FDA Program Alignment
Human and Animal Food Program
Fiscal Year 2016 Action Plan

I. General Information: Program Alignment Office of Global Operations (GO)/ Office of Regulatory Affairs (ORA), GO/ Office of International Programs (OIP) and Office of Foods and Veterinary Medicine (OFVM)/ Center for Food Safety and Applied Nutrition (CFSAN) and OFVM/ Center for Veterinary Medicine (CVM) Negotiated Action Plan

The Human and Animal Food Program (HAFP) Action Plan (hereafter the HAFP Action Plan or HAFP Plan) is the agreed-upon framework for shared strategic, policy and operational changes that will occur as part of the Program Alignment multi-year change management initiative to be carried out under the auspices of the Food and Veterinary Medicine (FVM) Governance Board (GB). The FVM GB is the cross-organizational joint governance body created by the Office of Global Regulatory Operations and Policy (GO) and the Office of Foods and Veterinary Medicine (OFVM) to ensure the proper coordination and vertical integration of the inspection, compliance, enforcement and other field-based activities of the FVM Program carried out by ORA, OIP, CFSAN, and CVM. The FVM GB is the highest decision-making body of the Program, with direct accountability to the Commissioner and a focus on significant strategic priority setting and resource allocation decision- making. [Its authority is described in the FVM Governance Charter.] The FVM GB is ultimately responsible for this Action Plan. In concert with the FVM GB and the FVM Executive Council (EC), the ORA, OIP, CFSAN and CVM management teams will implement the Action Plan and the senior leadership of each of the organizations will be accountable for the Action Plan's success. In the course of carrying out the Action Plan presented below, deliverables and recommendations that include significant change and/or require significant redirection or investment of resources will be vetted and decided through the FVM GB.

The fiscal year 2016 (FY2016) Plan carries on work begun by ORA, CFSAN, CVM and OIP under the FY2015 action plan. The Action Plan identifies specific deliverables under select Program Alignment initiative target areas as identified by the Commissioner and senior FDA leaders to be accomplished during that fiscal year. ORA, CFSAN, CVM and OIP managers responsible for FDA's HAFP will be assigned responsibility for specific deliverables and subsequent implementation activities.

II. Objectives of the FY2016 Human and Animal Food (formerly Food and Feed) Program Action Plan

The objectives and deliverables in the FY2016 HAFP Plan align with and promote FDA's Food Safety Modernization Act (FSMA) program implementation efforts and the guiding principles in the May 2014 *Operational Strategy for Implementing FSMA*[1]

[1] http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm

document. Our ability to establish and complete the FY2016 HAFP Plan as outlined is based on receiving the full funding requested in the President's budget.

The FY2016 HAFP Plan is intended to:

1. Address one or more of the target areas identified in the Commissioner's February 2014 memo[2], including transitioning to a specialized vertically-integrated HAFP with cross-organizational decision-making and transparency in resource planning and allocation.
2. Align with and support current FSMA implementation efforts and other HAFP priorities.
3. Ensure that clear, current, outcome-based and effectively communicated compliance policies and enforcement strategies are available, with CFSAN/ CVM taking the lead for establishing the compliance policy, compliance programs, and enforcement strategies, with ORA and OIP collaboration and support; and with ORA taking the lead for execution of the strategies and policies, with CFSAN, CVM, and OIP collaboration and support.
4. Serve as the foundation for the communication on the HAFP Plan.

III. Guiding Principles for FY2016 HAFP Plan Development

- FSMA implementation activities will be in full swing and consume the time of many HAFP leaders and managers in FY2016. As a result, the FY2016 HAFP Plan was developed with the goal of accomplishing a limited number of high priority deliverables focused on making major strides toward accomplishing the vision of Program Alignment (PA).
- The FY2016 HAFP Plan is not multi-year. It is a one-year Action Plan, since the HAFP will be implementing multi-year FSMA implementation plans concurrent with meeting obligations under PA. This decision will be revisited in FY2017.
- OFVM, GO and the FVM GB will continue work on establishing a vertically-integrated HAFP, to include specialization, resource allocation and performance metrics. See addendum to the HAFP Plan.
- The FY2016 HAFP Plan goals and deliverables will be in plain language and more descriptive than those in the FY2015 Action Plan, with expectations, deliverables, and the clearance level explicitly defined.
- As the HAFP Plan deliverables are defined and workgroups are established to complete the deliverables, the Centers and Offices will ensure that any intersection with current and anticipated projects/workgroups are identified and limited or

[2] http://www.fda.gov/AboutFDA/CentersOffices/ucm392738.htm

expectations for coordination are clearly described. When new HAFP projects/workgroups are initiated under the HAFP Plan, deliverables will be reviewed for overlap with existing projects/workgroups. If there is overlap, the situation will be rectified to avoid duplication of effort.

- To assist with enhancing resource allocation, workplanning and hiring strategies, innovative approaches such as geographic mapping will be used. Specifically, as resources allow, ORA, OFVM, CFSAN, CVM and OIP will expand geographic mapping modeling for the HAFP to include expanding inventory and high risk maps, developing and implementing a schedule for regular updates to these maps, and exploring options for automation of maps and related tools. ORA, CFSAN, CVM and OIP will continue to dedicate project managers to the PA initiative to assure the annual HAFP Plan is accomplished.

A. Transition to Commodity-Based and Vertically Integrated Regulatory Program

1. ORA will refine and implement the overarching transition plan covering the transition from geographic management to program-based management developed in FY2015 and provide regular progress updates.

2. ORA, CFSAN and OIP will form a cross-organizational workgroup and develop a plan to implement the produce safety network or specialized produce safety cadre.

3. ORA, CFSAN, CVM, and OIP will jointly identify recruitment and retention incentives for a specialized HAFP workforce.

B. Training

1. ORA, CFSAN, CVM, and OIP will establish a Human and Animal Food Curriculum Committee and develop a charter to address FDA and State training needs for the HAFP.

C. HAFP Work Planning

Risk-Based Resource Allocation for Field Operations and the Work Plan

1. ORA, CFSAN, CVM and OIP will continue work to improve the Official Establishment Inventory (OEI) upon which the work plan and resources are based. Specifically, in FY16:
    a. ORA, CFSAN, CVM and OIP will develop a training plan and deliver training to appropriate FDA staff and contractors on OEI maintenance;
    b. ORA will implement the revised FMD-130 to ensure consistency in OEI maintenance;

c. ORA will develop metrics to assess the implementation of the revised FMD-130; and,
d. ORA and CFSAN will develop and implement a plan to reduce the backlog of Bioterrorism Act-registered firms, or B-firms, in FY2016.

2. ORA, OFVM, CFSAN, CVM and OIP, will begin to design a risk-based resource allocation model(s) for field operation that incorporates Center risk analysis and prioritization activities, and culminates in a multi-year work plan for the HAFP. The model(s) will align with strategic priorities and consider future priorities and activities to allow for the adjustment of field resources to meet program needs. Specifically, the group will:
    a. Collect and review existing relevant documents and work completed that affects this effort;
    b. Plan and hold a visioning meeting for the future state of risk-based resource allocation and workplanning for field operations with senior program leaders and managers;
    c. Develop a concept paper for a multi-year HAFP work plan that integrates Center risk analysis and prioritization activities based on the outcome of the visioning meeting;
    d. Develop an implementation plan for the multi-year risk-based resource prioritization/workplanning model(s); and,
    e. Begin to transition to the new model(s) in FY2017.

D. Compliance Policy and Enforcement Strategies

1. Using the approaches developed by the FSMA Phase 2 Implementation Workgroups, ORA, OFVM, CFSAN, CVM and OIP will develop compliance implementation plans for the human food facility preventive controls rule (modernized current Good Manufacturing Practices (cGMPs) and hazard analysis and preventive controls) and the animal food facility preventive controls rule (cGMPs only). ORA, OFVM, CFSAN, CVM and OIP will also initiate work on the compliance implementation plans for the hazard analysis and preventive controls for animal food facilities, produce safety rule and the Foreign Supplier Verification Program (FSVP) rules.

2. CFSAN, CVM and ORA will execute the project management plan to address high priority gaps and updates in compliance policy, as developed under FY2015 PA Action Plan deliverable D.4.b.

3. ORA, CFSAN and CVM will implement approved recommendation(s) to expand direct reference warning letter authority to ORA, as outlined by the FY2015 PA Action Plan deliverable D.3. CFSAN will periodically audit a subset of warning letters issued by the districts under direct reference authority to ensure quality and consistency.

4. ORA, CFSAN, CVM and OIP will begin to develop an implementation plan for transitioning No Action Indicated (NAI) and Voluntary Action Indicated (VAI) foreign inspection review and classification to a process similar to the domestic inspection review and classification under new program aligned structure, as outlined in FY2015 PA Action Plan deliverable D.9. CFSAN will perform trending across all foreign inspections conducted on an annual basis to inform decisions on where to target inspections in out years.

5. ORA, OFVM, CFSAN, CVM and OIP will define a standard process and roles and responsibilities for recalls of imported and exported human and animal food.

6. ORA, CFSAN and CVM will implement the procedure developed in FY2015 PA Action Plan deliverable D.5./ E.2. documenting novel and innovative compliance and enforcement strategies concerning HAFP commodities using the Compliance Management System (CMS).

In future years:

- ORA, CFSAN, CVM, OIP and OEO will define a standard process and roles and responsibilities for consumer complaints related to imported human and animal food.
- ORA, CFSAN and CVM will address timeframes and business processes for administrative actions, judicial actions, and recalls.
- ORA, CFSAN, CVM, OIP and OCC will explore the possibilities of re-envisioning communication to firms regarding observations at the close of inspections.

E. Import Operations

1. ORA, CFSAN, CVM and OIP will develop recommendations to reduce duplication of efforts and streamline decision-making for human and animal food Import Alerts (IAs). This includes the development of new IAs and major and minor revisions to IAs, building on the business processes outlined in FY2015 action plan deliverable E.1. Once recommendations are approved, a plan for changes to the business processes for IAs will be developed and implemented.

2. ORA, OFVM, CFSAN, CVM and OIP will begin to implement the plan to retool human and animal food IAs (from FY2015 PA Action Plan deliverable E.3) to better align with a preventive controls paradigm (i.e., ensure that approaches for removal of firms/products from IA promote root cause analyses and corrective actions that prevent recurrence of similar adulteration/misbranding issues).

3. ORA, CFSAN, CVM and OIP will share sources of foreign intelligence and develop recommendations for using this information to better inform and improve decision-making (e.g., foreign inspections, Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) scores). In future years, ORA, CFSAN,

CVM and OIP will develop and implement a plan to facilitate collection and use of the data.

4. CVM, with participation from ORA, CFSAN and OIP, will develop and implement a systematic, review process to update product codes to improve system usability and application for animal food products. As the inherent risk process allows, the updated product codes will include the inherent risk that has been identified, and include an update to the CVM inherent risk matrix. (Until the inherent risk can be identified, risk will be determined through a case by case center review based on the intended use of the imported product.)

In future years, ORA, CFSAN, CVM, and when appropriate, OIP will:

- Identify opportunities for expansion to ORA of direct reference authority for import refusals and minor revisions. ORA, CFSAN and CVM will periodically audit use of such direct reference authorities to ensure consistency and quality.
- Review the current structure/staff involved in governance of the PREDICT and the decision-making processes for food and feed entries; provide recommendations for any necessary changes to the governance structure and resources/staff dedicated to PREDICT; evaluate PREDICT business rules for alignment with the workplan, sampling models, and priorities, and FSMA import programs; and, where there is not alignment, develop a strategy to address and establish a procedure for regular review and update of the business rules.
- Review and update the inherent risks in PREDICT associated with conventional foods and provide the information to ORA to ensure that business rules reflect the most current information available.

F. Laboratories

1. ORA, OFVM, CFSAN and CVM will implement the process to set strategic direction for HAFP analytical resources as developed under the FY2015 PA Action Plan deliverable F.2.

2. ORA, CFSAN, and CVM science leadership will jointly develop an electronic methods portal: an open, publicly-accessible internet resource that consolidates all analytical laboratory methods used to support the Agency's regulatory food safety mission.

G. IT

All workgroup leads are responsible for identifying and reporting potential IT modifications associated with recommendations for business processes improvements or changes. HAFP Plan project managers from each Office/Center will catalog this information as it is received and then send the data to the OFVM Information Technology Investment Review Board.

1. OIP will conduct an assessment of access to FDA systems by those in foreign offices that conduct inspections to ensure OIP generated inspection data is available to ORA and the Centers. OIP will share the findings of the assessment and establish a plan, if needed, to rectify any gaps in access to necessary IT systems.