FDA Program Alignment
Pharmaceuticals Action Plan
FY2015

The following Pharmaceuticals FY2015 Action Plan (the Action Plan), developed by the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), and the Center for Veterinary Medicine (CVM), is intended to facilitate operational and program alignment as FDA transitions to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, and well-designed and coordinated implementation. Core elements of Action Plans may include increased specialization, de-layered management structures and processes involving ORA and the Centers, jointly developing training programs, new work planning models, strategic enforcement approaches with aligned and updated compliance programs and policy, strategic import approaches, laboratory optimization, and coordination of internal and external communication on the Action Plan to ensure that FDA speaks with one voice on the policies and operations related to the pharmaceuticals program.

This Action Plan is the agreed framework of mutually-shared strategic, policy and operational commitments that will occur during the first year of a multi-year change management initiative. As part of this initiative, CDER, CVM and ORA agree to establish a multi-year plan to achieve fulfillment of the vision of the program, which will be reviewed periodically by all parties and revised, as necessary. These plans will work in concert with implementation plans. This Action Plan and associated implementation plans will be reviewed quarterly by the Center Directors and ACRA to assess progress and to make any necessary adjustments to the broader multi-year plan.

Senior managers in CDER, CVM and ORA will be assigned responsibility and held accountable for specified implementation activities. We envision that quality management practices will be built into the processes and development of all action plan implementation areas.

CDER, CVM, and ORA will develop and approve a 5 year Action Plan during **4th quarter FY2015** that will describe in detail the operational changes that will be needed to implement the vision provided in the February 3, 2014 memorandum from the Commissioner. This 5 year Action Plan will have specific performance efficiencies, metric goals and procedures that CDER, CVM and ORA have agreed upon.

A PA pharmaceutical steering committee comprised of senior executives from CDER, CVM, and ORA, will be formed in order to monitor the progress of the 1-year implementation and to resolve implementation issues as they come up. The steering committee will report to the Center Directors and ACRA and be responsible for overseeing specialization needs including: training; resource allocation to support workforce specialization; and, identify/resolve problems. The steering committee charter, membership, and 1st meeting will be completed no later than **October 31st 2014.**

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

1. Organizational Transition

a) ORA will establish the Senior Executive Program Directors and launch recruitment process during **2nd quarter FY2015**. The Senior Executive Program Director for the pharmaceutical program will have oversight over the pharmaceutical program. It is envisioned that ORS will have oversight over ORA field labs. For Senior Executive Program Directors, ORA will work with Centers on selection criteria that reflect Center interests and will include Centers participation in selection process.

b) ORA will develop a plan to transition from a regional oversight structure to a program structure, including transition plans for all regional staff and functions during **3rd quarter FY2015**. The plan will include, but is not limited to:

   i. A high-level concept of operations for the new organization that explains the envisioned structure, capabilities, functions, and goals
   ii. Plan for transitioning operational resources
   iii. Plan for pace and staging of the organization change process with the goal of achieving a dedicated FDA drug workforce capable of supporting both CDER and CVM distinctions.
   iv. A communication plan to explain the new organization, operations, goals, and change process to ORA, CDER, and CVM staff

2. Specialization

   a) ORA will establish the baseline of program specialization of its current operational workforce through a survey during **1st quarter FY2015**. This will include identifying the number of permanent (2+ years) OIP staff doing inspections, ORA lab analysts (microbiologists, chemists, engineers) who are accompanying investigators doing drug inspections, and import staff.

   b) CDER, CVM, and ORA will do an analysis to determine current and future resource levels for import pharmaceutical work and location during **3rd quarter FY2015**.

   c) CDER and CVM will similarly establish a baseline of its staff involved in inspection and compliance activities during **2nd quarter FY2015**.

   d) CDER, CVM, ORA will share the baseline analyses of their respective workforces during **3rd quarter FY2015**.

   e) Based on the baseline of program specialization mentioned above and associated analysis, the total number of people within ORA's dedicated drug workforce will be identified. From this number, CDER, CVM, and ORA will

determine during **4th quarter FY2015** the number of people including field investigators, compliance officers[1], and managers that will be dedicated to the drug program in ORA by the end of FY 2015.

i. ORA will dedicate the number of people determined in A.2.e. and report that progress to Centers by the end of **FY 2015**.

f) Jointly develop and begin implementing a plan during **4th quarter FY2015** to establish a cadre of Agency drug compliance officers that are dedicated to drug work. The plan will include, but is not limited to, establishing the roles and responsibilities for compliance officers and the necessary process changes to support establishment of this cadre. The following are a few guiding principles for this effort:

i. CDER, CVM, and ORA will establish joint compliance officer/investigator training with the goal for compliance officers to have a similar level of technical expertise as the specialized investigators.
ii. CDER, CVM, and ORA compliance officers will be responsible for developing draft regulatory correspondence/actions for foreign and domestic compliance cases while working as a team with ORA field investigations staff.
iii. CDER, CVM, and ORA compliance officers will work on compliance/enforcement actions related to foreign and domestic firms.
iv. The compliance processes established will incorporate best practices for compliance review that currently exists across the Agency.

g) Establish jointly agreed upon drug workforce sub-specializations based on the known facility inventory and the areas required for coverage during **1st quarter FY2015**.

h) Jointly conduct a drug workforce capacity needs assessment utilizing the known facility inventory, inventory location, jointly agreed upon drug workforce sub-specialization, and baseline analyses during **4th quarter FY2015**.

B. Training, Recruitment, Employee Skill and Career Enhancement: ORA and the Centers must jointly invest in employee training for it to be effective.

Employee Skill

[1] See Appendix A for definition of compliance officer

1. ORA will share recently-developed competencies and Job Task Analysis processes for the drug workforce with Centers during **1st quarter FY2015**.

Training

2. Establish leadership and oversight role for FDA's Council for Pharmaceutical Quality (CPQ) in training and professional development by **October 31, 2014.**

3. CDER, CVM, and ORA establish training point of contact and process for communication by **October 31, 2014.**

4. Establish a joint CDER,CVM, and ORA Oversight Committee for Course Curriculum Content during **1st quarter FY2015** to report to CPQ and advise PAG Steering Committee to do the following:
    a) Develop and approve training curricula to meet commodity-specific competency requirements for all dedicated drug workforce roles. The training curricula will aim to satisfy identified needs of the drug workforce and incorporate lessons learned from the New Inspection Protocol Project or other initiatives, where relevant, as well as ongoing efforts to ensure continuous learning.
    b) Establish a process for the development of FDA courses that defines the membership, roles and responsibilities of the Content Advisory Groups (CAGs).
    c) Jointly develop and obtain resourcing for a pharmaceuticals program training plan. The plan will include but not limited to:
        i. the number of trainings and attendee capacity of each training session,
        ii. and will ensure sufficient access to training for CDER, CVM, and ORA based on the subject matter and need.
    d) Develop and deliver a quarterly training report that lists the courses completed during that quarter, composition of the classes by Center, and list of attendees. The report will compare actual attendance in each class to access levels determined in the training plan (see item B.4.c)

Career Enhancement/Retention

5. Brief the PA pharmaceutical steering committee on developing a career ladder for dedicated drug workforce that marries training, certifications, educational level, and experience with GS level during **1st quarter FY2015**. This will factor in associated human resource related activities such as position description development and classification.

6. Jointly identify retention incentives for specialized drug workforce and report to PAG Steering Committee during **3rd quarter FY2015**.

C. Agency Resource Planning:

CDER, CVM and ORAwill establish a program-based resource planning regime. This program will improve FDA's targeting and utilization of compliance-related resources that are based on risk factors, such as: public health outcomes, past inspectional history, and operational experience. These will be reported through performance-based metrics clearly demonstrating public health and compliance outcomes. The program based resource plan will include a multi-year outlook on future priorities and activities that allow ORA and the Centers to adjust their resources to meet future program needs.

1. Program-based resource planning

   a) CDER, CVM, and ORA leadership will formulate a risk-informed process by **4th quarter FY2015** to ensure that resources are allocated to shared strategic priorities and work plan goals. Centers will provide a clear prioritization scheme for all Center pharmaceutical programs, including import and labs.
      i. Establish how CDER, CVM, and ORA will monitor adherence based on metrics and coordinate on a regular basis to ensure the resource plan is accomplished.

   b) CDER, CVM and ORA will improve data quality by doing the following:
      i. Improve accuracy of registration and firm inventory in systems to decrease wash-outs. CDER, CVM, and ORA will develop a plan during **1st quarter FY2015** to do the following:
         - ORA to provide update on which firms (foreign and domestic) on the risk rank lists have been already inspected and which ones are being planned for the rest of the year.
         - ORA will note which firms on the lists wash-out or have data inconsistencies and work with the Center to remove /correct firm data from ORA and Center databases.
         - CDER, CVM, and ORA to conduct retrospective analysis on previous wash-outs from lists and update firm data in ORA and Center databases.

      ii. CDER and CVM to provide business requirements for incorporation, to the extent feasible, in ORA's drug workforce time reporting system during **1st quarter FY2015**.

      iii. ORA to share plan for improving drug workforce time reporting data during **3rd quarter FY2015**.

   c) CDER, CVM, and ORA will expand the use of GIS data to better allow for efficient resource planning during **FY2015**.

d) Jointly develop plan during **2nd quarter FY2015** to transition from the budget driven, geography based annual work plan to multi-year, risk-based resource planning that is based on public health needs, the number of dedicated drug work force staff (include permanent OIP staff doing inspections), and tracked via performance based metrics that clearly demonstrate public health focus and compliance outcomes**.** The transition plan will identify the timeframe for incorporation of the following milestones in the resource planning process:

   i. Resource planning primarily based on the number of actual persons within the dedicated drug work force and operations (inspections, sample collections, etc.), rather than the current ORA and Center work plan process that allocates operational FTEs among various PAC codes.

   ii. Number of planned operations, corresponding assignments issued and operations to be accomplished will be agreed upon and considered a commitment by Centers and ORA. Centers and ORA will mutually develop a process for discussing and resolving modifications from this mutual obligation.

   iii. Number of planned operations is aligned with Center risk model.

   iv. Establish a deadline for CDER to supply ORA with the annual surveillance priority site list (along with accompanying risk-based rationale).

   v. Simplify and streamline the planning process.

   vi. Periodic reporting on the number and type of inspections completed by investigators and analysts, along with the certification level and sub-specialization, as appropriate, of the respective investigator. (as identified in section A.2.g under *Specialization*)

e) ORA to establish a work plan dashboard during **2nd quarter FY2015**

f) CDER and CVM to provide feedback on the dashboard and Centers and ORA reach agreement on any proposed changes during **3rd quarter FY 2015**.

g) ORA to fully stand up work plan dashboard by **October 1, 2015**.

D. Compliance Policy and Enforcement Strategy: Clear, current, outcome-based and effectively communicated compliance policies and enforcement strategies should be established. CDER and CVM have the lead on establishing enforcement strategies, compliance programs and compliance policy, with ORA participation. ORA has the lead in executing the enforcement strategy, collaborating with the Centers. To be

effective, ORA and the Centers will proactively seek out input and feedback from Office of Chief Counsel to inform us on possible risk to FDA's public health policy or legislation.

1. CDER, CVM, and ORA will develop a plan during **3rd quarter 2015** for modernizing commodity/program-specific enforcement standards and strategies based on public health impact to include the following:
    a) Measurement of industry compliance based on consideration of patient/public health impact; and
    b) Develop appropriate communication strategies to enhance internal and external transparency.

2. CDER and CVM will develop a plan during **2nd quarter FY2015** to determine pace and staging of how compliance programs and policy guides will be assessed, frequency of updates, and when they will be rolled-out.

3. The FDA Council on Pharmaceutical Quality (CPQ) will initiate a cross-center workgroup to develop FDA Staff Manual Guides (SMGs) for Compliance Program Guidance Manuals (CPGM) and Compliance Policy Guides (CPG) management (development through publication) during **3rd quarter FY2015**.

4. CDER, CVM, and ORA will develop a plan to establish performance based public health metrics for compliance activities during **FY2015**.

5. CDER, CVM and ORA will collaborate to improve consistency and establish clear guidance about the use of regulatory tools, including advisory and enforcement actions, to increase efficiency, reduce duplication of efforts, and provide clear accountability. The establishment of a specialized Agency drug compliance officer cadre (see A.2.f) will contribute to this effort. Additionally, in **FY2015**, CDER, CVM and ORA will identify a strategy to clarify roles and responsibilities, including lead roles and decision rights, and streamline and delayer the business processes associated with the following compliance activities:
    - Domestic and foreign Warning Letters;
    - Judicial Enforcement Actions;
    - Import Decisions;
    - Compounding;
    - FDASIA, and other administrative compliance tools;
    - Clinical disqualifications; and
    - Recalls;

    The strategy will include, but not be limited to:
    a) mapping the current compliance processes;
    b) evaluating the timeliness of the current processes;

c) conducting an analysis to determine the underlying reasons for OAI classification turndown and re-classifications;
d) incorporating process changes, as necessary, to reflect the establishment of a new specialized Agency drug compliance officer cadre: and,
e) identifying and incorporating best practices for compliance review that currently exists across the Agency.

6. To streamline use of the recall tool, CDER and CVM will initiate the process for delegation of Class 1 recall approval authority (e.g. ACRA sign-off on Class 1 recalls) to Centers for all Class 1 recalls during **1st quarter FY2015.**

7. Starting in **4th quarter FY2015**, CDER and CVM will provide ORA the strategic priorities across the pharmaceuticals program for inspections, analytical and import work in the coming fiscal year and as known for future years.

8. Team based processes and policies

a) In **FY2015**, jointly define and implement a pilot to utilize a team-based and streamlined approach for the development and issuance of high/top priority drug quality assignments (excluding compounding). This pilot will include but is not limited to the following:
   i. A team composed of ORA and Center managers and appropriate ORA and Center SMEs will develop and clear assignments.
   ii. Key metrics (e.g., whether the assignment was fit for use; the timeliness of the assignment development, clearance and issuance; assignment of personnel with the appropriate training and expertise for their role) to evaluate the pilot.
   iii. CDER, CVM, and ORA will make recommendations to the PAG steering committee during **4th quarter FY 2015** to adopt/modify the piloted approach or consider alternative models for FY2016.

b) To transition to the development of a cadre of Agency drug compliance officers, jointly develop a pilot for team-based domestic and foreign drug quality (excluding compounding) inspection and review, focused on OAI cases. The goal of the pilot is to investigate if a team-based approach to domestic and foreign inspections and reviews can enhance communication and increase efficiency (e.g. minimize OAI turndowns, reclassifications, and rework). While the pilot is envisioned to include a limited number of inspections, ORA and Center will jointly determine the exact scale and scope of the pilot. This pilot will include but is not limited to the following:
   i. Pre-inspection briefing with ORA investigator and Center.
   ii. Process for direct and early (preferably during inspection) communication of OAI situation from ORA investigator to ORA and Center compliance officers.

iii. ORA compliance officer drafts recommendation package with input from Center compliance lead. ORA and Center management to provide concurrent review of ORA compliance officer work products as a team. Center compliance lead to be included as needed.
iv. ORA compliance officer and their manager participate in case management review and decision process.
v. The Center will delayer its management review as part of the pilot.
vi. The pilot will include an evaluation with jointly agreed upon evaluation metrics (e.g. reclassification/turndown/rewrite rates, supportable citations, adherence to timeframes). ORA and Centers will make recommendations to the PAG steering committee during **4th quarter FY 2015** to adopt/modify the piloted approach or consider alternative models for FY2016.

c) CDER, CVM, and ORA will develop plan to make all drug EIRs and exhibits available via IT systems **during 2nd quarter FY2015.** This plan will include the following:
   i. Implement Center and ORA policy that will require the collection of inspection exhibits in an electronic format when available.
   ii. Articulation of start date for loading of drug EIRs and exhibits into IT systems.

d) CDER, CVM, and ORA will develop and implement a process and agreed upon timeframes for loading of OAI endorsed foreign drug inspection EIRs and exhibits into IT systems during 3rd quarter FY2015**.**

E. Imports:

1. CDER, CVM, and ORA will assess import program data and establish a strategic plan for imports that incorporates continued collaboration during **2nd quarter FY2015**. Where needed, CDER, CVM, and ORA will clarify how import screening strategies, policies and decision-making will be executed.

2. Share the PREDICT evaluation and adjust the risk scoring, consistent with program import strategic goals during **1st quarter FY2015**.

3. ORA will share the assessment of centralized entry review pilot with CDER and CVM during **1st quarter FY 2015**.

4. CDER, CVM, and ORA will develop a strategy during **1st quarter FY2015** to use positive FDA rapid screening results to meet the appearance standard under 801a without confirmatory testing and thus shift the burden of proof to the importer. The strategy should include collaborative engagement of OCC to address legal considerations surrounding the application and use of positive rapid screening results at the border.

5. Jointly develop a plan to promote informed decision-making by import staff and consistency within the pharmaceutical program across all ports of entry during **3rd quarter FY2015.**

6. Establish and implement a risk-based imports entry review strategy during **1st quarter FY2015**.

F. Laboratory Optimization

1. ORA will brief CDER and CVM on the current lab optimization plan and will discuss the need for further lab specialization during **1st quarter FY2015**.

2. Include CVM in ORA CDER Steering Committee on Strategic Science and Compliance to explore additional areas of lab efficiency and regulatory science competency development. The committee will jointly develop the following:

    a. Develop a plan for future laboratory resources (personnel and equipment) to match Center objectives to ensure firms are in compliance with required market standards for drug quality and able to respond to emerging public health risks during **3rd quarter FY2015**.

    b. Develop and implement a pilot for using laboratory testing to inform OPQ for risk based decision making with results/statistics available with inspection data in CDER IT systems during **2nd quarter FY2015**.
        i. The pilot will test streamlined protocol involving the acquisition of products (i.e. similar to survey samples). Products will be ordered by ORA staff directly from pharmacies or stores, without the need for chain of custody.
        ii. ORA and CDER will jointly assess the resource needs for the pilot as part of agency resource planning in section C if needed.

    c. Implement a pilot during **2nd quarter FY2015** for streamlined issuance of assignments (e.g. for-cause sampling and testing) and projects (e.g. protocol for comparative dissolution testing between two drugs) to ORA major labs and results coming to both ORA and Center.

G. IT: CDER, CVM, and ORA will develop an IT-focused program to enhance information sharing and collaboration to facilitate risk based inspection management. Goals may include evaluation of end-to-end data system analysis to assess how to improve integration of ORA and CDER, CVM information needed by parties to make risk based regulatory decisions. Approaches may include harmonizing data elements, such as the "Unique Facility Identifier" in their respective systems; enhanced collection and use of GIS information, eliminating legacy information

interfaces; and looking at ways to remove IT and security barriers. An objective is to integrate real-time visibility into ORA and CDER, CVM databases including information on inventory, applications, facilities, adverse events, risk information that allows for rapid analytics capability.

1. CDER and ORA will establish a data sharing agreement during **1st quarter FY 2015**.

2. CDER and ORA will establish a plan to identify opportunities to harmonize identifiers and business terminology during **2nd quarter FY 2015**. Includes but not limited to DUNS and FEI; NDC and product codes.

3. CDER and ORA will define modern, two-way integration between the Pharmaceutical Quality Platform (PQP) and ORA workflow systems during **3rd quarter of FY 2015**. CDER and ORA will implement a two-way integration between the PQP and ORA workflow systems during FY2016 contingent on availability of PQP.

4. CDER, CVM and ORA will identify software used by ORA and Center laboratories and develop plan for common software platforms (e.g. Chemometics, LIMS, etc.) during **2nd quarter FY2015**.

APPENDIX A

Definitions

- The term **compliance officers** include Consumer Safety Officers in CVM.
- The term **dedicated drug workforce** includes investigators, compliance officers, lab staff, management, and Center reviewers, when appropriate. ORA has not determined if import staff will be specialized by commodity area at the time of this plan.
- The preposition **during** used to modify dates in this document (e.g., develop and implement a plan during 2nd quarter FY2015), does not preclude implementers from working on commitments before their respective dates.
- The term **jointly** means CDER, CVM, and ORA will work together to produce the commitment deliverable, as applicable.

APPENDIX B (Future Year Commitments)

The PAG Pharmaceuticals team discussed the commitments in this appendix during the development of the FY 2015 Action Plan. The team concluded that these commitments are not FY 2015 activities, but recommends that they be considered during the development of the 5-year Action Plan.

Recruiting

- Jointly develop a recruiting and hiring plan to satisfy identified needs of the drug workforce.
- Implement the recruiting and hiring plan.

Certification requirements

- Develop certification requirements to demonstrate meeting competency requirements for drug workforce.
- Develop Continuing Education requirements to maintain certification requirements by role, such as drug investigator level and sub-specialization.

Agency Resource Planning

- Jointly develop plan to expand international data collection to institute global resource planning that relies on unique facility identifiers, agreed-on risk identification, and all available signal and intelligence information.
- CDER, CVM, and ORA collaborate on foreign work plan.

Compliance

- Begin development of streamlined inspection assignment processes, which incorporate the lessons learned from the team-based inspection pilots and include OIP, and begin phased implementation of new processes.

Imports

- Establish inherent risk-scores for each product code and other risk factors such as country to be included into the PREDICT application.

Information Technology

- Investigate data sharing agreement between CVM and CDER and potential integration of CVM IT systems into CDER Pharmaceutical Quality Platform and workflow system.