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MEMORANDUM

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Re: FSMA Update: FDA Issues Compliance Program Guidance Manual for Preventive Controls Inspections

This memorandum summarizes the U.S. Food and Drug Administration (FDA) Compliance Program Guidance Manual (CPGM) for food facilities subject to preventive controls and sanitary human food operation requirements. 1/ As an overview, FDA's "Compliance Programs" provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA) and other laws administered by FDA. This compliance program in particular covers inspections of businesses subject to the Preventive Controls for Human Foods (PCHF) rule that was issued under the FDA Food Safety Modernization Act (FSMA).

The CPGM outlines which facilities should be inspected based on risk, the type of inspection that should occur based on business activities, applicable enforcement activities based on the results of the inspection, and any follow-up required. Issued last fall, the CPGM is significant because it guided PCHF inspections until they were postponed due to the COVID-19 pandemic and will guide inspections going forward once they are resumed. Issuance of the CPGM marks a new phase in PCHF inspections and enforcement.

Background

At this time, all nonexempt businesses are required to be in compliance with the PCHF final rule. 2/ The goal of the regulatory strategy outlined by the CPGM is to obtain high rates of industry compliance with the PCHF rule and gain prompt voluntary correction of deficiencies noted during inspections.

1/ FDA Compliance Program Guidance Manual, Chapter 03: Foodborne Microbiological Hazards, Preventive Controls and Sanitary Human Food Operations, available at https://www.fda.gov/media/131744/download.

2/ Enforcement discretion has been granted for several types of facilities and some provisions in the regulations.

FDA states that objectives of the CPGM are to conduct inspections of human food facilities subject to 21 CFR Part 117 within mandated FSMA frequencies and enforcement follow-up timeframes, ascertain compliance and verify implementation of corrective actions taken during and after an inspection, and document inspectional findings and initiate compliance action for conditions as warranted.

Key issues addressed in the CPGM include the following:

- Inspection priorities;
- Regulator technical assistance network;
- Types of inspections;
- Findings assessments;
- Factors to consider when ranking deviations and considering enforcement actions; and
- Compliance and follow-up activities

We provide additional information on each below.

Key Issues Addressed in the CPGM

- Inspection Priorities: A list of FSMA high risk and non-high risk food facilities that are due for inspection in each cycle will be provided to Divisions prior to the beginning of each Fiscal Year (FY). 3/ This list will identify the likely scope of inspection under the PCHF final rule for each facility (e.g., limited scope or full scope PCHF inspection). Divisions are to prioritize the following types of facilities for full scope PCHF inspections:
    - Facilities that are responsible for a Class I recall since the previous inspection;
    - Facilities where the previous inspection was classified "Official Action Indicated" (OAI);
    - Facilities known to manufacture high-risk foods;
        - High-risk foods include those associated with one or more significant hazards including pathogen growth, pathogen cross-contamination, allergen cross-contact, and undeclared allergen hazards that must be controlled at the inspected facility to ensure food safety. High-risk foods and processes that should be prioritized for inspection coverage include:
            - Ready-to-eat (RTE) foods for which pathogen cross-contamination is a significant hazard because food is exposed to the environment prior to packaging;
            - Foods for which allergen cross-contact is a significant hazard; or
            - Foods that require a process control (such as cooking, refrigeration) where the food may be rendered unsafe if the control is not implemented properly.

3/ The term "high risk" is used in several ways in FSMA. FDA has defined high risk for purposes of inspection frequency and has released a draft proposed approach to define "high risk foods" for purposes of new traceability requirements. *See* HL Memo, FDA Explains "High-Risk" Criteria Under FSMA for Domestic Facility Inspections (Mar. 14, 2012); HL Memo, FDA Requests Comment on IFT Product Traceability Report Under FSMA (Mar. 14, 2013). The proposed rule on traceability requirements for high risk foods is expected this fall. *See* HL Memo, Settlement Reached in Lawsuit Seeking to Compel FDA to Implement FSMA Traceability Requirements (June 12, 2019).

- Facilities implicated in an event that may impact public health.

- Regulator Technical Assistance Network (TAN): The Regulator TAN (rTAN) is a resource primarily for FDA and state field inspection staff to request information assistance during inspections. The rTAN is an information assistance system designed to connect field inspection staff with subject matter experts (SMEs) to get answers and clarification on FSMA rule interpretation and commodity specific questions as needed. FDA field inspection staff may contact the designated SMEs from the rTAN either via e-mail or request that they operate in a reasonable "on call" capacity during an inspection window.

- Types of Inspections:

  - **Food cGMP Inspections**. Food cGMP inspections should be performed at facilities subject to 21 CFR Part 117 Subparts A [general provisions], B [cGMP requirements], and F [records requirements]. Most often, food cGMP inspections will be components of inspections with broader scopes, such as modified requirements inspections, full or limited scope PCHF inspections, or seafood HACCP inspections. However, food cGMP inspections may be standalone if other subparts of 21 CFR Part 117 do not apply and the food is not covered by an interacting program.

  - **Limited Scope PCHF Inspections**. Limited scope PCHF inspections may be performed at facilities subject to 21 CFR Part 117 Subparts C [hazard analysis and preventive controls] and Subpart G [supply chain program]. Importantly, the CPGM states that field inspection staff should not conduct their own hazard analysis or review written food safety plans including the firm's hazard analysis, written preventive control programs, or recall plan as part of their broad assessment. Rather, inspection personnel should conduct broad assessments of sanitation controls, 4/ allergen controls, 5/ and process controls. 6/

  - **Full Scope PCHF Inspections**. Full scope PCHF inspections should be performed at prioritized facilities according to the priorities listed above. These inspections include coverage of 21 CFR Part 117 Subpart C [hazard analysis and preventive controls] and Subpart G [supply chain program].

- Findings and Follow-Up Activities. The CPGM states that while agency tools exist for determining the regulatory significance of citations, the public health significance of observations noted in inspections and appropriate follow up activities must be determined on a case-by-case basis and should not replace the best judgement of the Division. There are three different types of observations:

4/ Including inspection of equipment cleaning and sanitizing, and the environmental monitoring program.

5/ Including inspection of the firm's cross-contact controls, employee practices, equipment cleaning between products with different allergen profiles, dedicated equipment and/or employees for allergen and non-allergen containing products, physical separation of allergenic ingredients, process scheduling, and the controls for labeling products containing allergens.

6/ Including any process controls that the firm has implemented to control significant hazards, e.g., cooking, formulation (e.g., pH, water activity), cooling, and refrigeration.

- **Critical Observations**. Observations that are categorized as "critical" are the most serious deviations from the PCHF rule. Specifically, critical observations indicate that a firm has a breakdown of a preventive control(s) that could result in a reasonable probability of serious adverse health consequences or death to humans or animals (SAHCODHA). An inspection of a food facility that identifies one or more observations categorized as "critical" will generally be classified as OAI and require immediate action to address violative product.7/

- **Major Observations**. Observations that are categorized as "major" are of significant public health concern. Specifically, "major" observations indicate that a firm has a deficiency that results in unsatisfactory conditions that present a food safety risk and are likely to result in a system breakdown. These major observations are significant and should be included on an FDA 483. An inspection of a food facility that does not identify a critical observation associated with the PCHF rule, but does document one or more observations categorized as "major," may be classified as OAI and issued an advisory action. Classification decisions will be made based on the evidence collected during such inspections.

- **Minor Observations**. Observations that are categorized as "minor" are not of significant public health concern. Specifically, "minor" observations indicate that a firm has a deficiency that results in unsatisfactory conditions that if not addressed may lead to a risk to food safety but is not likely to cause a system breakdown. These minor observations are typically included as discussion points. Firms should be urged to address minor observations during the inspection, where corrections should be verified and documented prior to close out of inspection.

These observations and potential follow-up are summarized in an Appendix to this memorandum.

- Factors to Consider when Ranking Deviations and Considering Enforcement Actions. The CPGM lists the following factors that should be considered when ranking deviations and considering enforcement action(s):

  - **Is the food ready-to-eat?** Insanitary conditions in RTE operations are generally more significant than those observed in operations where food will be further processed with an adequate "kill-step."
  - **Can the deficiency be corrected during the inspection and the correction be maintained in a sustainable manner?** It may be possible to verify and document correction of "minor" deviations; however, this is not likely for significant deviations as those generally require more time and resources to adequately address.
  - **Is the deficiency indicative of an isolated problem or system failure?** An isolated issue (e.g., one missing record) may be "minor," whereas, a repeat problem or pattern of deviations (e.g., numerous missing records or general lack of records) is considered "major."

7/ "Immediate action" may include ceasing production, root cause analyses, and potential recalls. The Division may consider enforcement action if warranted including but not limited to mandatory recall, administrative detention, and suspension of food facility registration.

- **Are controls in place?** A facility that is missing records or a component of their food safety plan may be implementing adequate controls for significant hazards in practice.
- **Is the facility or food associated with a recent outbreak or recall?** If so, deviations may rise to a "critical" ranking depending on the circumstances.
- **Is the finding a first-time observation or repeat over multiple inspections?** Repeat problems may be "major" if they are indicative of a general lack of control and inability to make lasting corrections.
- **Is the facility a qualified facility?** Some facilities (e.g., qualified facilities) will be subject to modified requirements and are exempt from Subparts C and G. Therefore, serious deficiencies indicating noncompliance with their attestation would be cited as "major" deviations from the modified requirements in subpart D.

- Compliance Activities and Follow-Up.

  - **Compliance Activities**. CFSAN has not given Direct Reference Authority for any compliance actions related to violations of 21 CFR Part 117 at this time. "Direct Reference" is a situation where the Center grants authority to issue a Warning Letter, enjoin firms, or seize product without direct Center review and approval. Therefore, a Division on its own cannot issue Warning Letters, enjoin firms, or seize products in response to a violation of the PCHF rule without direct Center review and approval. 8/ Appendix 1 to this memo includes a summary of potential compliance activities associated with ranking and classification outcomes. However, findings in the table in Appendix 1 should be used by Divisions as a starting point, and noncompliance activities should be assessed on a case-by-case basis and should consider the totality of the observations.

  - **Follow-Up**. To verify the implementation of corrective actions, Divisions should conduct follow-up inspections within 6 months of the compliance action being finalized for facilities with inspection classifications of OAI and that were observed to have significant CGMP deficiencies, significant food safety plan deficiencies, and/or that had significant environmental pathogen contamination. If there are critical deficiencies or a risk to public health, then follow-up must be conducted as soon as possible after the close of the inspection and completion of compliance action. Follow-up inspections may include the collection of environmental samples and/or product samples at the Division's discretion.

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We will continue to monitor FDA's implementation of the PCHF rule. Please contact us if you have any questions regarding this or other matters.

8/ The procedures for taking these enforcement actions are detailed in FDA's Regulatory Procedures Manual, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual.

Appendix 1: Compliance Activity Summary

Regulatory Significance	Example Deficiency	Classification	Follow-Up
Critical	• No written food safety plan (FSP), no hazard analysis conducted, or missing or inadequate FSP element; • AND observed lack of control; • AND food associated with illness, RFR, recall, or poses a SAHCODHA risk.	**OAI**	**Issue 483** **<u>Domestic</u>** Urge immediate voluntary shutdown and submission of corrective action plan, urge voluntary recall if warranted. Consider: Registration Suspension, Mandatory Recall, Administrative Detention, Injunction (Preliminary or Permanent), Seizure, Regulatory Meeting, Prosecution **<u>Foreign</u>** Urge immediate voluntary shutdown and submission of corrective action plan. Consider: Import Alert, modifying PREDICT score, following up with FSVP and VQIP importers, contacting foreign government authorities to recommend follow up as appropriate.
Major	• No written FSP • No hazard analysis conducted • No written procedures to ensure raw materials and other ingredients received only from approved suppliers (when suppliers control a hazard) • No environmental monitoring to verify sanitation to control an environmental pathogen hazard • Lack of allergen preventive control when necessary • Inadequate critical limits for a process preventive	**OAI**	**Issue 483** **<u>Domestic</u>** Consider: Warning Letter, Administrative Detention, Injunction (Permanent), Seizure, Prosecution, regulatory meeting **<u>Foreign</u>** Consider: Warning Letter, Detention/ Refusal, Import Alert, Modifying PREDICT score, following up with FSVP and VQIP importers
		VAI if public health significant is	**Issue 483** Consider Warning Letter if

Regulatory Significance	Example Deficiency	Classification	Follow-Up
	control • Egregious GMP conditions (pest infestation) • Lack of control for pathogen contamination or allergen	remote	there are uncorrected, repeat items that may lead to food safety risk
Minor	• Inadequate records related to training requirements • Food safety plan not prepared or overseen by a PCQI but controls appear adequate • Recall plan missing required elements • Inadequate GMP conditions related to quality or filth (not food safety)	NAI	Generally, minor observations are not significant to public health. Firms should be urged to correct observations during the inspection. Corrections should be verified and documented. Do not print on 483.
		VAI	**Issue 483** Consider Warning Letter if there are uncorrected, repeat items that may lead to food safety risk