FDA Update on the Food Safety Modernization Act

Manufactured Foods Regulatory Program

Joann M. Givens, Program Director
Office of Human and Animal Food Operations - West
U.S. Food & Drug Administration

April 9, 2019 | Houston, TX
FDA Welcomes

- Frank M. Yiannas, Deputy Commissioner for Food Policy and Response
- Dr. Stephen Ostroff retired January 2019

“Frank’s deep commitment to public health and the well being of consumers makes him a perfect fit for his new role at FDA.” – Mike Taylor
FDA Food Safety Modernization Act

• FSMA’s success depends on bringing about high rates of compliance.

• FDA is committed to educating before and while we regulate.
FSMA IMPLEMENTATION 2018-2019

- September 2018: Preventive Controls Human and Animal Food
- January 2019: Sprouts: Very Small businesses
- Spring 2019: Produce Safety
- March 2019: FSVP
- July 2019: Intentional Adulteration
Preventive Controls for Human Food

• Several FDA assignments issued since November 2016 for inspections of businesses based on staggered compliance dates.

• Inspections (domestic and foreign) of businesses subject to full requirements conducted by dedicated FDA staff who completed regulators and OJE training.

• Businesses of all “sizes” are subject to full requirements or modified requirements of the PC rule.
Preventive Controls for Animal Food

• FDA began conducting routine inspections of facilities subject to full requirements of the PC AF rule inspections in October 2018 of large businesses.

• FDA conducted routine inspections of facilities subject to CGMP of the PC AF rule since October 2017.
Operational Field Activities

Successes

- FDA, State partners, and industry participating alongside receiving consistent training.

- FDA Food Safety Staff learning and working more closely together in the implementation of the Rules.

- Feedback from industry, consumers, and state partners.
Operational Field Activities

**Challenges**

- Longer inspection times and more participants on inspections, partly due to OJE.

- Obtaining copies of Food Safety Plans and other documents as informational rather than supporting evidence of violation or significant observation.

- Continue inspections as outlined in FDA’s Food Safety Work Plan. Other inspectional and sampling obligations as directed by Centers through directed assignments.

- Continue with environmental sampling as directed or “for cause”.
FDA Pilot – Two Tier Inspections

• Notice to Industry issued through FDA’s website on 9/24/2018.
• Solicited (5) businesses that implement centrally-developed supply-chain program and recall plans.
• Tier 1 – FDA will assess adequacy;
• Tier 2 – FDA will assess implementation.
## FY2018 FDA Assignments

<table>
<thead>
<tr>
<th>Category</th>
<th>Planned Number of Inspections</th>
<th>Accomplishments (est.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls in Human Food (Issued December 18, 2017)</td>
<td>Domestic (400)</td>
<td>FDA 440 State 23</td>
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<tr>
<td></td>
<td>Foreign (100)</td>
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<tr>
<td></td>
<td>State (23)</td>
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</tr>
<tr>
<td>Preventive Controls in Animal Food (CGMP) (Issued October 16, 2017)</td>
<td>Domestic (304)</td>
<td>321</td>
</tr>
<tr>
<td>Sanitary Transportation (Issued April 2018)</td>
<td>Domestic (150)</td>
<td>119</td>
</tr>
<tr>
<td>Other Center directed assignments</td>
<td>Issued throughout year(s)</td>
<td>Inspections, Sample Collections (Product or Environmental)</td>
</tr>
</tbody>
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## FY2019 FDA Assignments

<table>
<thead>
<tr>
<th>Preventive Controls in Human Food (Issued October 2018)</th>
<th>Planned Number of Inspections</th>
<th>Accomplishments (est.)</th>
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<tbody>
<tr>
<td></td>
<td>Domestic (500)</td>
<td>FDA Domestic 396</td>
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<tr>
<td></td>
<td>Foreign (150)</td>
<td>FDA Foreign 147</td>
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<tr>
<td></td>
<td>State (207)</td>
<td>State 22</td>
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<tr>
<td>Preventive Controls in Animal Food (CGMP) (Issued October 16, 2018)</td>
<td>Domestic (250)</td>
<td>FDA 58</td>
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<td>Foreign (15)</td>
<td>State 41</td>
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<td>State (734)</td>
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<tr>
<td>Preventive Controls in Animal Food (Full Requirements) (Issued October 16, 2018)</td>
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<td>Foreign (10)</td>
<td>State 3</td>
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<tr>
<td></td>
<td>State (68)</td>
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<tr>
<td>Other Center directed assignments</td>
<td>Issued throughout year(s)</td>
<td>Other Inspections, Sample Collections (Product or Environmental)</td>
</tr>
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Number of Participants PC Human Food Regulators

Training

(September 2016 – February 2019)

<table>
<thead>
<tr>
<th>FDA CSO</th>
<th>State</th>
</tr>
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<tbody>
<tr>
<td>• 158</td>
<td>• 217</td>
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<tr>
<td>• (30%)</td>
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Most Common FDA Observations

PC Human Food (21 CFR 117, Subpart C)

• Hazard Analysis – Identification of Hazard
• Sanitation Controls Verification Procedures
• Food Safety Plan
• Allergen Controls Monitoring Procedures
• Sanitation Controls Monitoring Procedures
Educating Before and While We Regulate

- FDA issues Warning Letters to firms in violation of new requirements and other regulations;

- FDA continues to use other enforcement tools such as regulatory meetings to obtain prompt voluntary compliance.
What’s Next?

• FDA’s primary focus will continue to be on education, training and technical assistance to help industry comply with the new requirements.

• Inspection approach will focus on assessing the progress a company has made towards compliance and whether it is taking appropriate steps necessary to protect public health.

• Continue to have external engagement with industry, consumer groups, and state regulatory partners.
  
  o Promote increased participation from state regulatory partners to ensure public health objectives of the new law are implemented.
Have a FSMA Question?

FDA Food Safety Modernization Act (FSMA) web site

The FDA has a Technical Assistance Network specifically for #FSMA (Food Safety Modernization Act) issues. This team reached the 10,000-inquiry milestone! Responding to rules & regs questions #TAN helps keep our food supply one of the safest in the world. go.usa.gov/xPfk3
Thank You