%</b>
<i>Trans</i> Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>12%</b>
Dietary Fiber 4g	<b>16%</b>
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

## New Label

### Nutrition Facts

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

**Amount per serving**

**Calories** **230**

**% Daily Value\***

<b>Total Fat</b> 8g	<b>10%</b>
Saturated Fat 1g	<b>5%</b>
<i>Trans</i> Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>13%</b>
Dietary Fiber 4g	<b>14%</b>
Total Sugars 12g	
Includes 10g Added Sugars	<b>20%</b>

**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.



# NEW LABEL / WHAT'S DIFFERENT

Servings:  
 larger, —  
 bolder type

New:  
 added sugars —

Change  
 in nutrients —  
 required

<b>Nutrition Facts</b>	
8 servings per container	
<b>Serving size</b>	<b>2/3 cup (55g)</b>
<b>Amount per serving</b>	
<b>Calories</b>	<b>230</b>
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>10%</b>
Saturated Fat 1g	<b>5%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
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\* 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.

— Serving sizes updated

— Calories: larger type

— Updated daily values

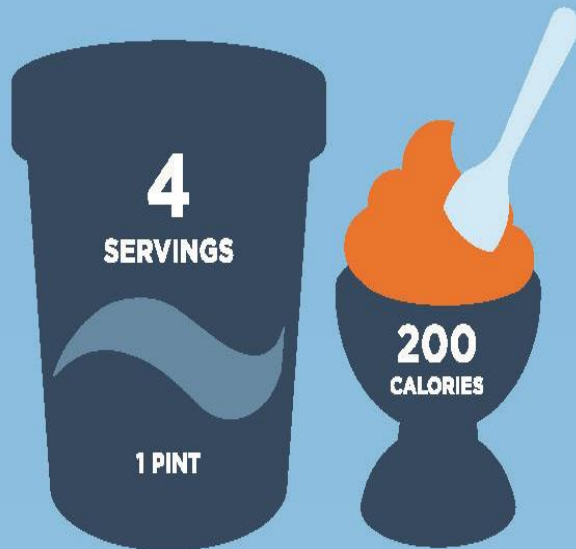
— Actual amounts declared

— New footnote

## Serving Size Changes

What's considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

### CURRENT SERVING SIZE



### NEW SERVING SIZE

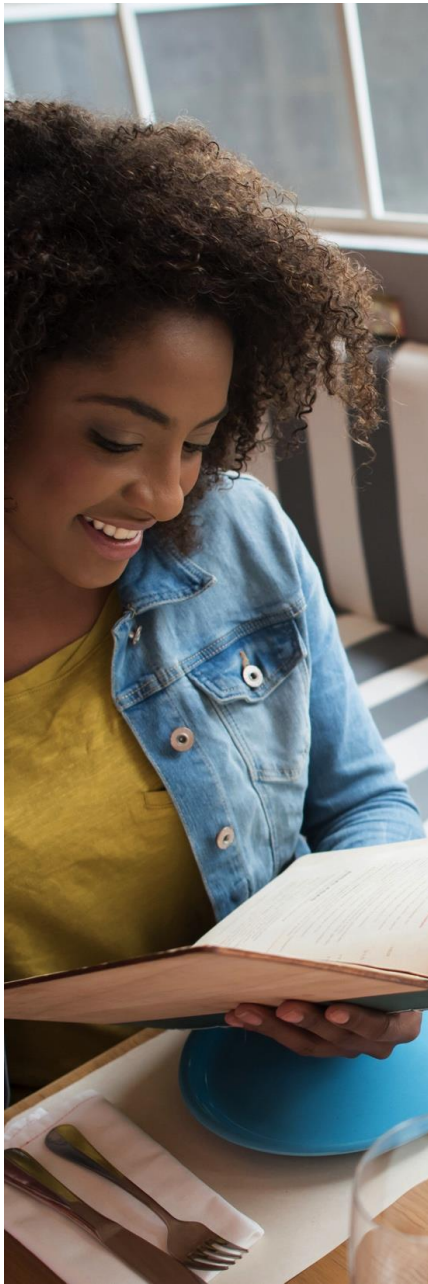


## **Nutrition Facts – Already Appearing on Shelves**

- Draft Guidance and RFI on Fiber – 11/23/16
  - Comment period on both extended to 2/13/17
- Draft Guidance (2) on NFL Updates -1/4/17
- Compliance date
  - July 26, 2018 for manufacturers with annual food sales at or above \$10 million. One additional year for all others.

# Menu and Vending Machine Labeling

- People increasingly eat food away from home
- Applies to restaurants and similar retail food establishments that are part of a chain with 20 or more locations
- Applies to a person who is engaged in the business of owning or operating 20 or more vending machines or who voluntarily registers with FDA
- Compliance dates
  - December 1, 2016 most vending machines
  - May 7, 2018 menu labeling



# Strategic Priority: Organizational Excellence

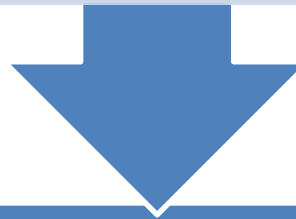
- Goal: Continuously improve leadership, management, staffing and organizational capacity of the FVM program to protect public health. Examples:
  - Improving outbreak response
  - Advancing regulatory science
  - Ensuring transparency
  - Engaging stakeholders
  - Conducting outreach and education

# SCORE

Strategic Coordinated Oversight of Recall Execution

Team of key senior FDA leaders

Created to support CORE, field staff and district offices by evaluating compliance and enforcement options and making swift decisions about best course of action.



Review and direct operations for complex cases

While CORE responds to foodborne illnesses, SCORE also gets involved in food contamination that has not yet caused illnesses or worse, but is detected in a product or facility.

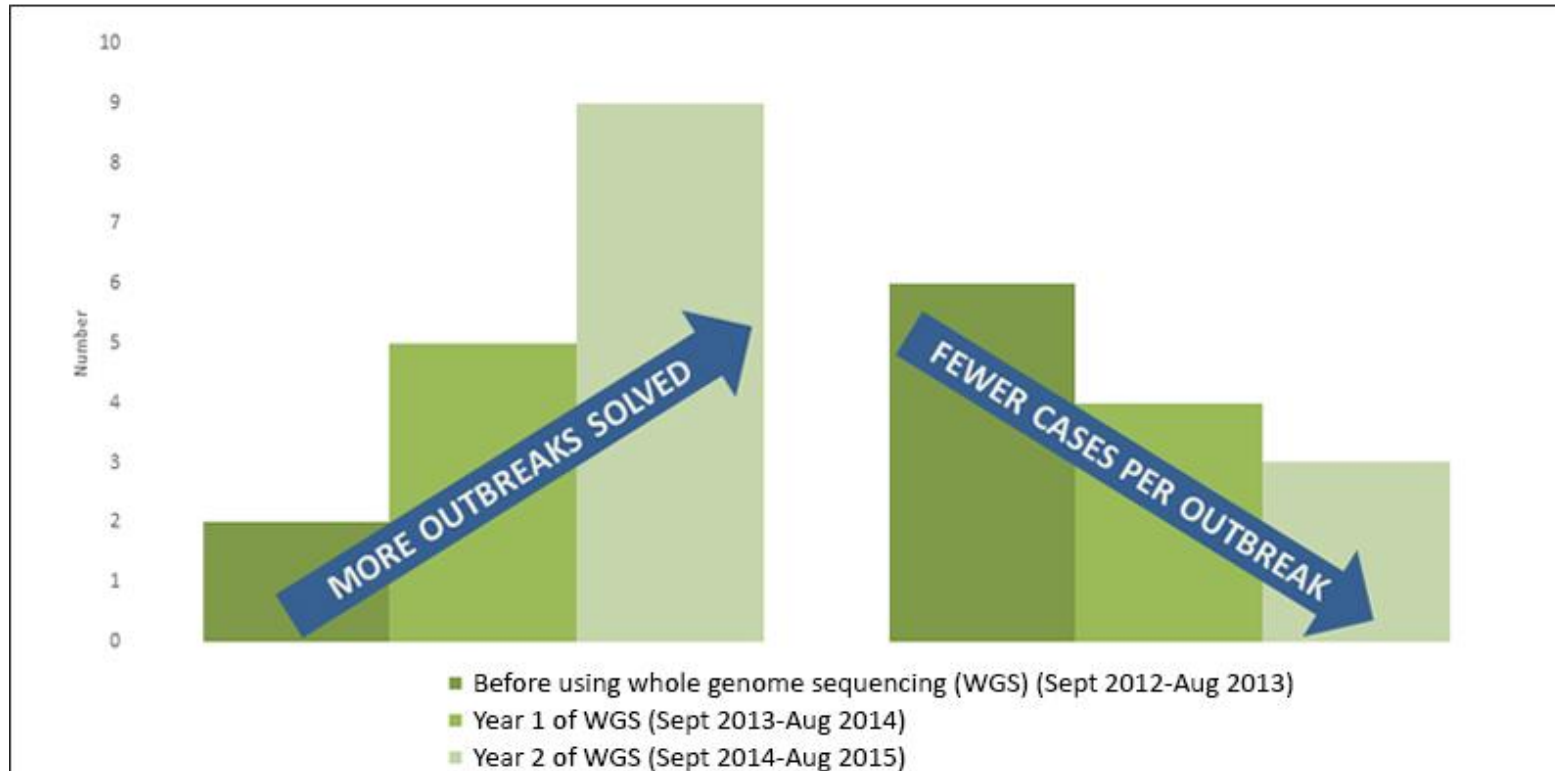


# Using State-of-the-Art Science to Solve Foodborne Outbreaks Quickly

- Whole genome sequencing helps speed up outbreak investigations
- The faster that public health officials can identify the food or ingredient that caused the illness and where it came from, the faster the harmful ingredient can be removed from the food supply -- and the more illnesses and deaths that can be averted



# Whole Genome Sequencing Prevents *Listeria* Illness



<http://www.cdc.gov/listeria/surveillance/whole-genome-sequencing.html>



# **Authenticity of Herbal Dietary Supplements Using Chemical and DNA Barcoding Methods**

- To evaluate recent reports of the absence of labelled botanical ingredient in supplements and evaluate the accuracy of DNA barcoding methods.
- Analyzed 112 supplements containing ginkgo, soy-isoflavones, valerian, yohimbe and St. John's wort.
- Used validated HPLC methods and DNA barcoding using ITS2 and PsbA-TrnH genes.
- Determined accuracy of quantitative label claim and compared results of chemical analysis and DNA barcoding methods.

# Summary of Chemical Analysis

	Chemical Analysis			
	No. of Products	Products Containing Marker Compounds	Products Making Quantitative Claims	Meet/Exceed Claim
Ginkgo	20	20	19	19
Soy	22	22	20	18
Valerian	24	23	12	11
Yohimbe	23	23	20	15
St. John's wort	23	23	19	2
<b>Total</b>	<b>112</b>	<b>111</b>	<b>90</b>	<b>65</b>

- ➡ Some marker compounds found in virtually all products
- ➡ 72% appear to meet or exceed the label claim

# Summary of DNA Barcoding

	DNA Barcoding			
	No. of Products	Labelled to Contain Plant Part	Labelled to Contain only Extract	DNA of Labelled Ingredient Found
Ginkgo	20	4	16	2
Soy	22	0	22	13
Valerian	24	19	5	5
Yohimbe	23	1	22	0
St. John's wort	23	11	12	5
<b>Total</b>	<b>112</b>	<b>35</b>	<b>77</b>	<b>25</b>

- ➡ 22% showed DNA of the labelled botanical
- ➡ Processed products (extracts) may contain little or degraded DNA

# Conclusions

- ✓ Quantitative label claims of most products confirmed by chemical analysis
- ✓ DNA barcoding alone cannot confirm the identity of a finished product
- ✓ Both plant materials and extracts contain little or degraded DNA
- ✓ Use of mini-barcodes or next-generation sequencing show greater promise

Pawar, R. *et al.* 2017, Assessment of the authenticity of herbal dietary supplements: comparison of chemical and DNA barcoding methods. *Planta Medica*. eFirst 28 April 2017.

# CFSAN Adverse Event Reporting System (CAERS)

- CAERS captures data on adverse events and product complaints reported about food, dietary supplements and cosmetics
- Purpose: enable post-market surveillance of products to help detect signals of possible safety issues
- Data posted on FDA.GOV as of December 2016

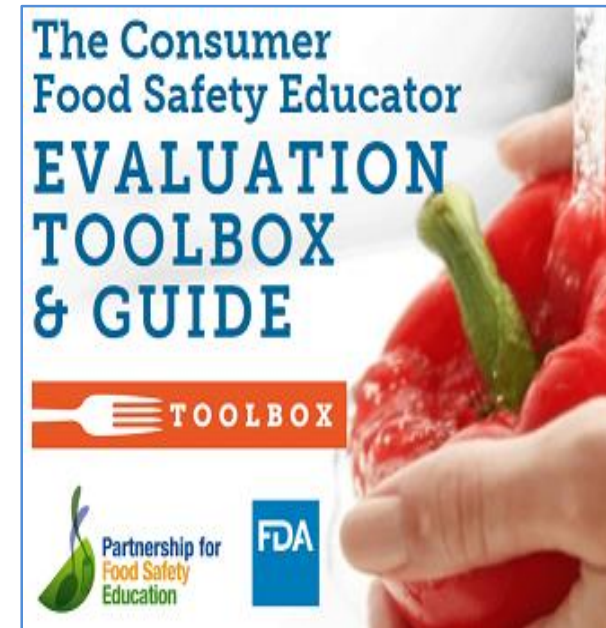


# Stakeholder Engagement

- Two public meetings this year engaged stakeholders in key food safety and nutrition discussions
  - Public hearing in February focused on **strategic partnerships to ensure the safety of imported foods.**
  - Public meeting in March sought input on use of the term '**healthy**' in food labeling.

# Raising Awareness of Food Safety and Making Information More Available to Consumers

- Education partnership with the AMA
  - Video on foodborne illness
  - Video on food safety
- Clear Information Tool
  - Information is clear and written in plain language
  - Communications are effective for the target audience
- Educator Evaluation Toolbox & Guide







# Dietary Supplements

- Newly established Office of Dietary Supplement Programs
- Issued more than 20 warning letters on illegal ingredients, for example:
  - methylsynephrine
  - acacia rigidula
  - picamilion
  - pure powdered caffeine
- Published draft guidance on new dietary ingredients
- Education and outreach to consumers and health professionals
- Research on probiotics



# Cosmetics

- WEN Cleansing Conditioners
- Tattoo Ink
- Lead
  - Published draft guidance recommending no more than 10 ppm of lead in lip products and externally applied cosmetics (12/22/16)
- Formaldehyde in hair straightening products

