

Message from the Center Director, Peter Marks, MD, PhD

As Director of the Center for Biologics Evaluation and Research (CBER) I am pleased to issue the *CBER Interim Strategic Plan FY 2017–2019*, which outlines our strategic direction and plans over the next three years for achieving our mission and contributing to the strategic priorities of the Food and Drug Administration.

CBER's interim strategic plan follows from our mission and vision, and outlines our strategic goals, related objectives, and strategies for achieving those goals through FY 2019. Our plan is aligned with the FDA Strategic Priorities 2014 – 2017 document and the Department of Health and Human Services Strategic Plan 2014 - 2018. Our plan reflects the contributions of all Offices and Divisions, and sets forth the Center's five overarching program goals and final cross-cutting goal:

- Goal 1: Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases.
- Goal 2: Improve global public health through international collaboration including research and information sharing.
- Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products.
- Goal 4: Ensure the safety of biological products.
- Goal 5: Advance regulatory science and research.
- Goal 6: Manage for organizational excellence and accountability.

We view this strategic plan as a living document that will allow us to modify our direction and approach as new regulatory challenges, obligations, and opportunities to serve the public's health emerge. This plan extends the original *CBER Strategic Plan FY 2012-2016: Innovative Technology Advancing Public Health* to cover the period from FY 2017 through FY 2019, which will carry us through to the establishment of new HHS and FDA strategic plans in 2018.

Together, these goals, objectives, and strategies form our vision for how CBER can contribute to improving public health in the years to come. We have a clear direction, and look forward to rising to the challenge of building on our successes to serve the American public.

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research

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INTRODUCTION

MISSION The mission of the Center for Biologics Evaluation and Research (CBER) is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, allergens, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Through our mission, we also seek to protect the public against the threats of emerging infectious diseases and bioterrorism.

VISION CBER uses sound science and regulatory expertise to:

- Protect and improve public and individual health in the United States and, where feasible, globally;
- Facilitate the development, approval of, and access to safe and effective biological products and promising new technologies; and
- Strengthen CBER as a preeminent regulatory organization for biological products.

ORGANIZATION CBER is composed of the Office of the Director and seven program offices (see Appendix A). Three of the program offices are responsible for regulatory oversight of biological products -- vaccines and allergens; blood and blood products; and tissues and advanced therapies. The four remaining offices provide cross-cutting support in the areas of compliance; surveillance, epidemiology and biostatistics; communication, outreach and development; and administrative services. The Office of the Director provides leadership and policy direction to the program offices and coordinates Center activities and resource management.

Rationale for Interim Strategic Plan

This document provides a broad overview of how CBER seeks to fulfill its mission of protecting the public's health over the next three years. CBER has experienced a number of changes – both internal and external – since publication of the *CBER Strategic Plan FY 2012-2016* four years ago. Some changes, such as new legislative mandates from the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), have expanded our responsibilities for ensuring access to safe and effective biological products. Other changes, such as the physical relocation and consolidation of all eight offices and associated laboratories to FDA headquarters for the first time in the Center's history, have expanded opportunities for cross-Office and cross-Center collaboration to accomplish our mission. In 2015, CBER conducted a comprehensive review of the oversight and management of its regulatory science program and in 2016 gained a new Center Director and Deputy-- both of which entailed taking stock of current progress and identifying future needs and direction. For all these reasons, it was important for the Center to engage in a gap analysis that identifies where we currently are in fulfilling our mission, where we are headed in the next few years, and how we propose to get there.

The *CBER Interim Strategic Plan FY 2017-2019* builds on the Center's prior strategic plan, retaining the six overarching goals and associated objectives while updating the strategies through which these goals and objectives will be achieved. Early in the revision process, we concluded that the goals and objectives initially developed in 2011 were still vital to CBER's overall mission. Furthermore, these goals and objectives remained aligned with key strategic goals and priorities in the HHS Strategic Plan 2014-2018 and FDA Strategic Priorities 2014-2018 documents (see Appendix B). However, many of the strategies required revision to reflect the Center's new legislative mandates, expanded role in addressing global health needs, recent innovations in regulatory science and technology, and expanded opportunities for collaboration and partnership resulting from the move to FDA headquarters.

Development of CBER's interim strategic plan occurred over a nine-month period, with initial review and revision of strategies done by CBER subject matter experts in the areas of counterterrorism; international affairs; compliance and postmarket surveillance; epidemiology and biostatistics, communication and training, budgetary and administrative services; regulatory policy; regulatory science; and regulatory review of vaccines, blood and blood products, and tissues and advanced therapies. Subsequent drafts were reviewed and refined by CBER Office Directors and senior leaders, with final revisions made by CBER's Center Director. In short, this document represents a Center-wide effort to describe how we propose to focus our attention and allocate resources over the next three years in carrying out our mission to ensure the safety, purity, potency, and effectiveness of biological products for the American public.

Strategic Goals

The CBER Interim Strategic Plan FY 2017-2019 outlines the following six strategic goals:

- Goal 1: Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases.
- Goal 2: Improve global public health through international collaboration including research and information sharing.
- Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products.
- Goal 4: Ensure the safety of biological products.
- Goal 5: Advance regulatory science and research.
- Goal 6: Manage for organizational excellence and accountability.

The six goals and their associated objectives and strategies are presented in separate sections of this document. It is important to note that these goals and objectives are inherently interrelated, and that successful achievement of one can influence success of the others. Providing a framework for how CBER can most effectively allocate its resources – fiscal and human – in achieving these goals will better position the Center to successfully navigate the challenges and opportunities of 21st Century medicine.

Goal 1: Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases.

CBER seeks to ensure the nation and the world are prepared to respond quickly to public health threats resulting from pandemic influenza, outbreaks of emerging infectious diseases (EIDs), and terrorism by improving the availability of safe and effective biological medical products. These threats have the potential to harm the health of the American public, overwhelm our health care infrastructure, and contribute to national security risks.

The safety and availability of the nation's blood and tissue supply are also threatened by pandemic influenza, EID outbreaks, and terrorism. Infectious agents transmitted from donated blood and tissues to patients may spread an infectious disease. Similarly, a radiological or nuclear attack could incapacitate collection and transfusion facilities for extended periods of time.

CBER will continue to work proactively to prepare for and respond to threats as they emerge, collaborating with other Department of Health and Human Services (HHS) agencies; federal government partners; FDA's Centers and Office of Regulatory Affairs (ORA), Office of Counterterrorism and Emerging Threats, and Office of Safety, Security, and Crisis Management; the World Health Organization (WHO); other National Regulatory Authorities (NRAs); and stakeholders from the private and public sector.

Objective 1.1: Increase the nation's preparedness for pandemic influenza.

CBER is responsible for the regulatory oversight of both seasonal and pandemic influenza vaccines. Moreover, CBER's laboratory programs contribute in multiple ways to facilitate influenza preparedness. These efforts include the identification and proposal of candidate strains for seasonal and pandemic vaccines, and beginning in 2017 the generation of candidate reference viruses. CBER is also responsible for the preparation of reference strains to support development by licensed manufacturers of seed stocks for seasonal and pandemic vaccine production, and development of reference reagents for use in lot release testing of seasonal and pandemic influenza vaccines.

CBER collaborates closely with the National Institutes of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and other key stakeholders to facilitate development and licensure of pandemic influenza vaccines to expedite availability and increase national preparedness. CBER supports efforts to increase manufacturing capacity using new and existing technologies, and is engaged in developing more efficient methods for testing influenza vaccine potency.

CBER provides regulatory support to industry in developing sustainable influenza vaccine production capacity. Through consultation with outside experts such as the Vaccines and Related Biological Products Advisory Committee, CBER obtains recommendations and advice related to vaccines, such as the safety and effectiveness of influenza vaccines and the selection of strains for future seasonal influenza virus vaccines for the Northern and Southern Hemispheres.

Together, these critical activities help ensure the safety, quality, and potency of pandemic and seasonal influenza vaccines, as well as facilitating the manufacture and availability of these vaccines.

CBER intends to prepare for pandemic influenza through the following strategies:

1. Develop and evaluate improved tools and methods to enhance safety, quality, and potency testing of influenza vaccines, including more efficient methods to develop reference reagents for potency testing and alternatives to the traditional test used to measure influenza vaccine potency.
2. Develop and evaluate new preclinical methods to screen novel adjuvants for their potential adverse effects prior to starting clinical trials. Availability of new adjuvants may enhance the immune response to the influenza vaccine antigens, and may also result in the increased availability of a vaccine during a pandemic event.
3. Maintain the Electronic Lot Release System to support pandemic preparedness.
4. Continue close monitoring of influenza vaccine manufacturing facilities both domestically and internationally.
5. Pre-define the parameters for when FDA will issue guidance regarding the safe collection and transfusion of blood during a pandemic.

Objective 1.2: Facilitate development, evaluation, and availability of high priority medical products (including medical countermeasures).

CBER works with the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and industry on a broad array of initiatives aimed at making our nation better prepared to respond to chemical, biological, radiological, and nuclear (CBRN) threats through medical countermeasures (MCM). The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response, in partnership with FDA, NIH, CDC, and our interagency partners in the Department of Defense, Department of Homeland Security, Department of Veterans Affairs, and Department of Agriculture to identify and monitor MCM needs and approaches. As part of this partnership, CBER is responsible for ensuring that vaccines, blood and blood products, tissues, and cellular therapies are readily available in the event of a public health emergency. For example, cell-based therapies may be needed for wound repair, regeneration of tissues, and reconstitution of bone marrow. Similarly, blood and blood components may be essential for patient treatment after a burn/blast or radiological attack.

CBER also participates in the FDA MCM Initiative, providing leadership and coordination, facilitating the review process, advancing regulatory science for biologics-based MCM development and evaluation, and contributing to Agency efforts to enhance the legal, regulatory, and policy framework for an effective public health response. We participate in devising risk communication strategies for public health emergencies, contribute to health informatics/scientific computing, perform intramural research to support MCM regulatory science, facilitate external science partnerships, and modernize laboratories to conduct MCM-related regulatory research.

The development and approval of vaccines and therapeutics to address the effects of CBRN threats on health presents unique challenges, as clinical trials involving randomized control studies with human subjects are often not ethical or feasible. Instead, review and approval of these products must often rely on animal models and adaptive clinical trial designs to support the claims of safety and efficacy required for licensure.¹

¹ For more information on the requirements for licensure under these conditions, refer to the following final guidance document commonly referred to as the “Animal Rule”: *Product Development under the Animal Rule: Guidance for Industry*, issued October 2015.

CBER intends to facilitate the development, evaluation, and availability of high priority medical products through the following strategies:

1. Develop and evaluate nonclinical models to study pathogenesis and identify relevant correlates of immunity.
2. Create methods and nonclinical models to evaluate the safety of vaccines, including adjuvants.
3. Determine biomarkers of pathogenicity and develop new methods to evaluate and ensure the safety of vaccines and other therapeutic, diagnostic, or medical intervention strategies.
4. Study the mechanisms of innate and adaptive immunity against viral and bacterial diseases and mechanisms of immunopathology, including new approaches to induce protective immunity.
5. Assist BARDA, CDC, and other stakeholders in the development of counterterrorism products utilizing the Animal Rule and other regulatory pathways, and help them navigate the pre-Emergency Use Authorization process to make unlicensed counterterrorism products more readily available in the event of an emergency.
6. Collaborate with BARDA, CDC, and other stakeholders regarding counterterrorism products developed under the Animal Rule.

Objective 1.3: Develop reagents, evaluate new methods, and implement policies to maintain a continued safe and adequate supply of blood and tissues during emergencies.

CBER is responsible for ensuring that blood, blood products, and tissues remain free of infectious agents and contamination – which may occur naturally through product processing or through bioterrorism -- and that these biologic products are available to all individuals who need them during a public health emergency. Contamination of biological products can result from both known and unknown infectious agents. New infectious agents can compromise product safety and availability, whether due to the spread of disease vectors (e.g. Zika, dengue, babesiosis), travel and immigration (e.g. malaria, Leishmania), terrorism (e.g. anthrax), or previously rare or unknown infectious agents (e.g., Ebola virus, vCJD, SARS-CoV, Chikungunya virus, Zika virus, Q-fever agent). Due to their labile nature, biological products cannot always be safely subjected to currently available sterilizing or removal methods to ensure the absence of bacteria, fungi, parasites, viruses, or prions. Therefore, CBER must be vigilant in its efforts to minimize the risks associated with potential contaminants of biological products.

CBER will support a proactive, systematic, and comprehensive approach to pathogen detection and response to potential microbial threats by engaging in the following strategies:

1. Improve the microbial safety of human tissue products by developing new molecular assays for sensitive and rapid detection of high-risk microbial pathogens and enhancing methods to inactivate pathogens.
2. Continue to inspect facilities that manufacture human tissue-based products to monitor compliance with all applicable regulations.
3. Continue to enhance collaborative efforts to identify, monitor, prioritize, and act on EID issues and emerging threats to blood and tissues.
4. Develop new scientific capability for detection and characterization of microbial agents, previously known and unknown, in infected or contaminated tissues and cells using Next Generation Sequencing technology and other novel approaches.
5. Anticipate and proactively prepare for economic, social, and political impacts of regulatory interventions in collaboration with HHS and other federal departments and agencies.
6. Work cooperatively with test kit manufacturers to facilitate development of reference materials and panels for assays for detection of viral and parasitic agents in blood donor screening.

7. Work collaboratively with FDA's Office of Crisis Management to develop more efficient information-sharing strategies during public health emergencies.
8. Work collaboratively with FDA's Office of Crisis Management to develop real-time Geographic Information System mapping capability to display the location of CBER-regulated manufacturers of critical products in relation to imminent environmental threats.
9. Support efforts by the CDC to develop the National Health Care Safety Network as a potential clinical trial data tool for pathogen reduction technology clinical trials of blood products.

Goal 2: Improve global public health through international collaboration including research and information sharing.

CBER works with the global community to improve public health, as the need for safe and effective vaccines, blood and blood products, and other biological products to treat or prevent disease and emerging threats remains a challenge for international health care agencies. Our international engagements have been informed by the knowledge that protection of global public health against infectious disease threats translates into protection of public health in the U.S. as well. Increasing availability and access to safe and effective biological products protects both our national and global public health interests.

We recognize the importance of actively playing both leadership and partnership roles in global health; this approach has driven our engagement in a number of significant international activities. Because we live in an increasingly global and interdependent environment where international travel to the U.S. is increasingly common, infectious diseases rampant in other countries can threaten our population as well. Medical innovation, manufacturing, and regulation are also increasingly global, posing challenges and opportunities. New paradigms are emerging in the form of nongovernmental organizations (NGOs) and product development partnerships (PDPs) to address unmet product development needs, with unique regulatory pathways and associated regulatory science challenges.

CBER plays a critical role in contributing to global public health. We conduct a robust International Program, engaging in international activities using a range of mechanisms to realize global public health goals, including regulatory harmonization/convergence, regulatory capacity building where feasible, information sharing, international standards development, and collaborative research. Incorporating these tools in a cross-cutting approach, CBER is pursuing the following four objectives to enhance its role in improving global public health.

Objective 2.1: Promote research and information-sharing globally to address diseases and emerging threats impacting human populations.

Promoting regulatory research and sharing scientific and regulatory information are critical to advancing the development of safe and effective products of global need. Not-for-profit NGOs and PDPs are increasingly important contributors to global efforts for developing medical products to address the world's unmet needs. Working on global priority issues with these organizations, as well as with federal partners, is critical for the successful launching of new products in the global market. For example, CBER has been an integral partner in advancing the goals of the Global Polio Eradication Initiative. The endgame strategy for polio eradication includes switching from use of trivalent to bivalent oral polio vaccines, with the introduction of at least one dose of inactivated polio vaccine (IPV) for routine global immunization. After all wild-type poliovirus transmission is stopped, the proposed strategy envisions immunization solely with IPV. Thus, demand for IPV is expected to increase significantly, and new manufacturing facilities, including those in developing and emerging economy countries, will be needed to meet the global demand. CBER continues to develop approaches for the evaluation of new vaccines, and plays an integral role in providing scientific and regulatory guidance on data needed to support routine use of a new immunization regimen for polio eradication, long-term risk management for the post-eradication era, and development and evaluation of new tools and strategies to more rapidly interrupt wild poliovirus transmission globally.

Sharing both scientific and regulatory information with foreign regulatory counterparts and international health agencies contributes to best regulatory practices and product oversight. This exchange also strengthens and better informs our own regulatory decisions. For example, pharmacovigilance data sharing can enhance detection of safety concerns and their evaluation.

CBER intends to promote research and information-sharing globally through the following strategies:

1. Advance research and information sharing in global health areas through interactions with federal government agencies, foreign regulatory counterparts, international health agencies, NGOs, and PDPs.
2. Support the President's Emergency Plan for AIDS Relief (PEPFAR) training efforts as appropriate.

Objective 2.2: Facilitate global access to vaccines and biological products that address critical health needs.

Collaborations with international health bodies such as WHO and the Pan American Health Organization (PAHO) are essential for facilitating global access to needed biological products. CBER collaborates with these organizations and others to help provide assurances of quality, safety, and efficacy for products supplied to the global community through such programs as the WHO Vaccine Prequalification program.

Regulatory capacity building strengthens the ability of foreign counterpart organizations to implement science-based policies, supporting consistency of a science-based approach to regulation worldwide and assuring access to safe and effective products in developing countries. Such efforts can also lead to adoption of similar policies by other NRAs, and can enhance data integrity and human subject protections for clinical trials conducted abroad. Likewise, Good Manufacturing Practice compliance can be enhanced in foreign manufacturing sites when an NRA's on-site regulatory oversight complements FDA efforts. Regulatory capacity building by CBER takes many forms, including developing training materials, directing training exercises, facilitating personnel exchanges, and mentoring foreign regulators.

The WHO Vaccine Prequalification program provides a vital mechanism for assuring the quality, safety, and effectiveness of vaccines purchased by agencies of the United Nations for distribution to countries in need. In support of this WHO program, CBER serves as the NRA responsible for overseeing the quality, safety, and effectiveness of selected U.S.-licensed vaccines throughout the product lifecycle. These vaccines are critical for addressing global public health needs in developing countries by preventing infectious diseases and reducing mortality and morbidity.

CBER intends to facilitate global access to vaccines and other biological products through the following strategies:

1. Facilitate the development of vaccines to prevent diseases in the developing world vital to global public health.
2. Improve information sharing on the efficacy and safety of vaccines and blood and blood products with WHO, the European Directorate for the Quality of Medicines and HealthCare, and other NRAs to address critical global health needs.
3. Collaborate with WHO, other NRAs, manufacturers, and NGOs to help build regulatory capacity globally and enhance efforts to control significant infectious diseases.

Objective 2.3: Harmonize existing regulatory standards and work towards prospective harmonization of standards on new biological product areas to promote global public health.

Harmonization of existing product standards and prospective harmonization of newly emerging therapies remains an important means to facilitate global access to safe and effective products. Regulatory harmonization is a process by which divergent regulatory guidance is brought into alignment. Models for regulatory harmonization range from the higher level perspective of shared principles to explicit concurrence of technical specifications.

Harmonization occurs through various established formal processes such as the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Pharmaceutical Regulators Forum (IPRF), and the International Medical Device Regulators Forum; through confidential exchanges with counterpart regulatory agencies during guidance and policy development such as dedicated cluster discussions with the European Medicines Agency; voluntary blood manufacturing standards development with the European Directorate for the Quality of Medicines and HealthCare (EDQM); and through outreach efforts to engage stakeholders to establish common perspectives in emerging areas. Similarly, the IPRF's Cell Therapy Working Group and Gene Therapy Working Group bring together international regulators to discuss emerging regulatory issues.

CBER intends to harmonize existing regulatory standards where possible through the following strategies:

1. Continue to engage in regulatory dialogue with foreign counterparts on topics such as product manufacturing issues, potential product shortages, post-marketing product safety signals, preapproval issues, and regulatory standards harmonization.
2. Recommend tactical ways to achieve greater harmonization in the interpretation and application of technical guidelines with the ICH.

Objective 2.4: Collaborate in international scientific efforts to establish and maintain reference materials and standards for biologics.

Standards, both written and physical, are fundamental to the control of biologic products, with international standards having served as the underpinning for the global control of biologics for more than a century. Collaborative laboratory work and research to establish international physical standards contribute to the streamlining and consistent global development of biological products. Establishing reference materials and standards for biologics in the international community will advance CBER's efforts to facilitate global access to vaccines and other biological products.

CBER works with many standards-setting bodies in addition to WHO, including the National Institute for Biological Standards and Control, the Paul Ehrlich Institute, ASTM International, EDQM, and the Pharmaceutical Inspection Cooperation Scheme.

CBER intends to collaborate with international scientific efforts through the following strategies:

1. Advance efforts to develop and improve sharing of reference materials and biological standards with the international scientific community and foreign regulatory bodies, to include laying the groundwork for accreditation to ISO Guide 34 standard for reference material manufacturers.
2. Continue to implement relevant international collaborations on global health issues such as pandemic influenza, Ebola virus, Zika virus, Dengue virus, Babesia, and HIV.

3. Serve as a PAHO/WHO Collaborating Center for Biological Standardization and as an Essential Regulatory Laboratory within WHO's influenza vaccine network.
4. Serve as a WHO Collaborating Center for biologics, including hematologic products and in vitro diagnostics.
5. Collaborate with the WHO Prequalification Team – Diagnostics Working Group on dossier instructions and guidance for HIV diagnostic assays.

Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products.

CBER is committed to facilitating the development of new biological products for a broad range of complex and oftentimes life-threatening diseases. We seek to expedite the development of innovative and complex biological products, including those representing the exciting medical promise of precision medicine; vaccines against pandemic influenza and other infectious diseases; and new technologies to enhance the safety and availability of blood and blood products.

To expedite the development and review of innovative biological products, CBER utilizes established FDA programs such as fast track, breakthrough therapy, accelerated approval, and priority review for products that address an unmet medical need in the treatment of a serious or life-threatening condition and show promising preliminary evidence of substantial efficacy over existing therapies. CBER's scientific expertise and knowledge provides a strong foundation for these efforts.

Following recommendations of the FDA Science Board, CBER uses its considerable scientific expertise in developing new methods and technologies designed to expedite product development and testing. We draw on advances in science and technology to design better ways of predicting the safety of biological products early in their life cycle, and conduct mission-related research to facilitate product development. We also collaborate with private and public institutions to create new tools for developing and testing new products.

In addition, CBER is participating in an FDA task group charged with implementing the abbreviated approval pathway for biosimilar and interchangeable biological products established by the Biologics Price Competition and Innovation Act of 2009². This task group is developing technical standards and criteria to address specific scientific, legal, and policy issues associated with biosimilars.

Objective 3.1: Integrate genomics, proteomics, and other cutting-edge scientific technologies into regulatory oversight to expedite product development and review.

CBER continues to integrate novel, applicable scientific technologies into its regulatory oversight to facilitate review of innovative and novel products in a timely manner. Advances in science and technology show great promise for the development of safe and effective biological products. CBER is working to expedite the use of advanced technologies and methods - such as newly identified clinical biomarkers, innovative clinical trial designs, and genomics - in regulatory policy and guidance for industry. In addition, CBER is identifying opportunities to expand the use of new scientific technologies in genomics, proteomics, and structural biology to strengthen science-based regulatory review.

CBER uses the best science available to develop new standards for testing products; provide advice to product sponsors, professional societies, researchers, and other government agencies; and facilitate the development of new methods and technologies for enhancing the safety, efficacy, and quality of biological products. We evaluate state-of-the-art tools and approaches, such as nuclear magnetic resonance (NMR), mass spectroscopy, microarray,

² For the current list of FDA proposed rules and guidance documents governing biosimilar and interchangeable biological products, see [Information on Biosimilars](#).

and Next Generation Sequencing (NGS) to assess the purity, potency, and quality of biological products and relevant manufacturing intermediates such as cell substrates for biologics production.

CBER continues to integrate genomics and related sciences with the goal of enhancing biological product development and safety. To this end, CBER launched a multidisciplinary resource called the Highly Integrated Virtual Environment (HIVE), which consists of high performance computing hardware, bioinformatics and computational expertise, and governance. This resource supports the use and evaluation of NGS to improve the evaluation of biologics safety and effectiveness. The overall strategy is to work collaboratively with CBER product offices, other FDA Centers, NIH, CDC, academia, and industry to help shape optimal policy, education, and research on the use of NGS in medical product development and evaluation. The HIVE team assists in the development of methods to facilitate development and review of medical products that may rely on NGS data and enhance postmarket evaluation of their safety and effectiveness. In addition, the HIVE team provides support for high level computational analysis for multiple aspects of medical product safety and effectiveness.

CBER intends to integrate genomics, proteomics, and other cutting-edge scientific technologies into regulatory oversight through the following strategies:

1. Demonstrate the feasibility of novel technologies such as genomic and proteomic approaches to assess the consistency and purity of biologic products.
2. Develop and evaluate new methods to assess the safety of novel cell substrates to facilitate development and availability of new cell substrates for vaccines.
3. Explore biomarkers and mechanisms of vaccine-related adverse events with the goal of decreasing their occurrence.
4. Develop highly sensitive, high throughput, multiplex assays and standards for detecting emerging infectious agents.
5. Develop preclinical models, including identification of product quality attributes, for plasma derivatives and blood components that have undergone pathogen reduction treatments to assist in the evaluation of the safety and effectiveness of these products.
6. Advance the use of registries and large observational study databases to address scientific product issues not readily addressed in prospective randomized control trials (e.g. genotypic basis for inhibitor development against clotting factors).

Objective 3.2: Improve the evaluation of product efficacy in clinical trials through the use of biomarkers³ and adaptive designs.

CBER seeks to enhance the evaluation of biologic products in clinical trials through the use of new clinical biomarkers and innovative approaches. CBER will continue its efforts to identify and evaluate new clinical biomarkers that make it easier to assess adverse reactions to novel biological products early in the development process and improve overall evaluation of data gathered. In addition, new clinical biomarkers will provide opportunities to enhance the overall evaluation of data gathered during clinical trials of treatments for patients with complex medical problems. This work is part of CBER's overall goal to design new ways of conducting clinical trials of biomedical products.

³ Biomarkers are characteristics that can be scientifically measured and evaluated as indicators of normal biologic processes, disease, or response to drug therapy, and can include specific types of molecules as well as routine measurements like blood pressure.

CBER will work with industry to implement novel approaches to clinical trial design and analysis, such as Bayesian and adaptive clinical trial designs. New approaches could result in improved evaluation of product effectiveness.

CBER intends to improve the evaluation of product efficacy in clinical trials through the following strategies:

1. Continue collaboration with other FDA Centers, NIH, and industry through the Biomarkers Consortium to develop pathways to qualify biomarkers.
2. Utilize workshops to survey the current state of science for biomarker development.
3. Develop general principles for utilizing genomic biomarkers in clinical trials through the International Conference on Harmonisation.
4. Facilitate the application of advanced technologies and methods — such as newly identified clinical biomarkers, adaptive clinical trial designs, and genomics — to regulated products.
5. Incorporate relevant new knowledge from studies of advanced technologies and methods into recommendations embodied in new regulatory guidance for industry.

Objective 3.3: Advance regulatory science research and update regulatory policy to facilitate product review, including development of relevant animal models.

CBER advances regulatory science research and updates regulatory policy to reflect the new generation of product evaluation tools and innovative products we expect to see. To sustain our efforts in regulatory science research, we have developed new governance, communication, and management processes to evaluate and manage our regulatory science and research portfolio; leverage resources via scientific collaborations; and enhance the scientific expertise of our scientific and technical workforce.

CBER updates regulatory policy on a consistent basis, with a staff dedicated to policy development throughout the Center. Through the use of expert working groups for policy development and review, policy issues can be identified and new policies developed using standard criteria and practices/procedures designed to assure consistency across product offices. Updated regulatory policy is continually shared in the form of internal procedures and industry guidance to ensure product reviews and site inspections are conducted in a consistent manner.

CBER intends to advance regulatory science research to facilitate product review through the following strategies:

1. Test and validate methods for rapid detection of microbial contaminants in biologics.
2. Maintain International Standards Organization (ISO) accreditation for CBER lot release testing and processing.
3. Continue to develop and update Agency standards, guidance, and policy for biosimilars in collaboration with CDER.
4. Develop collaborative scientific programs to evaluate stem cells and other technologically advanced therapeutic approaches to facilitate development, evaluation, and availability of novel therapies.
5. Expand the biological drug compliance program to incorporate inspection of new therapies, and modernize the review and inspection training program to include new technology for investigators, compliance officers, and reviewers.
6. Facilitate the development of new and improved animal models and assays to measure activity and potential drug-induced toxicity at an early stage in product development.
7. Develop and evaluate animal models that can support the basis for efficacy for certain medical countermeasures used to treat or prevent serious conditions caused by biological, chemical, radiological, or nuclear substances when human efficacy studies are not ethical or feasible.

8. Utilize the Transfusion Transmitted Infections Monitoring System to provide molecular surveillance and facilitate development of diagnostic and blood screening standards.

Objective 3.4: Facilitate increased biologics manufacturing capacity and improved product quality.

CBER helps to increase manufacturing capacity by interacting with researchers, developers, and manufacturers through outreach efforts and global coordination to facilitate the development of new manufacturing methods, technologies, and best practices.

CBER intends to facilitate increased biologics manufacturing capacity and improved product quality through the following strategies:

1. Modernize regulations and guidance to provide flexibility, which in turn could foster manufacturing innovation and adaptation in the increasingly global regulatory environment.
2. Foster improved manufacturing technologies and product characterization techniques through a combination of research and interactions with stakeholders including sponsors.
3. Optimize oversight of manufacturing processes by applying risk and science-based principles that will help determine more efficient approaches to manufacturing.
4. Enhance methods to track source materials, raw materials, ingredients, and components used for manufacturing CBER-regulated products.
5. Lead advanced methods development and validation programs for improved methodologies that monitor product quality.

Goal 4: Ensure the safety of biological products.

Goal 4 aligns with CBER's core mission to ensure the safety of biological products. Under FDASIA and the Drug Quality and Security Act, FDA gained additional authorities to enhance product safety through monitoring of drug shortages and reducing the risk of counterfeit and other harmful products from entering the drug distribution supply chain. Coupled with these new authorities and working collaboratively with ORA, CBER carries out compliance and surveillance activities to enhance safety throughout the product life cycle.

Objective 4.1: Improve the use of healthcare data to enhance monitoring of the safety and quality of licensed biological products.

CBER's vision for postmarket safety monitoring entails expanding access to information regarding patients' use of a biological product and health outcomes in automated databases, enabling optimal detection and analysis of potential biologics safety concerns. To this end, we continue to expand our use of large databases from healthcare providers, insurers, and other partners to identify safety problems associated with biologic product use. We continue to build capabilities to evaluate potential safety concerns with vaccines in real time using Centers for Medicare & Medicaid Services data. We also continue to evaluate biologic product safety using population-based systems such as the Post licensure Rapid Immunization Safety Monitoring system and Blood Safety Continuously Active Surveillance Network in the FDA Sentinel program. Similarly, the newly launched Transfusion-Transmitted Infections Monitoring System (TTIMS), a 5-year collaborative project with NHLBI, the American Red Cross, and Blood Systems Research Institute, will provide invaluable data for estimating the incidence and prevalence of HIV, hepatitis B virus, and hepatitis C virus infection among voluntary blood donors.

CBER intends to improve the use of healthcare data to enhance postmarket safety and quality monitoring of licensed biological products through the following strategies:

1. Continue to expand access to and utilize population databases for biologic product safety.
2. Enhance the active electronic safety monitoring system to strengthen our ability to monitor postmarket performance of medical products and augment existing safety monitoring systems.
3. Develop and assess methods to improve safety signal detection, refinement, and validation.
4. Establish and maintain TTIMS as a flagship monitoring program to evaluate donation by potentially high risk blood donors as a means of supporting future donor eligibility policy determinations that will ensure safe blood is available for transfusion.
5. Expand the use of registries and observational studies to leverage "real world data" in determinations of product safety and efficacy pre- and postmarket.

Objective 4.2: Enhance statistical data analysis and mathematical models for improved epidemiological and risk assessments of regulated products.

CBER is facing increasing challenges and opportunities as we work to ensure the safety of biological products. The success of our efforts requires careful and effective integration of a variety of safety-relevant activities throughout a product's lifecycle. Our efforts include developing new methodologies to enhance product safety surveillance through the use of large datasets (e.g., Medicare and public and private health systems) that reflect real-life experiences of consumers treated with the product. Using this comprehensive approach to product safety surveillance, CBER will incorporate enhanced scientific tools such as genomics, advanced statistics, and

mathematical modeling. We will continue to use the powerful tools of bioinformatics and new approaches to statistics and modeling to develop new scientific data and methods to evaluate safety signals.

CBER intends to enhance statistical data analysis and mathematical models through the following strategies:

1. Evaluate new statistical methods that have the potential to improve the efficiency, consistency, and rigor of our review of safety issues in clinical trials, surveillance systems, and epidemiological studies.
2. Develop new approaches to meta-analysis to identify potential safety signals within a class of products.
3. Participate in Agency and Center initiatives to develop the information technology and computational science infrastructure and data standards to enhance evaluation of clinical trials and other sources of safety data.
4. Develop, evaluate, and apply novel data-mining methods to assess safety concerns throughout the product lifecycle.
5. Develop standard approaches for data mining of the FDA Adverse Event Reporting System (FAERS) and Vaccine Adverse Event Reporting System (VAERS), including standardized queries for extracting more useful data from FAERS, VAERS, and the Medical Device Reporting database.
6. Improve processes and guidelines for deciding when benefit-risk assessment and modeling methods can inform the assessment of safety issues.
7. Utilize large healthcare databases through Sentinel to answer questions related to the safety of product classes.

Objective 4.3: Promote safe product use through effective risk management and risk communication.

CBER's regulatory oversight of biological products requires a focus on all facets of risk management and communication both internally and externally with consumers, industry, and healthcare professionals.

Following product approval, CBER monitors postmarketing reports for risk when information from healthcare databases suggests cause for concern. If warranted, CBER will implement risk management strategies and employ suitable risk communications to protect the public's health. CBER Safety Teams for blood, tissues, and vaccines provide coordinated assistance for communication and follow-up on complex safety issues within CBER. Safety Team activities include coordinating investigations with other agencies and regulatory partners, formulating appropriate responses, and communicating with stakeholders.

CBER intends to promote safe product use through the following strategies:

1. Continue to apply principles of risk management to improve our regulation of products throughout their lifecycle.
2. Leverage the Managed Review Process to ensure compliance with regulatory standards and internal practices.
3. Continue to issue new guidance, rules, and standards that provide important direction to manufacturers of CBER-regulated products.
4. Utilize formal risk assessment tools as a foundation for benefit-risk assessments and related communications.

Goal 5: Advance regulatory science and research.

The goal of CBER's regulatory science and research program is to conduct high quality research that is integral to the Center's regulatory mission and public health portfolio; proactive in anticipating emerging regulatory and public health needs; and in direct support of CBER's regulatory decision-making and policy development responsibilities.

CBER's regulatory science and research program is coordinated by the Office of the Center Director with advisement from the CBER Regulatory Science Council to provide oversight of CBER's research activities. Together they strengthen CBER's research management strategy, which includes forward-looking priority setting coupled with periodic, portfolio-level review to ensure mission relevance, regulatory impact, and the breadth of expertise required to nimbly respond to public health needs. This strategy supports a researcher-reviewer model essential for regulating complex biological products. CBER ensures accountability to its stakeholders through a combination of internal annual and cyclic evaluations, external scientific peer reviews, and input from other external sources.

By working towards the four objectives described below, CBER will achieve this goal and ensure that CBER's regulatory actions and policies are informed by the best scientific evidence available.⁴

Objective 5.1: Advance the scientific basis for regulation of biologics, human tissues, and blood to enhance safety, effectiveness, quality, and consistency through development and evaluation of new concepts, methods, models, and reagents.

Effective regulation of biologics, human tissues, and blood relies on using the best available science. Due to the complexity and ever-changing science and technology underlying CBER-regulated products, intramural research is used to augment existing knowledge to specifically address scientific gaps and challenges. These advancements in regulatory science enable CBER to provide better guidance to industry and make better-informed regulatory decisions that will enhance the safety, effectiveness, quality, and consistency of both currently licensed and future products.

CBER intends to advance the scientific basis for regulation of biologic products through the following strategies:

1. Assess and promote safety and effectiveness of approved and in-development manufactured biologic products derived from blood or plasma and their analogs derived from recombinant DNA technology.
2. Assure and promote safety and effectiveness of retroviral and other infectious agent diagnostics, donor screening tests including development of standards, and other devices and technologies used in the manufacture and quality control of blood products.
3. Develop and evaluate methods and standards for improved characterization and lot release testing of cell therapy, gene therapy, and immunotherapy products, cancer vaccines, therapeutic vaccines, and xenotransplantation products.
4. Evaluate methods and conditions for improved tissue processing, pathogen inactivation, and pathogen detection relating to human tissues.

⁴ The objectives for Goal 5 were developed as part of the Visioning CBER Research in 2025 initiative conducted in collaboration with McKinsey & Company Inc., and approved by the CBER Regulatory Science Council in March 2016.

5. Enhance and improve the safety and effectiveness of vaccines and related biological products through the development of models, methods, and reagents.
6. Develop and study approaches to enhance the availability of vaccines and related biological products.

Objective 5.2: Develop and assess nonclinical models and methods with improved predictive value, and, as feasible, reduce, refine, or replace the use of animals for evaluation of safety and effectiveness of CBER-regulated products.

Nonclinical models and methods are fundamental to the development and evaluation of CBER-regulated products, especially those under evaluation for “first-in-man” /Phase 1 clinical trials. However, nonclinical models have been noted by many to often have limited predictive value, particularly for efficacy, resulting in many products making it to Phase 3 efficacy clinical trials and then failing. Poor efficacy prediction has contributed significantly to the high costs and long lead time for development of new medical products. Having nonclinical models and methods with improved predictive value will be invaluable to society by reducing costs, time, and potentially the use of animals. In addition, better predictive models and methods may speed the development of products to address urgent public health needs by providing a better understanding of safety, efficacy, and mode of action of regulated products, allowing more efficient assessment of new treatments and improved regulatory decisions. Nonclinical models are also critical to support the development of products against bioterrorism agents in which clinical studies may not be ethical or feasible.

CBER intends to develop and assess nonclinical models and methods through the following strategies:

1. Develop suitable models to assess blood and blood product preclinical safety and efficacy.
2. Improve understanding of the underlying biology of *in vitro* and *in vivo* preclinical models of pharmacology, toxicology, product rationale relevant to the risks of cell therapy, gene therapy, immunotherapy products, cancer vaccines, therapeutic vaccines, and xenotransplantation products.
3. Develop new approaches to study potential toxicity of vaccine components, including adjuvants.
4. Improve the understanding of disease pathogenesis, and identify correlates of protection and biomarkers to predict the effectiveness of vaccines and related products.

Objective 5.3: Improve clinical evaluation related to CBER-regulated products through the use of new biomarkers, large scientific and healthcare datasets, and innovative design and analysis of clinical studies by applying new statistical, epidemiological, and mathematical modeling approaches, and considering patient input to inform benefit-risk assessment of general and special populations.

CBER will explore a variety of approaches to enable clinical development and evaluation to proceed more quickly and efficiently by using and developing new biomarkers, research tools, and statistical and epidemiological methods to aid in clinical trial design and analysis. These approaches will lead to enhanced evaluation of product safety and efficacy.

CBER intends to improve clinical evaluation of CBER-regulated products through the following strategies:

1. Improve clinical evaluation of product efficacy and safety in pre- and postmarket settings through research on biomarkers, bioassays, adaptive designs, and other innovative statistical approaches.
2. Improve the use of healthcare data to enhance monitoring of the safety and effectiveness of licensed biological products.

3. Improve analyses and benefit-risk assessments of regulated products by developing enhanced statistical methods, mathematical modeling and computer simulation, and patient input methods.

Objective 5.4: Prepare for future regulatory and public health challenges through investments in emerging science and technology, and develop and sustain varied scientific expertise.

Science and technology that is used to develop, evaluate, and support products regulated by CBER is evolving rapidly. Emerging and re-emerging infectious diseases highlight the need for rapid initiation and deployment of scientific research to support nimble regulatory review of products to combat these public health threats. CBER will prepare for these challenges by continued enhancement of the regulatory science program, including improving research facilities, scientific computing capabilities, scientific skill sets, and portfolio evaluation. This ensures that CBER will remain current on scientific knowledge, anticipate emerging scientific and technological advances, and have the best resources available to fulfill our goals to address regulatory and public health challenges.

CBER intends to prepare for future regulatory and public health challenges through the following strategies:

1. Strengthen scientific, technical, and computational infrastructure that supports high-quality state-of-the-art scientific investigations.
2. Provide training opportunities to ensure that research staff remain at the cutting edge of relevant scientific and technical knowledge.
3. Leverage resources for collaborative research to address novel regulatory issues that require a wide range of scientific expertise.
4. Prepare for future science-based regulatory challenges by executing periodic horizon scanning for emerging science and technology that are likely to be or are being translated into CBER-regulated medical products.
5. Periodically assess CBER's regulatory science portfolio for scientific quality, productivity, and relevance to CBER strategic goals and objectives, and use this review to identify and address major scientific/technical gaps.

Goal 6: Manage for organizational excellence and accountability.

CBER has established this goal to ensure its human and capital resources are effectively allocated and managed to support the mission of the Center. This goal also supports CBER's efforts to improve program administration, strategic communications, and business process modernization. This cross-cutting goal supports the achievement of the five program goals outlined above.

Objective 6.1: Recruit, develop, retain, and strategically manage a world-class workforce.

Employees at CBER are its most valuable resource. CBER is committed to having the expertise needed to accomplish its mission and meet the anticipated demands of the future. Recruitment, development, retention, and management are more than just human resource issues; they have the potential to impact the public's health and safety as well. To this end, CBER is committed to attracting the best scientific and administrative talent, and supporting and developing these employees.

CBER is also committed to having knowledgeable and skilled staff who can provide timely regulatory oversight so that safe and effective products reach the market and remain safe and available to the American public. This broad public health mission requires that staff constantly hone and update their knowledge, skills, and expertise in order to keep pace with scientific and technological advances. The Center provides and supports these crucial training needs, beginning with a comprehensive orientation for all new employees and a diverse array of training courses and professional development activities throughout an employee's career.

CBER intends to recruit, develop, manage, and support a skilled workforce through the following strategies:

1. Identify and attract a pipeline of diverse and qualified candidates with a wealth of experience and talent through effective outreach and recruitment strategies.
2. Address under-representation using targeted recruitment strategies to reach those populations.
3. Develop and implement workforce planning initiatives.
4. Consider recruitment and retention incentives that will effectively allow CBER to compete in the marketplace for skilled talent.
5. Evaluate, update, and implement CBER training programs based in part on competencies that further develop skills and knowledge of our employees.
6. Leverage external training programs, as well as training programs of other FDA Centers on medical device review, to further develop skills and knowledge of our employees.
7. Establish a culture within CBER that provides opportunities for employee development and engagement, and recognizes and rewards employee productivity and achievement.
8. Establish a definitive plan to ensure adequate office space and telework policies for efficient business operations.

Objective 6.2: Ensure program integrity and responsible stewardship through effective administration of resource and financial management responsibilities.

CBER will continue to make improvements in program administration to ensure programs are adequately resourced and have the capability to respond to future needs. CBER will strengthen its fiscal oversight, internal

controls, and program accountability by integrating and aligning federal requirements, as well as ensuring compliance with financial reporting.

CBER intends to ensure program integrity and responsible stewardship through the following strategies:

1. Implement processes to promote timely financial planning for allocating resources, ensure oversight of financial accountability, and strengthen internal controls for identifying and correcting program deficiencies.
2. Ensure compliance with financial and program requirements and reporting.
3. Ensure program needs are adequately resourced to build the capability to respond to future needs.

Objective 6.3: Foster a safe, secure, and healthy work environment for CBER employees.

CBER is committed to providing a safe and healthy work environment for its employees by implementing policies and procedures designed to reduce the risk of accidents and injuries that may arise when conducting mission-critical work. As part of CBER's physical consolidation and relocation to FDA headquarters, the Center established an expanded occupational safety program, collaborating closely with the Agency's Office of Safety, Security, and Crisis Management (OSSCM), Office of Laboratory Science and Safety, and Institutional Biosafety Committee to ensure workplace safety practices are communicated, implemented, and enforced. This expanded program has enabled CBER to continue providing a safe working environment for office and laboratory personnel, in compliance with all applicable federal, state, and local environmental regulations and guidelines.

CBER intends to foster a safe, secure, and healthy work environment through the following strategies:

1. Implement a general occupational safety program that includes workplace inspections, safety communications, and incident reporting to ensure employees are provided a work environment free from recognized hazards and unnecessary risk.
2. Implement a robust laboratory safety program that minimizes employee exposure to bloodborne pathogens, hazardous chemicals, and other biohazardous agents through training programs, laboratory safety inspections, and hazard communications signage.
3. Coordinate with OSSCM to maintain an updated Occupant Emergency Plan and ensure employees are familiar with all fire safety, sheltering-in-place, and evacuation procedures in the event of an emergency.

Objective 6.4: Ensure effective strategic communication to address information needs and concerns of both internal and external audiences.

CBER seeks to strengthen its practices regarding communication to all audiences. CBER will improve its strategy for providing clear and concise messages about product safety, and will ensure those messages reach the right audiences using the most effective channels. To this end, CBER supports implementation of the FDA Strategic Plan for Risk Communication (see [Reports > Strategic Plan for Risk Communication](#)).

CBER intends to improve communication effectiveness through the following strategies:

1. Evaluate and improve key communication channels including CBER intranet and internet websites, and support FDA efforts to transition to a new web content management system.
2. More effectively coordinate the development and execution of internal and external CBER communications.
3. Assist in implementation of the FDA Strategic Plan for Risk Communication.

4. Use social media (e.g., Twitter) to disseminate public health messages about CBER-regulated products.
5. Leverage other Centers' communication channels to provide consistency in information shared with the public.

Objective 6.5: Implement an IT modernization program to provide state-of-the-art integrated information and shared data resources.

CBER is committed to modernizing its information technology systems to handle the increased complexity involved in the regulation of biological products. Modern integrated systems provide the cutting-edge analytic tools necessary to achieve CBER's public health mission. Working with the Office of Information Management and Technology and Chief Information Officer's Council, CBER continues to implement FDA's Informatics and Enterprise Information Technology initiatives.

CBER intends to refine its information technology strategy to strengthen information integration and shared data resources through the following strategies:

1. Evaluate, recommend, and coordinate CBER IT projects with the Chief Information Officer's Council.
2. Leverage and collaborate on IT projects that impact CBER and cross-Agency business processes.
3. Ensure CBER concerns are addressed in standards development and Data Standards Committee activities.

Objective 6.6: Foster a culture of continual business process improvement to enhance the overall operation and effectiveness of the FDA.

CBER will continue to improve its business processes so that mission-critical work is performed in an effective and efficient manner. CBER seeks to make improvements in quality and overall program performance management. We strive to implement quality standards for mission-critical programs.

CBER intends to foster a culture of continual business process improvement through the following strategies:

1. Develop and implement improved strategic operational planning processes to execute strategies and support resource decisions.
2. Conduct analyses of business processes and procedures to improve efficiency and ensure effectiveness, leveraging processes and procedures of other Centers as appropriate.
3. Evaluate program processes and implement improvements to address deficiencies where needed.
4. Develop and implement enterprise risk management processes in the Center.
5. Implement an electronic Review Management Process System (eMRP) to ensure compliance with regulatory standards and internal practices.
6. Develop a Quality Management System at the Center level and apply quality assurance principles throughout the Center.
7. Assist in the development and implementation of the FDA plan to enhance cross-Center consultation/collaboration during the review of combination products.

Objective 6.7: Improve transparency, collaboration, and participation.

In June 2009, FDA introduced its Transparency Initiative to make useful and understandable information about FDA activities and decision-making more readily available to the public. In addition to the Transparency Initiative, CBER also supports implementation of the recent White House Office of Science Technology and Policy memo on

sharing of federally funded research data. CBER is committed to assisting in these important endeavors of accountability and open government.

CBER intends to increase transparency, collaboration, and participation with the public through the following strategies:

1. Continue to seek feedback from customers/stakeholders through mechanisms such as customer satisfaction surveys to achieve a level of excellence in both performance and customer service.
2. Continue to engage all CBER Offices in the FDA-TRACK Initiative for managing performance by tracking and evaluating program results, and sharing progress with the public on a regular basis.
3. Implement FDA's responsibilities covering CBER under the HHS Open Government Plan.
4. Foster implementation of data sharing and public access policies through training and development of resources to enhance these practices.

APPENDIX B

Alignment of CBER Strategic Goals with FDA and HHS Strategic Objectives

CBER Strategic Goals	FDA Objectives	HHS Objectives
Goal 1: Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases.	Objective 1.4	Objectives 3.E, 3.F
Goal 2: Improve global public health through international collaboration including research and information sharing.	Objectives 1.2, 1.3, 1.4	Objectives 2.D, 3.E
Goal 3: Utilize advances in science and technology to facilitate development of safe and effective biological products.	Objective 2.2	Objective 2.B
Goal 4: Ensure the safety of biological products.	Objectives 1.2, 1.3, 2.3, 3.2	Objectives 2.C, 2.E
Goal 5: Advance regulatory science and research.	Objectives 1.1, 2.1, 4.1, 4.3	Objective 2.C
Goal 6: Manage for organizational excellence and accountability.	Objectives 3.3, 4.1, 4.2, 4.3	Objectives 4.A, 4.B, 4.C

For more detail on FDA and HHS goals and objectives, see:
<http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm>
<http://www.hhs.gov/about/strategic-plan/index.html>

APPENDIX C

Glossary of Acronyms

BARDA – Biomedical Advanced Research and Development Authority

CBER – Center for Biologics Evaluation and Research (at FDA)

CBRN – Chemical, Biological, Radiological, and Nuclear threats

CDC - Centers for Disease Control and Prevention

CDER – Center for Drugs Evaluation and Research (at FDA)

CDRH – Center for Devices and Radiological Health (at FDA)

DHHS or HHS – Department of Health and Human Services

EDQM – European Directorate for the Quality of Medicines and HealthCare

EID – Emerging Infectious Disease

EMA - European Medicines Agency

eMRP – Electronic Managed Review Process

FAERS - FDA Adverse Event Reporting System

FDA – Food and Drug Administration

FDASIA – Food and Drug Administration Safety and Innovation Act

HIVE - Highly Integrated Virtual Environment

ICH – International Council on Harmonisation

IPRF - International Pharmaceutical Regulators Forum

IPV – Inactivated Polio Vaccine

ISO – International Standards Organization

MCM – Medical Countermeasure

NGO – Non-Governmental Organization

NGS – Next Generation Sequencing

NIH - National Institutes of Health

NRA – National Regulatory Authority

ORA - Office of Regulatory Affairs (at FDA)

OSSCM – Office of Safety, Security, and Crisis Management (at FDA)

PAHO – Pan American Health Organization

PEPFAR – President’s Emergency Plan for AIDS Relief

PDP – Product Development Partnership

SARS-CoV – Severe Acute Respiratory Syndrome Coronavirus

TB – Tuberculosis (short for *tubercles bacillus*)

TTIMS – Transfusion-Transmitted Infections Monitoring System

VAERS – Vaccine Adverse Event Reporting System

vCJD - variant Creutzfeldt-Jakob Disease

WHO – World Health Organization

APPENDIX D
Major Laws Governing CBER Actions

CBER currently operates under the following legal authorities:

1. Public Health Service Act
2. Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
3. Medical Device Amendments of 1976*
4. Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
5. Safe Medical Devices Act of 1990*
6. Medical Device Amendments of 1992*
7. Food and Drug Administration Modernization Act*
8. Medical Device User Fee and Modernization Act of 2002*
9. Public Health Security and Bioterrorism Preparedness Response Act of 2002*
10. Project BioShield Act of 2004 (21 U.S.C. 360bbb-3)
11. Medical Device User Fee Stabilization Act of 2005*
12. Food and Drug Administration Amendments Act of 2007*
13. Biologics Price Competition and Innovation Act of 2009*
14. Patient Protection and Affordable Care Act, 2010*
15. Food and Drug Administration Safety and Innovation Act, 2012*
16. Drug Quality and Security Act, 2013*

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.