DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

August 17, 2015

Catherine E. Heigel
Director
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Director Heigel:

Enclosed please find the Food and Drug Administration (FDA) report of the *Manufactured Food Regulatory Program Standards* (MFRPS) audit conducted with the South Carolina Department of Health and Environmental Control (SCDHEC), Bureau of Environmental Health Services, in South Carolina on April 14-15, 2015. As you know, this 60 month audit was conducted to determine the current status of implementation and conformance with the 2013 MFRPS by the SCDHEC, Bureau of Environmental Health Services and covered Standards 1 through 10.

The audit results indicate that the SCDHEC, Bureau of Environmental Health Services, is moving forward toward full implementation and conformance with each of the standards. FDA's ORA, Office of Partnerships', Standards and Implementation Staff will be receiving a copy of the final report and can assist with any corrections that need to be made as a result of the audit.

If you have any questions regarding the audit findings please contact Ellen Buchanan at ellen.buchanan@fda.hhs.gov.

I would like to express my sincere gratitude for the hospitality extended to our audit team during their visit with the SCDHEC.

Sincerely,

[redacted]

Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs

**South Carolina Department of Health and Environmental Control**
Bureau of Environmental Health Services
Division of Food Protection and Rabies Prevention
*60 Month Program Audit*
*April 14 - 15, 2015*

*Background*
The food safety regulatory system in the United States is a tiered system that involves Federal, State, and local governments. The Food Drug Administration (FDA) is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure that safe food is produced, processed, or sold within their jurisdictions. Many State agencies also conduct food plant inspections under contract with the FDA. These inspections are performed under the States' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both. To maximize the use of resources among the FDA and the States, particularly when their jurisdictions overlap, their inspection programs should be equivalent in effect. South Carolina Department of Health and Environmental Control (SCDHEC), Bureau of Environmental Health Services received $108,213 this year in the form of a grant award to implement and conform to the *Manufactured Food Regulatory Program Standards (MFRPS).*

The program standards are the essential elements for designing, measuring, and improving the manufactured food regulatory programs in states that conduct food plant inspections under contract with FDA. Each of the ten standards has corresponding self-assessment worksheets, and several standards have supplemental worksheets and forms to assist state program managers in determining their level of conformance with the criteria in each standard.

*Summary of Audit*
This program audit was conducted to assess the implementation of and conformance with the MFRPS in the SCDHEC, Bureau of Environmental Health Services. This program audit was conducted by the FDA, Office of Regulatory Affairs, Audit Staff on April 14 - 16, 2015, in Columbia, SC. This 60 month audit was conducted using the 2013 MFRPS, Office of Management and Budget (OMB) Control No. 0910-0601. The audit results indicate that the SCDHEC, Bureau of Environmental Health Services is working towards full implementation and conformance with each of the MFRPS.

Prior to the audit, management under the SCDHEC, Bureau of Environmental Health Services provided FDA with their self-assessment, improvement plan, and supporting documentation for Standards 1 – 10. The FDA Audit Staff evaluated the information obtained prior to and during the audit for Standards 1 - 10 and provided feedback to the

SCDHEC, Bureau of Environmental Health Services during the audit. During the closeout meeting, the Audit Staff provided the SCDHEC, Bureau of Environmental Health Services with their assessment observations. Below is a summary of the SCDHEC, Bureau of Environmental Health Services self-assessment conclusions on their implementation of the program standards and FDA's audit conclusions on implementation and 60 month conformance of each of the program standards.

| *Summary of South Carolina Department of Health and Environmental Control Self-Assessment and FDA Audit Conclusions* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Standard | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| *South Carolina* | | | | | | | | | | |
| Complete | X | X | X | X | X | X | X | X | X | X |
| Implemented | P | P | P | F | F | P | F | F | F | P |
| *FDA* | | | | | | | | | | |
| Complete | X | X | X | X | X | X | X | X | X | X |
| Implemented | F | F | F | F | F | P | F | F | F | P |
| Conformance | Yes | No | No | No | No | No | Yes | Yes | Yes | No |

Note: F=full implementation of standard P=partial implementation of standard

*Objectives, Scope and Methodology*
The MFRPS establish uniform standards for the design and management of state programs responsible for the regulation of manufactured food plants. The Audit Staff's objectives were to:

1. Validate the conclusions of SCDHEC, Bureau of Environmental Health Services self-assessment, focusing on the evaluation of elements of the state's implementation of the program standards. This included evaluation of their self-assessment on implementation of the MFRPS.
2. Determine SCDHEC, Bureau of Environmental Health Services progress in working towards the complete implementation of the 2013 MFRPS.

The Audit Staff evaluated the self-assessment, improvement plans, worksheets, appendices and the documents required under Section (x).5 of each standard. These documents were evaluated for content and cross-referenced to ensure validity. Additional records were requested to assist with independently evaluating the State's self-assessment.

- The Audit Staff interviewed:
  - Officials from the SCDHEC, Bureau of Environmental Health Services who had knowledge and responsibility for their specific program areas as they pertain to the State's implementation of the MFRPS; and,
  - Officials from the laboratory.

- The Audit Staff analyzed and evaluated:
  - South Carolina State's statutes, regulations and attorney reviews;
  - training records and certifications;
  - inspection and sample collection reports;
  - audit and summary reports;
  - standard operating procedures and protocols (inspectional, enforcement, emergency response);
  - equipment records including calibration documentation; and,
  - analytical worksheets and corresponding records.

*Observations*
This section summarizes the Audit Staff's assessment of each standard. Please note that the identified referenced sections in parentheses correspond to standard elements and appendixes of the 2013 MFRPS.

*Standard 1: Regulatory Foundation* requires that the State has laws comparable to the FD&C Act and regulations comparable to specific sections of Title 21 Code of Federal Regulations. The State program should have the legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take enforcement actions. The Audit Staff conducted an administrative review – not a legal evaluation - of State laws, rules, and administrative guidelines.

- *This standard was found to be fully implemented and in conformance.*

*Standard 2: Training Program* requires the State to have a training plan that ensures all inspectors receive training required to adequately perform their work assignments. This plan should provide for basic and advanced food inspection training as well as continued training for professional development and updating in the field of food manufacturing.

- *The state program does not have a training plan that ensures all inspectors receive basic food inspection training. (2.3 a) - Corrected*

  - *State Response: The Inspector Training Plan has been updated to include all SC DHEC and FDA required basic food inspection training, including food defense awareness and sampling technique and preparation. This document was approved and signed by the Director of the Division of Food Protection and Rabies Prevention.*

- *The state program does not document the participation in a minimum of ten joint or audit inspections and receive a minimum of two acceptable evaluations with a qualified trainer for basic field training. (2.3 a field training ) - Corrected*

- *State Response: The 24-month basic coursework training period and 18-month basic fieldwork training period have been defined in the Inspector Training Plan. Additionally, the required participation in ten (10) audit/joint inspections with a minimum of two (2) acceptable evaluations with a qualified trainer are documented in Appendix 2.2 for the inspector (James Hiott), who was hired after DHEC's enrollment in the MFRPS in 2008. Inspectors hired prior to DHEC's enrollment in the MFRPS signed a fieldwork training affidavit confirming that they are qualified to perform inspections based on experience (Rushton Training Affidavit, Saul Training Affidavit and Williamson Training Affidavit). The MFRPS Coordinator determined the fieldwork training completion date for each of these inspectors and documented this information in Rushton Completion Date, Saul Completion Date and Williamson Completion Date, as well as Appendix 2.2.*

- *The state program does not ensure that each inspector meets the continuing education requirements of 36 contact hours of classroom training and two joint inspections every 36 months. (2.3 b) - Corrected*

  - *State Response: The 36-month intervals for inspectors to receive 36 contact hours of continuing education and two joint inspections has been established and documented in the Inspector Training Plan and Appendix 2.2 for all inspectors.*

- *The state program does not include a definition of "qualified trainer" within their training plan. (2.3 c) - Corrected*

  - *State Response: The Inspector Training Plan was updated to include criteria and a definition for eligible Qualified Trainers as provided by the Program Manager.*

*Standard 3: Inspection Program* requires that the State program incorporate an on-site inspection system that includes (1) an established recall system, (2) a system to respond appropriately to consumer complaints, (3) a system to resolve industry complaints, and (4) a recordkeeping system for all elements of the inspection program.

- *The state program does not have a risk-based inspection program that:*
  - *categorizes the food plant inventory by degree of risk associated with the likelihood that a food safety or defense incident will occur (3.3 a) - Corrected*
  - *prioritizes inspections, assigns frequencies, and allocates resources based on risk categories assigned to a food plant, product, or the manufacturing processes (3.3 a) - Corrected*

- *State Response: The Risk-Based Inspectional Frequency has been updated to include risk classification criteria for firms based on type of processing, type of foods, volume of product manufactured/distributed, target population and compliance history. The Risk-Based Inspectional Frequency has been updated to indicate that inspectional frequencies, inspectional priorities and resource allocation for each type of firm will be based on risk categories.*

- *The state program does not have written policies and procedures for inspecting food plants that address selection of appropriate product for inspection. (3.3 b.4) - Corrected*

  - *State Response: The Inspection SOP now includes criteria and directions on selecting which product should be inspected.*

- *The state inspection program recall procedure does not include:*
  - *promptly remove recalled product from the market (3.3 c2) - Corrected*
  - *conducting recall audit checks (3.3 c3) - Corrected*
  - *identifying and maintaining records about essential recall information (3.3 c4) - Corrected*

  - *State Response: DHEC has recently developed a fully documented recall system based on FDA guidance. The Recall Protocol has been updated to include instructions on removing recalled products from the market, performing recall audit checks and maintaining recall records.*

*Standard 4: Inspection Audit Program* requires that the State program implement a quality assurance program (QAP) aimed at overseeing its inspection and sample collection processes. This includes on-site reviews of its field inspections and desk audits of inspection and sample collection reports.

- *The state program does not have a quality assurance program that contains all the required elements in standard 4. (4.3)*
  - *The quality assurance program does not address the timeframes and frequencies required for Field Inspection Audits. (4.3a) - Corrected*
  - *The quality assurance program does not have a documented process for evaluating ratings for a single performance factor. (4.3) - Corrected*

  - *State Response: The Inspection Audit Program (IAP; also known as the Quality Assurance Program or QAP) has been updated to include audit timeframes and minimum frequency requirements. The Inspection Audit Program (IAP) has been updated to include the evaluation of single performance factors. Evaluations of an*

*overall performance factor and single performance factors can be seen in Appendix 4.2 – 4.4 for each inspector. The Inspection Audit Program was updated to include criteria and definition of a Qualified Auditor as provided by the Program Manager, who is a FDA Certified Auditor. For all inspectors, Appendix 4.8 – Corrective Action Plans has been updated to include an additional column in which the date of the next audit is documented. This audit date is the date that the success of the corrective action is verified.*

*Standard 5: Food-Related Illness and Outbreaks and Food Defense Preparedness and Response* requires the State program to have a system and procedures in place for investigating food-related illnesses and outbreaks that include coordinating roles and responsibilities with other authorities and notifying the public. If the responsibility for food-related illness and outbreak investigations is assigned to another agency, a memorandum of understanding (MOU) with this agency is needed to fulfill the requirements of this standard.

- *The state program does not have a written procedure to update the list of relevant agencies and emergency contacts. (5.3 c) - Corrected*
    - *State Response: The Written Description of Epi Support has been updated to include a SOP for updating the ERT Master Contacts list, which is a contact list obtained from DHEC's Emergency Response Team.*
- *The state program's written procedure to establish criteria for releasing information to the public (including identifying a media person and developing guidelines for coordinating media events with other jurisdictions) is in draft form. ( 5.3 i) - Corrected*
    - *State Response: A finalized Communications Plan was obtained from the Division of Media Relations.*

      *Additional Changes/ Notes: The Written Description of Epi Support has been updated to include a SOP for intentional contamination events (in additional to what is stated in the ICS Policy). The Written Description of Epi Support has been updated to include a SOP for outbreaks related to foodborne illnesses (in addition to what is stated in the Enteric Outbreak Policy).*

*Standard 6: Compliance and Enforcement Program* requires the State to have a compliance and enforcement program that contains enforcement strategies; tracks critical and chronic violations and violators; uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed; establishes a timeline for

progressive actions; and has a system to communicate verbal and written guidance to staff.

- *The state program does not have a compliance and enforcement program that:*
  - *contains written enforcement strategies (6.3 1)*
  - *tracks critical and chronic violations (6.3 2)*
  - *uses a risk based system to determine when a directed investigation, follow-up, or re-inspection is needed (6.3 3)*
  - *establishes timelines for progressive actions (6.3 4)*

  - *State Response:*
    *1) The state program does not have a compliance and enforcement program that contains written enforcement strategies (6.3 1).*

    □ *Personnel Responsible: MFRPS Coordinator, Program Manager & Enforcement Auxiliary Staff*
    □ *Expected Implementation: 12/31/2015*
    □ *Corrective Action: The compliance and enforcement SOP will be evaluated, updated, documented and implemented.*

    *2) The state program does not have a compliance and enforcement program that tracks critical and chronic violations (6.3 2).*
    □ *Personnel Responsible: MFRPS Coordinator, Program Manager & Enforcement Auxiliary Staff*
    □ *Expected Implementation: 12/31/2015*
    □ *Corrective Action: Within the new compliance and enforcement program, critical and chronic violations and violators will be tracked and documented.*

    *3) The state program does not have a compliance and enforcement program that uses a risk-based system to determine when a directed investigation, follow-up or re-inspection is needed (6.3 3).*
    □ *Personnel Responsible: MFRPS Coordinator, Program Manager & Enforcement Auxiliary Staff*
    □ *Expected Implementation: 12/31/2015*
    □ *Corrective Action: The new compliance and enforcement program will have risk-based criteria developed and documented, and facilities will be evaluated based on new risk criteria.*

    *4) The state program does not have a compliance and enforcement program that establishes timelines for progressive actions (6.3 4).*
    □ *Personnel Responsible: MFRPS Coordinator, Program Manager & Enforcement Auxiliary Staff*

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□ *Expected Implementation: 12/31/2015*
□ *Corrective Action: A timeline and sequence of events for enforcement and compliance actions will be evaluated, developed and documented.*

- *The state program does not conduct an annual performance review of enforcement actions, record the results on appendix 6.2 or use results to identify improvements, modify procedures or develop strategies. (6.3)*

  - *State Response:* □ *Personnel Responsible: MFRPS Coordinator, Program Manager & Enforcement Auxiliary Staff*
    □ *Expected Implementation: 12/31/2016*
    □ *Corrective Action: Once the other gaps in Standard 6 have been addressed, Appendix 6.2 will be completed and the results will be used to enhance the procedures.*

*Standard No. 7: Industry and Community Relations* requires the State's outreach efforts to be effective and suitable for providing information about food safety and defense issues to regulators, industry, academia, and consumer representatives.

- *This standard was found to be fully implemented and in full conformance.*

*Standard 8: Program Resources* standard is aimed at assessing the adequacy of the resources (including staff, equipment, and funding) needed to support the State's manufactured food regulatory program. The process and calculations used to determine the number of inspectors, an inventory/list of assigned and available inspection equipment, and records identifying the number and function of administrative support staff should be documented.

- *This standard was found to be fully implemented and in full conformance.*

*Standard 9: Program Assessment* requires State managers to conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards.

The results of the self-assessments are used to determine areas or functions of the State program that need improvement. The results of the initial self-assessment are used to develop an improvement plan that moves the State program toward conformance with each of the program standards and establishes timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.

- *This standard was found to be fully implemented and in full conformance.*

*Standard 10: Laboratory Support* requires the State to have laboratory services capable of analyzing a variety of samples, including but not limited to food, environmental, and clinical samples. The State program should maintain a record of services for routine and non-routine analyses such as biological hazard determinations. The laboratories used by the State program should be accredited or certified. They should have a quality assurance program in place that includes calibration, verification, and maintenance of equipment; documentation of analytical results, control and maintenance of documents; sample accountability; sample integrity and chain of custody; specified qualifications and training for analysts; and audit procedures such as scheduled performance reviews of staff and instrument checks.

- *The state program does not utilize laboratories that have quality assurance programs that incorporate all management and technical requirements found in ISO/IEC 17025:2005. (10.3 e)*

    - *State Response: The state program does not utilize laboratories that have quality assurance programs that incorporate all management and technical requirements found in ISO/IEC 17025:2005 (10.3 e).*
        - *Personnel Responsible: MFRPS Coordinator & Lab Personnel*
        - *Expected Date of Implementation: 12/31/2015*
        - *Corrective Action: The FML Lab will receive ISO 17025:2005 certification and it will be determined if the ARESD Lab is significantly ISO-like by meeting EPA requirements.*