# FDA Program Alignment
# Biological Products
# FY2016 Action Plan

**Specifics of the Biological Products Action Plan**
The following Biological Products FY16 Action Plan (Action Plan) developed by the Office of Regulatory Affairs (ORA) and the Center for Biologics Evaluation and Research (CBER) is intended to facilitate increased 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.

This Action Plan is the agreed upon framework of mutually-shared strategic, policy and operational changes occurring during the second year of this multi-year change management initiative. Each year, starting with FY15, ORA and CBER establish specific action items for implementation during that fiscal year. Where possible, Action Plans also include target dates agreed on by CBER and ORA. Senior managers in both CBER and ORA are assigned responsibility for specified implementation activities. Where appropriate, defined roles and responsibilities for all parties are incorporated into this plan; which includes streamlined decision making and final decision rights. The annual plan is reviewed quarterly to assess progress and make any necessary adjustments to the Action Plan.

## 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.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Implementation of the transition plan (would be evidenced by stand up plans for operations, new programmatic SOPs, alignment of ORA staff, etc.) & updates on the status of transition
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Updates to Steering Committee on the status

2. ORA will continue to work on the development of career ladder position descriptions (PDs) that support the Biologics program.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Progress made in FY16
    - Deliverable Format (e.g. SOP, Process Map, White Paper): TBD

3. CBER will participate in the selection process for the Biologics Program Director position, including the quality review board.
    - Lead Organization(s): CBER
    - Due Date: 3/31/16
    - Acceptance Criteria: Participation
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Participation in process

4. CBER will prepare a report of its employee baseline survey.
    - Lead Organization(s): CBER
    - Due Date: 12/31/15
    - Acceptance Criteria: Report shared with ORA
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Report developed by CBER

5. Jointly identify recruitment and retention incentives for specialized Biologics workforce and report recommendations to the Biologics Steering Committee.
    - Lead Organization(s): ORA and CBER
    - Due Date: 6/30/16
    - Acceptance Criteria:
    - Deliverable Format (e.g. SOP, Process Map, White Paper): White paper/options paper

**B. Training**

1. ORA and CBER will collaborate to conduct and complete a job analysis for the HCT/P investigator position with the intent to make a decision regarding certification of HCT/P investigators by the end of FY16.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Job Analysis report
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Job Analysis report

2. In FY2016, ORA and CBER will continue to collaborate in completing the steps outlined for the Blood Bank/Plasma certification development processes (exam item review, exam forms, and passing score study).
    - Lead Organization(s): ORA and CBER
    - Due Date: 9/30/16
    - Acceptance Criteria: Memo outlining progress for each step of the process completed in the timeline.
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Progress memos for each step in the development process.

3. ORA and CBER will collaborate to facilitate a decision regarding the path forward for certification for Team Biologics.
    - Lead Organization(s): ORA and CBER
    - Due Date: 9/30/16
    - Acceptance criteria: Memo outlining decision and discussion/ outlining next steps in the process for accomplishing a certification process for this team
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Memo outlining the process defined in the decision process/next steps

4. Establish and charter a Training Curriculum Committee to act as an advisory board for ORA and CBER to provide guidance for Biologics workforce training and collaboratively serve the needs of the employee development for the Biologics workforce.
    - Lead Organization(s): ORA and CBER
    - Due Date: 9/30/16
    - Acceptance Criteria: Charter developed by Training Workgroup for group responsibilities and task assignments and membership roster for initial curriculum committee.
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Group charter and membership roster

5. CBER, with ORA participation, will develop a continuing education training module for the new blood donor eligibility regulations.
    - Lead Organization(s): CBER
    - Due Date: 4/30/16
    - Acceptance Criteria: Audience for module is the entire Biologics workforce, not only the investigators. Training on changes to the regulations, probably done by webinar
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Module ready for rollout

**C. Agency Work Planning**

1. Further refine GIS mapping that supports the Biologics program
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
        a) Acceptance Criteria: Determine a schedule and format for regular check-ins with stakeholders that would influence updates of current GIS map products and implement.
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    - Deliverable Format (e.g. SOP, Process Map, White Paper): SOP for updates to GIS map products for the Biologics program

2. CBER and ORA will continue to refine the risk-informed process to ensure resources are allocated to shared work plan goals.
    - Lead Organization(s): CBER and ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Work done in FY16
    - Deliverable Format (e.g. SOP, Process Map, White Paper):

3. In FY17, ORA will implement a work plan to reflect the commodity-based organizational structure.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Work plan that reflects new ORA structure
    - Deliverable Format (e.g. SOP, Process Map, White Paper):

4. Training opportunities will be provided by OIM and ORA/DPEM starting in the 1st quarter of FY16 to introduce and help new users become familiar with the Tableau tool and the Work Plan Dashboard.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria:
    - Deliverable Format (e.g. SOP, Process Map, White Paper):

5. CBER and ORA will continue to address data quality in CBER and ORA systems to improve the accuracy of registration data and the official establishment inventory, specifically the failure to register processes for blood and HCT/P establishments.
    - Lead Organization(s): CBER and ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Progress made in FY16
    - Deliverable Format (e.g. SOP, Process Map, White Paper):

**D. Compliance Policy and Enforcement Strategies**

1. CBER and ORA will continue to assess options developed in FY15 to further streamline the advisory action compliance process.
    - Lead Organization(s): CBER and ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: TBD
    - Deliverable Format (e.g. SOP, Process Map, White Paper): TBD

**E. Imports**

1. CBER will finalize the Import Compliance Program evaluation protocol, perform the evaluation, and present the results to the Biological Products Field Committee.
    - Lead Organization(s): CBER
    - Due Date: 4/30/16
    - Acceptance Criteria: Evaluation report and presentation
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Evaluation report and presentation

2. CBER will work with ORA's ACE/ITDS team to amend, as appropriate, and finalize the Biologics portion of the Partner Government Agency (PGA) Supplemental Guide, following the completion of the pilot, by December 31, 2015.

- Lead Organization(s): CBER
- Due Date: 12/31/15
- Acceptance Criteria: Finalizing and delivering the Biologics portion of the guide
- Deliverable Format (e.g. SOP, Process Map, White Paper): Guide portion delivery

3. CBER and ORA will complete three Job Aids for CBER-regulated imports under the Initial Admissibility Project.
    - Lead Organization(s): CBER and ORA
    - Due Date: 6/30/16
    - Acceptance Criteria: Job Aids completed
    - Deliverable Format (e.g. SOP, Process Map, White Paper): Job Aids

4. In FY15, CBER shared their website for imported CBER products with ORA. In FY16, ORA will finalize content for related ORA public internet pages and launch their updated site.
    - Lead Organization(s): ORA
    - Due Date: 9/30/16
    - Acceptance Criteria: Web site launched
    - Deliverable Format (e.g. SOP, Process Map, White Paper): web site

## F. Laboratory Optimization

CBER has ISO accredited lot release laboratories for testing of biological drug and device products. CBER products are not currently tested in other FDA laboratories. There is no planned work in this area. CBER and ORA will collaborate on science-based projects, as necessary.