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FDA INSPECTIONS & RECORDKEEPKING POST-FSMA

Wisconsin Association for Food Protection
Food Safety Training and FSMA Compliance Workshop
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Agenda

- FDA's Expanded Powers
  - Shift from reactive to proactive means FDA is more inspection-oriented and enforcement-minded
- FY2016 Budget Status
- Final Rule Recordkeeping Requirements
  - Food Safety Plan
  - Implementation Records
  - Records Retention Requirements
  - Electronic Records

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FDA's Expanded Powers

- Inspection allowed under a lower threshold
- Mandatory recalls
- Expanded administrative detention
- Suspension of registration
- Stronger records access authority
- Focus on "high–risk" foods

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FSMA's Impact on Inspections

- More inspections mandated by FSMA
- FDA to use systems-based approach to conducting inspections
- FDA will have increased access to records during routine inspections

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Human Food Final Rule (Sept. 17, 2015)

- "We are implementing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. This new paradigm involves a major reorientation and retraining, for which we are seeking funding, of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors." 80 Fed. Reg. 180, 55921.

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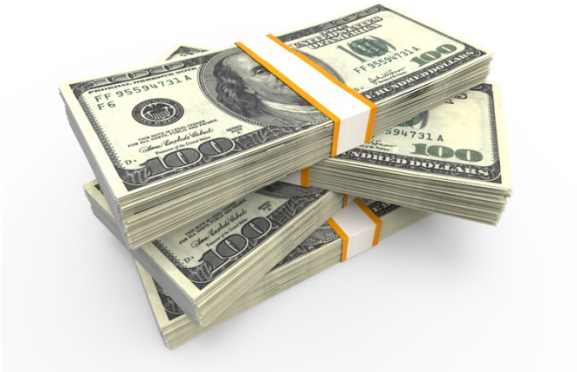
FY2016 Requested Budget Authority

- $1.3 billion request *(+ $109.5M)*
  - 1. Inspection Modernization and Training - *$25M*
  - 2. National Integrated Food Safety System - *$32M*
  - 3. Education and Technical Assistance for Industry - *$11.5M*
  - 4. FDA Technical Staffing and Guidance Development - *$4M*
  - 5. New Import Safety Systems - *$25.5M*
  - 6. Risk Analytics and Evaluation - *$4.5M*



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Inspection Modernization &Training Budget Request

- Not requesting more inspectors for domestic inspections but will increase "efficiency and effectiveness" of current inspectors through new models/approaches focused on whether firms are implementing systems that effectively prevent food contamination (not on finding evidence of violations and bringing enforcement cases).
  - More specialized inspectors, supported by technical experts, to assess the soundness and performance of a facility's overall food safety system
  - Use data to guide risk-based inspection priority, frequency, depth, and approach.
- FDA will also focus on **ensuring consistency** among inspections conducted by FDA or the states on behalf of FDA.
- **Improving risk-based targeting**, which will require better **data** about facilities, new IT systems to identify and track risk, and **methods for assessing and tracking inspection efficiency and inspector competency**.

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Budget Status

- Budget deal struck last week increases non-defense discretionary spending by $25B in fiscal year 2016.
- “Alliance for a Stronger FDA” considers the budget deal a win for FDA Appropriations
  - "It puts the Appropriations committees back in charge, to sort national priorities and allocate the additional funds to areas of greatest need. **Details about the process have not been released, but we believe that each subcommittee will be given an amended allocation of funds to spend and then would have the chance to make adjustments to their committee-passed bill**. We do not know if this will result in the passage of individual appropriations bills or an omnibus." Grossman also acknowledged that the outlook remains uncertain…” Steven Grossman, Deputy Director for the Alliance.

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Food Safety Plan

- 21 CFR § 117.126 requires that the written food safety plan include:
  - Hazard analysis
  - Preventative controls
  - Supply-chain program (21 CFR § 117.475)
  - Recall plan
  - Procedures for monitoring the implementing preventative controls
  - Corrective action procedures
  - Verification procedures
- *Each* requirement has additional recordkeeping obligations

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Implementation Records required for Food Safety Plan

1. Documentation of the basis for not establishing a preventive control (§ 117.136(a);
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;
4. Records that document verification, including, as applicable:
   (i) Validation;
   (ii) Verification of monitoring;
   (iii) Verification of corrective actions;
   (iv) Calibration of process monitoring and verification instruments;
   (v) Product testing;
   (vi) Environmental monitoring;
   (vii) Records review; and
   (viii) Reanalysis;
5. Records that document the supply chain program; and
6. Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

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Requirements that Apply to Records

- Subpart F, 21 CFR §§ 117.301 – 335
- Records must:
  - Be kept as original records, true copies or electronic records
  - Contain the actual values and observations obtained during monitoring and, if appropriate, during verification activities
  - Be accurate, indelible and legible
  - Be created concurrently with performance of the activity documented
  - Be as detailed as necessary to provide history of work performed

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Requirements that Apply to Records, Cont'd

- Records must include:
  1. Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);
  2. The date and, when appropriate, the time of the activity documented;
  3. The signature or initials of the person performing the activity; and
  4. Where appropriate, the identity of the product and the lot code, if any.

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Record Retention Requirements – 21 CFR §117.135

- All required records must be retained at the plant or facility for at least 2 years after the date they were prepared.
- Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued
  - For example, the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.155(b)).

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Availability of Records

- Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite.
  - Electronic records are considered to be onsite if they are accessible from an onsite location.
- All required records must be made "promptly available" to a duly authorized rep. for official review and copying upon oral or written request.
- Records obtained by FDA are subject to the disclosure requirements of 21 CFR Part 20.

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Electronic Records

- Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in 21 CFR § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter.
  - Modification from proposed rule to reduce burden
  - Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to 21 CFR Part 11.
  - "Electronic record" – "any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."
  - Food Safety Plan – still needs to be signed & dated

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FSMA Expands FDA's Access to Records

- FDA can now reach records in 2 ways
  - If reasonably believe the food is adulterated and presents a serious adverse health consequence or death; or
  - Reasonable probability that the use of, or exposure to, food would cause a serious adverse health consequence or death
- Under either route, FDA has greater access to records
  - Records related to the article of food that FDA has the evidence about;
  - Any other article of food that FDA reasonably believes is likely to be affected in a similar manner
  - Pre-FSMA: reasonable belief that the article is adulterated and presents a threat of serious adverse health consequences or death to humans or animals

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FDA's Inspection Authority

- FDA has the authority to inspect any establishment that manufacturers, processes, packs, or holds food, drugs, devices, tobacco products, or cosmetics for interstate distribution
  - Reasonableness standard (considered a violation of the Act if an inspection that meets the reasonableness threshold is not permitted)

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Managing an FDA Inspection & Enforcement

- Before the inspection begins understand the scope
- After the inspection, understand the inspector's observations (exit interview)
  - Be clear about any issues raised
  - Correct any misunderstandings/errors in FDA's findings
  - Note all observations, comments, commitments made by the parties
- If a Form 483 or Warning Letter is issued, respond in writing and document corrective actions

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Documentation Best Practices

- Manage FSMA's recordkeeping requirements on a continuous basis
- Have a written policy
  - Follow it!
  - Address release of documents, photography, interviews, etc. in advance
- Designate response person and/or team
  - Think about access to records (electronically, off-site, etc.)

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Questions?

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