

# FDA News: Regulatory Updates

## FSMA Updates

### FSMA Enforcement in Full Effect

The U.S. Food and Drug Administration (FDA) is actively enforcing Food Safety Modernization Act (FSMA) regulations during routine inspections. In 2018, FDA issued 396 citations relating to Preventive Controls rules, such as having an inadequate Hazard Analysis and Risk-based Preventive Controls (HARPC) plan, and 278 citations to importers for failing to develop Foreign Supplier Verification Programs (FSVP). In 2019, FDA has continued this trend, sending numerous warning letters to companies for violating both of these rules.

FDA expects facilities to have a HARPC Food Safety Plan that identifies all reasonably foreseen hazards and establishes controls for those hazards. Importers are expected to verify and approve their suppliers under FSVP. Registrar Corp's Food Safety Specialists can help you comply with FSMA regulations.

### First Intentional Adulteration Compliance Deadline Has Passed

FDA's Intentional Adulteration rule requires businesses that average over \$10 million in annual sales to write Food Defense Plans for their facilities. The deadline for businesses with more than 500 full-time equivalent employees passed on July 26, 2019 while businesses with fewer than 500 full-time equivalent employees have until July 27, 2020.

A Food Defense Plan must include a vulnerability assessment that identifies aspects of a facility's processes where an attacker may intentionally adulterate food as well as the severity and scale of potential impact on public health in the event of adulteration. The plan must also establish specific mitigation strategies to minimize or prevent the impact of identified vulnerabilities. Registrar Corp's Food Safety Specialists can develop a Food Defense Plan for your facility or review your current plan for compliance.

## Many Food Businesses Have Less Than 4 Months to Comply with New Label Rules

FDA finalized significant changes to food, beverage, and supplement labeling, including updates to daily values, serving sizes, the Nutrition Facts chart, and more. Updates to daily values may affect what nutrient content claims, such as "high in fiber," a label may bear. FDA's compliance deadline for these rules is January 1, 2020 (or January 1, 2021 for manufacturers with less than 10 million in annual sales).

We urge industry to comply now. FDA extended the previous compliance date due to industry concern for meeting the original deadline. Registrar Corp can update your labeling to be compliant with FDA's new regulations. Start now for a smooth and efficient transition.

### Monitor Your FDA Registration With The FDA Compliance Monitor®

Food facilities can now continuously track the FDA registration status of their own facilities, their suppliers, and competitors through Registrar Corp's FDA Compliance Monitor®.

Additionally, the Monitor aggregates and supplements data from five FDA databases to provide comprehensive compliance reports on FDA-regulated companies.

### Schedule a Demo:

[www.registrarcorp.com/demo-now](http://www.registrarcorp.com/demo-now)

Nutrition Facts																						
Serving Size 2/3 cup (55g) Servings Per Container About 8																						
<b>Amount Per Serving</b>																						
<b>Calories</b> 230	Calories from Fat 72																					
<b>% Daily Value*</b>																						
<b>Total Fat</b> 8g	<b>12%</b>																					
Saturated Fat 1g	5%																					
Trans Fat 0g																						
<b>Cholesterol</b> 0mg	<b>0%</b>																					
<b>Sodium</b> 160mg	<b>7%</b>																					
<b>Total Carbohydrate</b> 40g	<b>12%</b>																					
Dietary Fiber 4g	16%																					
Sugars 1g																						
<b>Protein</b> 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.																						
<table border="0"> <tr> <td>Calories:</td> <td>2,000</td> <td>2,500</td> </tr> <tr> <td>Total Fat</td> <td>Less than 65g</td> <td>80g</td> </tr> <tr> <td>Sat Fat</td> <td>Less than 20g</td> <td>25g</td> </tr> <tr> <td>Cholesterol</td> <td>Less than 300mg</td> <td>300mg</td> </tr> <tr> <td>Sodium</td> <td>Less than 2,400mg</td> <td>2,400mg</td> </tr> <tr> <td>Total Carbohydrate</td> <td>Less than 300g</td> <td>375g</td> </tr> <tr> <td>Dietary Fiber</td> <td>25g</td> <td>30g</td> </tr> </table>		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	Less than 300g	375g	Dietary Fiber	25g	30g
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Old format

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8 servings per container	
<b>Serving size 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	5%
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 40g	<b>13%</b>
Dietary Fiber 4g	14%
Total Sugars 1g	
Includes 1mg Added Sugars	20%
<b>Protein</b> 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 format