FDA Program Alignment
Biological Products
FY2015 Action Plan

Specifics of the Biological Products Action Plan
CBER and ORA have a long history of collaboration. In 1997, Team Biologics was established as a specialized inspectorate for licensed biological drug and device products (Core Team) and for blood and blood products for transfusion (Blood Cadre). Today, Team Biologics inspects licensed biological drug and device establishments with CBER product specialists and compliance support. The Biologics Cadre, working out of the districts, inspects and evaluates blood and blood products and human cells, tissue and cellular and tissue based products (HCT/Ps) regulated under section 361 of the Public Health Service Act and provides recommendations to CBER. CBER and ORA work closely together on all aspects of the biologics program and look forward to additional refinements to our successful program.

The following Biological Products FY2015 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. Core elements of the Action Plan may include increased specialization and de-layered management structures and processes involving both CBER and ORA, jointly developed training programs, new work planning, 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 biological products regulated by CBER.

This Action Plan is the agreed upon framework of mutually-shared strategic, policy and operational changes that will occur during the first year of this multi-year change management initiative. Each year starting with FY2015, ORA and CBER will establish specific action items for implementation during that fiscal year. Where possible, Action Plans will also include target dates agreed on by CBER and ORA. Senior managers in both CBER and ORA will be assigned responsibility for specified implementation activities. Where appropriate, clear roles and responsibilities for all parties will be incorporated into the plan, which will include streamlined decision making and final decision rights. The annual implementation plan will be reviewed quarterly by the Center Director and ACRA to assess progress and make any necessary adjustments to the Action Plan.

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

To further strengthen our collaborative approach and success in specialization of investigators, CBER and ORA commit to the following:

1. ORA will establish the baseline of program specialization of its current operational workforce through a survey during 3rd quarter FY2015.

2. CBER will similarly establish a baseline of its staff involved in these activities during 3rd quarter FY2015.

3. ORA will establish the Senior Executive Program Directors and launch recruitment by October 1, 2014.

    a) ORA will work with CBER on selection criteria that reflect Center interests and include Center participation in the selection process.

4. In FY2015, CBER and ORA will establish the parameters for program specialization for investigators, compliance officers, and managers within the biologics program in the areas of (1) blood bank and source plasma, (2) HCT/Ps, and (3) biological drug and device products (currently covered by Team Biologics investigators and compliance officers), to include: staff position competencies, skills, and experience; training and certification programs; and, staffing levels.

    a) Once they are established, ORA will target the specialization competencies described in #A4 as biologics specific staff positions are filled.

5. In FY2015, ORA will develop specific plans for transitioning operational resources within ORA to commodity-specific structures and costs associated with both implementation and maintenance and work with the Center to establish plans for the pace and staging of the organizational change process.

B. Training

ORA and CBER will continue jointly investing in training. CBER currently invests significant compliance and product office resources on course advisory groups and training for blood, plasma, HCT/Ps, and Team Biologics. ORA will work with CBER towards a redesign of investigator certification and development of a qualification program for the biologics program. This redesign will include establishment of priorities and timelines for investigator certification programs for the blood bank and source plasma program, HCT/Ps, and Team Biologics. BIMO will be addressed separately under the BIMO Action Plan. The training program will address the needs of investigators, compliance officers, and managers within the biologics program in ORA and CBER as well as other CBER staff, as necessary. Training programs will include development of metrics for evaluating effectiveness. To this end, in FY2015:

1. CBER will continue to work with ORA and provide input to develop a commodity-based set of competency requirements for: (1) Team Biologics, (2) HCT/Ps, and (3) blood bank and source plasma. ORA will complete a job task analysis for the blood bank and plasma investigators.

2. ORA and CBER will continue to develop training curricula to meet commodity-specific requirements, in the following priority order: (1) Team Biologics, (2) HCT/Ps, and then (3) blood bank and source plasma. Training curricula should address career development program and retention for biologics program staff.

3. ORA and CBER will continue to work together on the current blood bank/source plasma level II certification board and discuss a redesign of the investigator certification program, to include a qualification program for Team Biologics, HCT/Ps, and blood banks and source plasma investigators.

4. ORA and CBER will continue to develop Continuing Education requirements for all staff positions to remain current in commodity area.

5. ORA and CBER will collaborate on any necessary additional plans to improve the training process, including adjustments related to content, delivery methods, frequency and target audience. ORA and CBER will also use all available technologies (e.g., web-based tools, video conferencing, etc.) to provide more frequent updates in program areas.

6. ORA and CBER will establish a work group to further explore and leverage training and development resources and continually assess and improve such training and to explore opportunities for cross-training of ORA and Center staff (e.g., enhanced field participation in PAI, detail opportunities, etc.). This workgroup should include representatives from both ORA and CBER's training staff as well as pertinent operational SMEs.

7. ORA and Centers will establish a leadership and oversight role for FDA's Council on Pharmaceutical Quality (CPQ) in training and professional development for biological drug products regulated by CBER.

C. Agency Work Planning

Work Planning for CBER-regulated products is a collaborative effort discussed annually at the Biological Products Field Committee meeting. CBER uses a risk-based approach to identify blood, source plasma and HCT/P firms, as needed, each year and communicate them to ORA. CBER and ORA then work collaboratively

throughout the year. Program Alignment provides an opportunity to further strengthen the Work Planning process.

ORA and CBER will establish a program-based work planning regime that improves FDA's targeting and utilization of compliance-related resources that is based on risk factors, public health outcomes, past inspectional history, and operation experience, and that is reported through performance-based metrics. The program based work plan will include a multi-year outlook on future priorities and activities on a national level that allow ORA and the Centers to adjust their resources to meet future program needs.

1. Starting in FY2015, ORA and CBER leadership will formulate a risk-informed process over time to ensure that resources are allocated to shared strategic priorities and work plan goals.

2. 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.

3. In FY2015, ORA will expand the use of Geographic Information System (GIS) data to better inform staffing needs and for efficient work planning.

4. As an interim step, ORA will implement a national work plan for the biologics program by FY2016.

5. CBER will continue to provide an inspection priorities memorandum to ORA each year and will continue to check in with ORA during the FY to gauge progress and discuss obstacles and to ensure the work plan is accomplished.

6. As a future year effort, ORA and CBER will continue to expand international data collection to institute global work planning that relies on unique facility identifiers, agreed-on risk identification, and all available signal and intelligence information.

D. Compliance Policy and Enforcement Strategy

Development of timely and high quality compliance actions is the highest priority for CBER and ORA. Clear, current, outcome-based and effectively communicated compliance policies and enforcement strategies will be established. In addition, specifically in the area of blood banks and plasma centers, and HCT/Ps, CBER proposes moving to a more streamlined process that includes more communications of findings during the inspection and early collaboration on the compliance side, for

advisory actions, as has been done with injunctions, seizures and administrative HCT/P orders.

1. In collaboration with ORA, CBER will assess, update and implement compliance programs and policy guides on an annual basis.

2. CBER will continue to perform annual evaluations of all inspectional compliance programs. Evaluation findings will be shared with ORA, who will assess CBER's findings and develop a corrective action plan through ORA's Quality Management System, as needed.

3. Starting in FY2015, as new or novel products or technologies, which are not addressed in any existing programs, are identified, CBER will work with ORA to review and identify any changes to or the need to develop risk-informed enforcement strategies, and will collaborate to develop processes for policy development and communication and outreach approaches.

4. Together, CBER and ORA will clarify lead roles and identify process improvements for compliance activities. The following compliance areas will be addressed in FY2015:

    - *Advisory Actions*:
        1. CBER and ORA will review and update, as appropriate, the existing processes and procedures that govern Team Biologics compliance activities to identify areas of inconsistency and build on the efficiencies gained by using a team-based approach.
        2. ORA and CBER agree to evaluate the advisory action compliance process to identify weaknesses and/or gaps in training, policy or process. CBER and ORA will establish a working group, which will perform an analysis of the programs covering the training, policy and process (for both foreign and domestic work) as well as an analysis of program performance. The working group will develop for ratification an options paper and implementation plan that identifies solutions for current program weaknesses and incorporates the tenets of a more streamlined and collaborative process

    - *Judicial Enforcement Actions*: In FY2015, CBER and ORA will clarify the process for seizures and injunctions as it relates to Preliminary Assessment Call requirements when a collaborative compliance process is utilized.

- *FDASIA and DSQA*: CBER and ORA will continue to support the implementation of FDASIA and DSQA as it relates to compliance policy and enforcement strategy and will seek to incorporate the tenets described above, as applicable.

5. In FY2015, Class 1 recall approval authority (e.g. ACRA sign-off on Class 1 recalls) will be delegated to the Centers to streamline the recall process.

E. Imports

There are fewer imports of CBER regulated articles than articles regulated by the other FDA centers. CBER has been involved in PREDICT screening projects since 2008 and is one of the first centers to implement book auto lookups and expert rules which are cataloged in the "PREDICT Guide: Rules and Screening."

1. In FY2015, ORA and CBER will continue to work collaboratively on PREDICT, and to that end:
    a. CBER will continue to participate in monthly PREDICT Center Roundtable Meetings with ORA, and bi-weekly Import Systems Status Meetings.
    b. ORA will share the PREDICT evaluation with CBER and discuss any follow-on activities that may be necessary.
    c. Together with the OEIO/Division of Compliance Systems, OEIO/Division of Import Operations and NTELX contractors, CBER will continue to monitor the relevant PREDICT rules and innovate accordingly (e.g. CBER recently designed and implemented a "flu vaccine scenario" amendment to our lookups to facilitate the importation of flu vaccine when the correct data is transmitted).

2. CBER will continue to periodically review its existing Import Alerts and make adjustments where necessary.

3. CBER has two Import Compliance Programs, which provide instructions for entry reviewers and other FDA personnel (and outside stakeholders). CBER will periodically review and evaluate these programs, as described above in #D2.

4. CBER has a fairly extensive website for imported CBER products and will work with ORA in FY2015 to add links from related ORA internet pages as well as to incorporate this information in appropriate external training/speeches for stakeholders.

5. In FY2015, ORA will assess import program data and establish a strategic plan for biological imports.

6. ORA will assess import operational resources allocation and adjust commensurate with established program goals, as part of the work plan process.

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.

G. IT

ORA and CBER will continue to support the development of new IT systems as well as the enhancement of current ones to improve information sharing and to facilitate risk-based decision-making across the biological products program. Specific examples of this are contained in other sections of this action plan, to include the enhanced use of GIS information to assist work planning, the accuracy of facility registration information to ensure efficient work planning and inspection scheduling, and the automation of certain aspects of the Agency's export certificate program for biological products.

1. ORA and CBER explore use of handhelds or lightweight computers / rational questionnaires to guide the inspection process, record observations, and store photographs / evidence. These handhelds will allow investigators to have real-time access to compiled information on firms' products and processes. In FY15, ORA and CBER will work together to identify and prioritize biologics programs to utilize intelligent questionnaires.

H. BIMO

BIMO will not be specifically addressed in this action plan, because there is a cross-Agency working group analyzing what specialization might look like for the BIMO program(s).