FDA Program Alignment
Pharmaceutical Quality
FY2016 Action Plan

I. Introduction

On February 3, 2014, Commissioner Margaret Hamburg issued a memorandum that set a course for moving ORA and the Centers towards more collaborative and efficient operations to enhance the Agency's ability to protect and promote public health into the future. The memorandum set forth recommendations for program alignment to modify functions and processes; clarify roles, responsibilities, and decision rights; and require organizational and procedural changes to enhance communication, collaboration, and commitment of the programs across the agency. To facilitate the Program Alignment (PA) initiative, the Center for Drug Evaluation and Research (CDER), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) jointly developed a comprehensive FY15 Action Plan for the pharmaceuticals (pharma) program which detailed objectives in seven categories to address the Commissioner's recommendations. This collaboration continued throughout FY15 as numerous cross-Agency workgroups have worked diligently under aggressive deadlines to successfully complete the Action Plan deliverables.

The Pharmaceutical Program 5-Year Plan (the 5-Year Plan) developed in FY15 is a high-level multi-year plan to guide the operational changes needed to reach the Commissioner's vision of distinct commodity-based and vertically-integrated regulatory programs. The 5-Year Plan and corresponding Annual Action Plans will build on the FY15 accomplishments of the workgroups and continue the strong model of collaborative incremental progress. Annual Action Plans will include short and mid-term objectives and target dates that will collectively move the organization toward the envisioned future state in a logical and achievable manner, building on the results of previous year's successes. At the end of each year, Annual Action Plans will be evaluated against the 5-Year Plan.

The following FY16 Action Plan (the Action Plan) 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 will include increased specialization, de-layered management decisions 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 pharma program.

Quality management practices will be built into the processes and development of all action plan implementation areas. In FY16, the Pharma Steering Committee formed in FY15 will continue to meet quarterly or as needed to address Program Alignment implementation needs. In the 4th

quarter of FY16, the Pharma Steering Committee will evaluate progress against the 5 year Plan. In addition, the Steering Committee will develop and approve an Action Plan to guide ongoing activities in FY17.

A fast-moving effort is under way to develop a Concept of Operations for how components of the pharma program could work together once aligned. Some commitments included in this plan are on hold, and may change based on the outcome of the Concept of Operations to be finalized (March 2016). These contain TBD for all delivery dates.

NOTE: Commitments included in this document that involve continuation of work initiated in FY15 use the same section designation (letter and number) as in the FY15 Action Plan. As a result, deliverables completed in FY15 are not included, and lists of commitments in some sections appear out of sequence.

II. Pharmaceutical Program FY16 Action Plan

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

Goals:

- Highly trained drug workforce with specialized expertise is aligned with the pharma inventory.
- Staff and resources are managed effectively and are adaptable to future needs.

To reach these goals, the pharma program will continue the following:

- A.1.b – ORA transition strategy.
- A.2.f – Roles/responsibilities of drug compliance officers.
- A.2.h – Drug workforce capacity needs assessment.

Pharma A.1.b. ORA will refine and implement the overarching transition plan covering the transition from geographic management to program-based management developed in FY15 and provide regular progress updates.

- Lead Organization(s)[1]: ORA.
- Due Date: September 30, 2016.

[1] The organization designated in this Action Plan as "lead" for a commitment will be responsible for taking the lead in kicking off the work, organizing and scheduling workgroup meetings, tracking and reporting on workgroup progress, and elevating issues to the Implementation Workgroup as needed. The lead organization will act as a facilitator and ensure that the work is inclusive and accomplished.

- Acceptance Criteria: Implementation of the transition plan (would be evidenced by stand up plans for operations, new programmatic SOPs, alignment of ORA staff, etc.) and updates on the status of transition.
- Deliverable Format: Updates to Pharma Steering Committee.

Pharma A.2.f. Implement the plan to build a cadre of Agency drug compliance officers for the pharma program.

- Lead Organization(s): TBD.
- Due Date: TBD.
- Acceptance Criteria: TBD.
- Deliverable Format: TBD.

Pharma A.2.h. Continue the work begun in the FY15 Drug Workforce Capacity Needs Assessment deliverable. Identify next steps, required analysis and information sources, and what is needed for execution, e.g. key decisions, resources.

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

B. Training, Recruitment, Employee Skill and Career Enhancement

Goals:

- The drug workforce is modern, highly skilled, and qualified to meet needs of the pharma program.
- The pharma training program is collaborative and resourced to meet program needs.
- Resources for recruitment and retention are deployed and effective mechanisms are in place to promote career longevity.

To reach these goals, the pharma program will continue the following:

- B.4 – Pharma Curriculum Committee project plan.
- B.5 – Career ladder.
- B.6 – Retention incentives.

Pharma B.4. Implement the FY16 Pharma Curriculum Committee Project Plan.

- Lead Organization(s): ORA.

- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma B.5. Implement the career ladder for the dedicated drug workforce.

- Lead Organization(s): ORA.
- Due Date: September 30, 2016.
- Acceptance Criteria: Presentation to the Steering Committee.
- Deliverable Format: Presentation.

Pharma B.6. Implement retention incentives for the specialized drug workforce.

- Lead Organization(s): ORA.
- Due Date: September 30, 2016.
- Acceptance Criteria: Presentation to the Steering Committee.
- Deliverable Format: Presentation.

C. Agency Resource Planning

Goals:

- Resource planning is global, risk-informed, and public health focused.
- Strategic priorities drive the work.

To reach these goals, the pharma program will continue the following:

- C.1.a – Risk-informed process to prioritize assignments.
- C.1.b.iii – Improve drug workforce time reporting data.
- C.1.d – Multi-year, risk-based resource planning: Proposed transition and implementation plan.
- C.1.g – Work plan dashboard.

Pharma C.1.a. Implement the Risk-Informed Process to Prioritize Assignments.

- Lead Organization(s): CDER, CVM.
- Due Date: Final FY16 milestones by January 29, 2016; status report due September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: FY16 milestones, using template. Status report to Implementation Workgroup, using template.

Pharma C.1.b.iii. Execute pilot to improve drug workforce time reporting data.

- Lead Organization(s): ORA.
- Due Date: September 30, 2016.
- Acceptance Criteria: Pilot executed. Presentation to Steering Committee with results and next steps.
- Deliverable Format: Presentation.

Pharma C.1.d. Implement the Multi-Year, Risk-Based Resource Planning: Proposed Transition and Implementation Plan**.**

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; status report due September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Status update to Implementation Workgroup, using template.

Pharma C.1.g. Address system and business requirements submitted in FY15 for the work plan dashboard.

- Lead Organization(s): ORA.
- Due Date: September 30, 2016.
- Acceptance Criteria: Fully dispositioned requirements.
- Deliverable Format: Requirements spreadsheet.

D. Compliance Policy and Enforcement Strategy

Goals:

- Inspection, compliance and enforcement activities – both foreign and domestic – are collaborative, team-based and streamlined.
- Compliance activity success supported by clearly articulated roles, responsibilities and decision rights and documented by performance-based public health metrics.
- Strategic priorities across the pharma program are communicated to and accessible by all pharma staff.
- Up-to-date pharma compliance programs and compliance program guidance manuals are complemented by modern enforcement standards and strategies.

To reach these goals, the pharma program will continue the following:[2]

- D.1 – Plan for modernizing enforcement standards and strategies.
- D.2 – Update and disseminate CPGs and CPGMs.
- D.4 – Create performance-based metrics focused on public health to effectively communicate pharma program work.
- D.5 – Strategy to clarify roles, responsibilities, and decision rights.
- D.7 – Strategic priorities.
- D.8.a – Development and issuance of high/top priority drug quality assignments.
- D.8.b – Team-based domestic and foreign drug quality.
- D.8.c – Make all drug EIRs and exhibits available via IT systems.

Pharma D.1. Implement the approved plan for modernizing commodity/program-specific enforcement standards and strategies. Implementation will begin upon further guidance from Steering Committee.

- Lead Organization(s): CDER.
- Due Date: TBD.
- Acceptance Criteria: TBD.
- Deliverable Format: TBD.

Pharma D.2. Implement approved plan to determine pace and staging of compliance program and policy assessment.

- Lead Organization(s): CDER.
- Due Date: TBD pending briefing to Implementation Workgroup.
- Acceptance Criteria: TBD pending briefing to Implementation Workgroup.
- Deliverable Format: TBD pending briefing to Implementation Workgroup.

Pharma D.4. Implement approved plan to establish performance-based public health metrics for compliance activities.

- Lead Organization(s): CDER.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.

[2] During FY 15 implementation, oversight of the D3 deliverable shifted from the pharma PA Steering Committee to the Agency's Compliance Policy Council (CPC) since the SMG being developed cut across Agency programs. If the need arises, development of a pharma specific SMG can be included in future pharma program alignment activities.

- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma D.5. Implement approved strategy to clarify roles, responsibilities and decision rights for the given compliance activities. Implementation will begin upon further guidance from Steering Committee.

- Lead Organization(s): CDER.
- Due Date: TBD.
- Acceptance Criteria: TBD.
- Deliverable Format: TBD.

Pharma D.7. Establish process to communicate the current strategic priorities across the pharma program for inspections, analytical and import work, and begin to implement the approved process**.**

- Lead Organization(s): CDER/CVM.
- Due Date: Process due June 30, 2016. Annual strategic priorities memo issued on or before September 30, 2016.
- Acceptance Criteria: Process to ensure that current strategic priorities are communicated across pharma program. Produce and communicate annual update that states current strategic priorities.
- Deliverable Format: Written process; strategic priorities memo.

Pharma D.8.a. Continue pilot to utilize team-based approach for the development and issuance of high/top priority drug quality assignments. **Actions on other recommendations will be deferred until the Steering Committee provides further guidance.**

- Lead Organization(s): CDER.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma D.8.b. Continue piloting team-based domestic and foreign drug quality inspection and review. **Actions on other recommendations will be deferred until the Steering Committee provides further guidance.**

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.

- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma D.8.c. Implement approved plan to make all drug EIRs and exhibits available via IT systems, including plan for addressing legal and policy issues.

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma D.9. Initiate quarterly meetings between OIP, ORA, and the Centers in anticipation of future integration into pharma program alignment.

- Lead Organization(s): ORA.
- Due Date: TBD.
- Acceptance Criteria: Schedule and conduct meetings.
- Deliverable Format: Meeting invites and minutes.

E. Imports

Goals:

- Efficiently process compliant entries to speed time to release.
- Use risk-based methods to target high-risk drugs that pose the greatest threat to human and animal health.
- Conduct education and outreach to internal stakeholders to build a skilled workforce capable of executing the mission, and to external stakeholders to encourage compliant trade.
- Use consistent and coordinated policies that inform and drive these goals.

To reach these goals, the pharma program will continue the following:

- E.1 – Action Plan for Drug Imports.
- E.4 – Rapid Screening Results Strategy.
- E.5 – Plan for Consistent, Informed Decision Making.

Pharma E.1. Implement Action Plan for Drug Imports.

- Lead Organization(s): CDER.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma E.4. Implement Rapid Screening Results Strategy.

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma E.5. Implement Plan for Consistent, Informed Decision Making.

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

F. Labs

Goals:

- Accurate and timely analytical results are incorporated into risk-based decision making.
- Aligned and collaborative regulatory science activities with compliance objectives ensure consistency.

To reach these goals, the pharma program will continue the following:

- F.2.a – Plan for Future Laboratory Resources.

Pharma F.2.a. Under the leadership of the ORA/CDER/CVM Steering Committee on Strategic Science and Compliance (SCSSC), implement the FY15 Future Laboratory Resources Plan and pilots.

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

G. IT

Goals:

- Operation of pharma program IT systems is seamless, two-way, and service-based.
- Master and transactional data is shared and maintained in a cohesive manner to ensure a single version of the truth.
- A governance mechanism monitors and resolves data and informatics issues.

To reach these goals, the pharma program will continue the following:

- G.1 – Develop modern two-way communication and data sharing.
- G.2 – Harmonize identifiers and business terminology.
- G.3 – Define modern, two-way integration.
- G.4 – Plan for common software platforms.

Pharma G.1. Develop and begin implementation of detailed plans to develop modern two-way communication and data sharing between CDER and ORA workflow systems.

- Lead Organization(s): ORA.
- Due Date: Plan due by September 30, 2016; quarterly reporting due on or before March 31, 2016 and June 30, 2016.
- Acceptance Criteria: Detailed plan including milestones.
- Deliverable Format: Plan using milestones template. Quarterly updates to Implementation Workgroup, using template.

Pharma G.2. Implement approved plan to identify opportunities to harmonize identifiers and business terminology (not including DUNS and FEI, addressed by separate deliverable, G.5).

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma G.3. Develop detailed requirements for two-way integration between CDER Informatics Platform and ORA workflow systems contingent on availability of PQP.

- Lead Organization(s): CDER.
- Due Date: September 30, 2016.
- Acceptance Criteria: Requirements that can be fed to a system development project, measurable and objective requirements document.
- Deliverable Format: System Requirements document.

Pharma G.4. Implement the approved plan for common software platforms (e.g., Chemometrics, LIMS, etc.).

- Lead Organization(s): ORA.
- Due Date: Final FY16 milestones by January 29, 2016; quarterly reporting due on or before March 31, 2016; June 30, 2016; and September 30, 2016.
- Acceptance Criteria: Complete the FY16 milestones approved by the Pharma Implementation Workgroup.
- Deliverable Format: 2016 milestones, using template. Quarterly updates to Implementation Workgroup, using template.

Pharma G.5. Establish and operationalize a workgroup that includes policy, operations, and IT representatives to examine and analyze pharma-specific issues associated with the choice of unique facility identifiers (UFI), including FEI and DUNS numbers. Make recommendations for UFI with justifications supported by analysis**.**

- Lead Organization(s): ORA.
- Due Date: Report due September 30, 2016; quarterly reporting due on or before March 31, 2016 and June 30, 2016.
- Acceptance Criteria: Report of findings/recommendations and presentation to Steering Committee.
- Deliverable Format: Report; presentation. Quarterly updates to Implementation Workgroup, using template.

Pharma G.6. Evaluate the feasibility and utility of a data sharing agreement between CVM, CDER, and ORA, and potential integration of CVM IT systems with CDER

Pharmaceutical Quality Platform (PQP) and workflow system, and implement if feasible.

- Lead Organization(s): CDER, CVM.
- Due Date: March 31, 2016.
- Acceptance Criteria: Recommendations for moving forward. Presentation to Steering Committee.
- Deliverable Format: Presentation.

APPENDIX A: Addressed Outside of Implementation Workgroup

The following are identified as follow-on activities to commitments met in FY15. They are not included as FY16 commitments because they are addressed elsewhere and do not require monitoring by the Implementation Workgroup.

- Establish a transparent approach to tracking and managing use of pharma program funds, e.g. appropriated and user fees, building on efforts already underway. (FY15 A.2.a)
- Set hiring goals for future fiscal years to fill staffing gaps identified in FY15 commitment A.6.

APPENDIX B: Future Year Commitments

The Pharma Implementation Workgroup discussed the commitments in this appendix during the development of the FY16 Action Plan. The workgroup concluded that these commitments are not FY16 activities, but recommends that they be considered for implementation in future years.

- 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.
- Issues related to combination products and dual-jurisdiction firms will require the following:
  - An operations plan for selecting the appropriate inspection staff, the identification of any specific training that may be required for all roles, and the inspection approach(es) to utilize for dual-jurisdiction firms or those which manufacture combination products;
  - Clear guidance to determine which Center has lead for enforcement actions; and
  - Clearly defined roles and responsibilities and accompanying procedures for inspection and compliance activities involving combination products, as well as dual-jurisdiction firms. This will address multiple commodities (i.e., pharma and biologics) and whether combination products are a sub-specialty of devices or whether it is a jointly-held responsibility.
- Conduct annual reassessment of drug workforce capacity needs**.** (FY15 A.2.h)
- Using the drug workforce capacity needs assessment conducted in FY15, review sub-specializations in 2nd quarter FY16 to assure that they will meet the needs identified in the assessment. This review will be completed annually. (FY15 A.2.g)
- Identify methods for determining effectiveness for the specialized drug workforce. (FY15 B.6)