

Revitalizing ORA:

Protecting the Public Health Together In a Changing World



A Report to the Commissioner
Associate Commissioner for Regulatory Affairs
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Executive Summary

Introduction

During the late summer of 2007, the Office of Regulatory Affairs (ORA) within the U.S. Food and Drug Administration (FDA or Agency) embarked on a journey to revitalize operations and explore new strategies in response to its dynamic environment and the challenges presented by a changing world. Although the professionalism, responsiveness, and dedication of ORA employees to their public health mission remains steadfast, the fundamental changes occurring in the world and their corresponding impact on ORA can not be ignored. Globalization has led to more FDA regulated products being produced or manufactured overseas, and strong growth in regulated products being offered for import into the U.S. Technological innovation and advances have yielded products that are increasingly sophisticated, and manufacturing processes that are more complex. The environmental realities confronting ORA require examination of its workforce and tools to ensure responsiveness. Since ORA's force of dedicated employees play a pivotal role on the front lines of protecting public health, they deserve to have the improvements and tools necessary to perform their jobs.

As is often the case, these challenges have led to opportunities to strengthen and enhance ORA. The Food Protection Plan, developed by FDA, and the Action Plan for Import Safety,¹ developed for the President by the Interagency Working Group on Import Safety, provide frameworks for future public health protection efforts in which ORA will be a vital and active participant. In addition, the Food and Drug Amendments Act of 2007 (FDAAA) significantly expands FDA's authority in certain areas that will have an impact on ORA. The potential for increased resources in the coming budget cycles may allow ORA to hire additional personnel and strengthen its operational structure to an extent not seen in recent years. These initiatives, legislation, and budget implications will significantly influence the future of ORA.

ORA staff members are spread across the country, providing a valuable force of dedicated, diverse, and highly qualified employees who share a common vision of ensuring that *all food is safe; all medical products are safe and effective; and the public health is advanced and protected*. The revitalization effort expanded upon this common vision in developing a Strategic Frame that ultimately became a key driver of the ORA Revitalization Strategy:

ORA is an integral and vital part of FDA. We are a highly skilled, unified workforce dedicated to protecting and promoting public health. This is accomplished by continuously improving and utilizing all available tools and resources, and working collaboratively with our partners to protect the public from unsafe and ineffective FDA regulated products of foreign or domestic origin. Risk to public health is reduced, and regulatory compliance is maximized along the entire product lifecycle from origin to domestic use.

¹ The Action Plan for Import Safety is also known as the Import Safety Action Plan or ISAP.

The Revitalization Strategy supports the ORA mission statement developed previously to guide its work: “ORA protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.” ORA is not alone in this effort and must partner with FDA’s product Centers, the Office of the Commissioner, and other federal, state, local, and foreign regulatory authorities to provide the greatest protection for the public health.

In October of 2007, FDA Commissioner von Eschenbach highlighted trust as a key component of FDA’s Strategic Action Plan: “For in the end, this Strategic Action Plan is all about trust. It is about establishing trust by doing the right thing, and by doing it in the right way.”² ORA shares the goals of this plan, which are to:

- Strengthen FDA for Today and Tomorrow
- Improve Patient and Consumer Safety
- Increase Access to New Medical and Food Products
- Improve the Quality and Safety of Manufactured Products and the Supply Chain

There is clear symmetry between these shared Agency goals and ORA’s vision that *all food is safe; all medical products are safe and effective; and the public health is advanced and protected*. For ORA, trust was also a key component of the revitalization effort. The open and inclusive process described below ensured that the plans developed would be true to ORA’s mission and this vision.

ORA Examined Itself and the Changing World

To enhance and inform the revitalization journey, a comprehensive analysis of ORA was necessary, including an examination of both its external and internal environments. The breadth of ORA’s work to accomplish its public health mission cannot be understated. It includes, but is not limited to, such activities as:

- Inspecting both domestic and foreign firms producing FDA-regulated products;
- Reviewing information about and examining products offered for import into the U.S.;
- Collecting samples of products;
- Conducting laboratory analyses of samples;
- Engaging in enforcement actions to ensure compliance;
- Promoting compliance through education and training;
- Investigating allegations of criminal activity;
- Conducting consumer complaint and other special investigations;
- Efforts related to product recalls, including recall effectiveness checks; and
- Collaborating with other federal, state, local, and foreign regulatory authorities.

ORA also plays a critical role in responding to natural disasters or other threats to public health. As ORA’s response to public health emergencies and natural disasters has demonstrated in the

² Message from the Commissioner, FDA Strategic Action Plan, p. i, October 2007.

past, this list is by no means exhaustive; ORA will adapt its activities as necessary to achieve its public health mission.

As ORA examined its future, it also engaged in an unprecedented effort to strengthen and enhance relationships, among its employees and with stakeholders both within and outside of FDA. To gain a more complete understanding of ORA and its operations, outside entities that have a stake in ORA's work, such as the five FDA product Centers, the FDA's Office of the Commissioner, and state regulatory authorities, were consulted for their views. Most importantly, ORA simultaneously embarked on an effort to have widespread and open communication with its employees, both through visits to the ORA district offices by the Associate Commissioner of Regulatory Affairs (ACRA) and establishment of mechanisms to provide anonymous feedback electronically that could be widely shared with ORA's workforce.

Summary of the Process and Recommended Proposals

In recognition that ORA must fully understand the challenges presented by a changing world to determine an effective response, it engaged in an inclusive and transparent process of examination, study, and planning for its future. Nominees were solicited from throughout ORA to participate in the effort, "Revitalizing ORA: Protecting the Public Health Together in a Changing World," and 110 participants were selected by an 11-member Steering Committee. These individuals, along with representatives from the Centers, Office of the Commissioner, and the states, began their role in the process by participating in a Future Search Conference³ in November, 2007. Such a conference is a useful mechanism for guiding institutions facing change, and, as a result of ORA's Future Search, seven areas of common ground were identified for further analysis.

These areas of common ground led to the formation of seven work groups to conduct more in-depth assessments of those areas and propose improvements. The work groups focused on the seven areas of inspections and compliance, laboratories, information technology, leveraging, imports, administrative support, and training and career development.⁴ An additional work group was later established to address incorporation of Quality Management Systems (QMS). Over the next several months, the work groups were diligent and tireless in their efforts to research and develop recommendations for improving ORA to position it to meet the challenges posed by the rapidly changing environment in which ORA must regulate.

An additional meeting of the revitalization group was held in December, 2007, and a Strategic Frame to further focus their work was created. From this Strategic Frame, five strategic objectives for the effort emerged:

- *Ensure continuity of mission and leadership.*

³ Future Search: An Action Guide, Weisbord and Janoff (Berrett-Koehler, 2000). Additional information can be found at www.futuresearch.net for more information.

⁴ The work groups were ultimately named Focused Inspections and Better Compliance; ORA's National Laboratory Resource; ORA Revitalization: We Make IT (Information Technology) Happen; Collaboration and Leveraging; Imported Product Safety; Mission Support; and Training and Career Development.

- *Foster regulatory compliance throughout the life cycle of imported and domestic products.*
- *Enhance tools and scientific resources.*
- *Embed scientific risk based assessments and approaches.*
- *Encourage collaboration and leveraging to maximize regulatory impact.*

The workgroups put forth many ideas and proposals for consideration during the revitalization process. Ultimately, 28 of those proposals were developed into business cases that articulate the goals of the proposals, their supporting rationale, and detailed action steps and milestones. Since resources are not unlimited, and so many valuable ideas were presented in the 28 business cases developed by the workgroups, a sorting mechanism was needed to identify how the proposals could be most efficiently and effectively staged for implementation. The criteria established by management for sorting the business cases included furtherance of the five strategic objectives, above, and alignment with the Action Plan for Import Safety, Food Protection Plan, and FDAAA. In addition, the business cases were reviewed to ascertain those that would be key to enabling ORA operations in the future, and would therefore be instrumental to the success of the revitalization effort.

Using the above staging criteria, 13 proposals and supporting business cases were identified for stage one analysis, development, and implementation. The remaining 15 proposals will be further analyzed for development in later stages of implementation. These proposals will also be examined to ascertain whether any of the action steps or milestones contained in those supporting business cases should be developed as part of stage one. All 28 proposals are located in Appendix 1 in this report. The 13 business cases, identified for the first stage of implementation, are summarized on pages 30 through 37.

Because of strict time constraints confronting the original work groups, the business cases require further analysis before full implementation. In addition, those groups were not privy to business cases under development by other work groups, so a systemic analysis must be conducted to view all of the proposals in concert, including their resource implications, and to ascertain their overall impact on ORA. To begin the implementation phase of ORA's revitalization, action groups will be established to continue development of the 13 proposals in this first stage. Each action group will be led by a manager at the level of ORA District Director, or above, and will have subject matter experts to provide a cross-representation of ORA personnel. In addition, although individuals who participated in the revitalization process may be engaged in this next phase, leaders will be encouraged to give others in ORA a chance to participate in the implementation process.

The implementation phase of the revitalization process will be overseen by the Deputy ACRA for Field Operations. The action groups will develop plans for achieving milestones, including creation of timelines with detailed deliverables. A reporting mechanism will also be created to track progress on regular intervals, and to ensure accountability as the business cases are implemented. Communication and transparency will continue to play a vital role in the revitalization process as ORA implements the proposals.

Using the knowledge, insight, and broadened perspective gained during the revitalization journey, ORA will strive to strengthen and enhance its workforce, and to provide it with the tools necessary to meet the challenges of its environment. This report presents the results of ORA's inclusive effort, demonstrates how the ORA Revitalization Strategy was developed, discusses the implementation process, and explains the plan for managing implementation. ORA's dedicated employees remain committed to protecting U.S. citizens, and to promoting public health far into the 21st Century; the revitalization process has provided ORA with a plan to ensure its success.

Background

The Current Status of ORA

To effectively revitalize and plan for the future, ORA must have a thorough understanding of its current status and operational challenges. Stationed in more than 160 offices, resident posts, and laboratories from coast to coast and in Alaska, Hawaii, Puerto Rico, and the Virgin Islands, ORA's highly trained staff is the frontline of FDA as it implements the Agency's high public health standards. Although ORA accounts for about one-third of all FDA employees, it has experienced a decline in staffing over the past several years, losing approximately 800 personnel since 2003. ORA was under a hiring freeze between Fiscal Year (FY) 2004 and FY 2006, and employee losses across the country have created imbalances in staff in highly critical locations and gaps in skill sets.

FY 2007 brought change to ORA's budget that allowed ORA to do its first wide-scale hiring in four years, hiring 104 new investigators in targeted locations. These new hires will require intensive coaching and supervision at the hands of more experienced ORA personnel for several months to achieve independence, and it will be even longer before they will be ready to assume all of their diverse and complex responsibilities. Training of both new and current employees will be critical to fill the gaps created by the loss of expertise over the last few years and by the increasing technological complexity of FDA-regulated products.

ORA's work involves conducting foreign and domestic pre-market and post-market inspections, investigations, and laboratory analyses. Pre-market activities include bioresearch monitoring of clinical research, pre-approval inspections, laboratory method validations to support premarket application decisions, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in its application. The largest portion of ORA's work involves post-market inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers. These post-market inspections assess the manufacturers' compliance with Good Manufacturing Practice (GMP) requirements. ORA's radiological health activities include inspecting certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). ORA also inspects radiological health products such as lasers, sunlamps, and x-ray equipment to ensure they are in compliance with performance standards. In addition, ORA must monitor, examine, and sample imported products in each of these critical areas to ensure they meet the same rigorous safety and effectiveness standards as domestic FDA-regulated products. The Prior Notice Center receives and reviews prior notice and intelligence data on food products, including animal feed, which will be

imported or offered for import into the U.S., and provides guidance to the field and Customs and Border Protection (CBP) on appropriate actions related to those products. ORA's 13 laboratories perform microbiological, chemical, or radiological analyses on samples of domestic and imported FDA-regulated products.

ORA's Current Performance Goals

ORA's work is driven by achievement of performance goals set out in FDA's budget for each fiscal year, by performance plans, and by a comprehensive Workplan. The 13 performance goals for the 2008 fiscal year are in the following areas:

- Focus inspectional coverage on the device research enterprise to assure the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies.
- Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk.
- Perform import food field exams on products with suspect histories.
- Perform Filer Evaluations of import filers.
- Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported.
- Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products.
- Expand federal/ state/ local involvement in FDA's Electronic Laboratory Exchange Network (eLEXNET) system by having laboratories submit data into the system; beginning in FY 2007, expand the capability of the system to detect and provide notification of potential events; and, beginning in FY 2008, convert five data entry labs to automated data exchange.
- Increase risk-based compliance and enforcement activities to ensure drug product quality by conducting drug manufacturing inspections prioritized with risk-based criteria.
- Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations.
- Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities.
- Focus inspectional coverage on device firms to ensure consumers are protected and that the public health is advanced.
- Maintain a quality system in the ORA Field laboratories which meets the requirements of ISSO 17025 (American Society for Crime Laboratory Directors for the Forensic Chemistry Center) and maintain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation).
- Increase laboratory surge capacity in the event of terrorist attack on the food supply.

Working with the FDA product Centers, ORA develops an annual Workplan that provides overall guidance to the field on the types and level of inspectional, investigational, and analytical activities planned for each program. The Workplan serves to ensure that ORA adheres to

funding allocations as intended by Congress and priorities set forth by the Agency. There are five program-specific Field Committees (one for each product area regulated by FDA), and each Field Committee has a membership consisting of field managers and field program experts. The Field Committees work in concert with the Centers and ORA headquarters to prepare the annual Workplan. Every year, the Field Committee members and representatives from the respective Center meet to discuss the ORA Workplan and address common issues of importance in the given product area to reflect priorities for the Center and trained resources within ORA. There continue to be interactions throughout the year on operational activities, such as work assignments, executing the Workplan, and fostering collaboration on a variety of issues as they arise.

ORA Foreign and Domestic Collaboration and Inspection

In addition, ORA collaborates extensively with state, local, foreign, and other federal regulatory counterparts to protect public health. These programs provide states with technical training and familiarity with federal requirements in order to achieve more uniform enforcement of consumer laws through cooperation and coordination with FDA. In 2007, ORA funded over 16 million dollars in state contracts, grants, and cooperative agreements for additional inspections in areas such as shellfish, milk and food safety, medical devices, and for building laboratory capacity. The increased inspectional coverage achieved through partnerships with the states provides greater knowledge and coverage of regulated industry and allows ORA to focus its resources on high risk inspections.

In addition to collaboration with state counterparts, international agreements with foreign governments provide mechanisms for obtaining valuable information about a given country's regulatory system and foreign-produced products being offered for import into the U.S. For example, in December 2007, FDA entered into two Memoranda of Agreement (MOAs) with China's General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) and State Food and Drug Administration (SFDA). These MOAs provide for greater information sharing, increased access to production facilities in China, and the creation of a certification with verification program for food exports.

To supplement knowledge gained from foreign regulatory counterparts, ORA conducts inspections of foreign facilities that offer FDA-regulated products for import into the U.S. These products, which include every type subject to FDA regulation, come from more than 230 countries and more than 300,000 manufacturers.⁵ In FY 2007, ORA inspected 1,003 foreign facilities, the largest number of foreign inspections in a fiscal year by ORA to date. However, as a result of increasing imports and budget and staffing limitations, there remain a high number of firms in the foreign arena with no known compliance history that are shipping products to the U.S. Increasing the number of targeted foreign inspections, complemented by additional information from foreign regulatory partners, would help identify problem products before they are offered for import and enter U.S. commerce.

⁵ FDA's Fiscal Year 2008 Budget Summary, Field Activities Section, p. 13, which can be found at <http://www.fda.gov/oc/oms/ofm/budget/2008/8-FieldNarrative.pdf>

ORA Emergency Response Capability

ORA partners with federal agencies on a daily basis, including collaborative efforts with CBP at ports of entry and joint criminal investigations conducted with sister law enforcement agencies. In coordination with the U.S. Department of Agriculture (USDA), ORA established the Food Emergency Response Network (FERN), a nationwide network of federal, state, and local laboratories capable of microbiological, chemical, and radiological testing of food commodities. Speed in identifying whether food is contaminated is critical to reducing the risk of death and illness resulting from human exposure, and such collaborative efforts are vital to ORA's future success. Currently, 138 laboratories representing 50 states and Puerto Rico have satisfactorily completed the FERN Laboratory Qualification Checklist, which provides the FERN National Program Office (NPO) with vital information to determine if a laboratory meets the criteria for participation. To enhance their capacity and capabilities, 13 of these chemical and radiological laboratories receive funding and other support from FDA, and USDA funds microbiological laboratories.

Another key responsibility for ORA, in coordination with the Centers and the Office of Crisis Management, is to respond to public health emergencies or outbreaks involving FDA-regulated products. Within the last few years, ORA has responded to many highly-publicized and widespread outbreaks, such as *E.coli* in spinach; melamine in pet food; *C. botulinum* in canned chili; and a poisonous chemical, diethylene glycol (DEG), in toothpaste. The importance of rapid response and recalls of adulterated products cannot be overstated. The emergencies and outbreaks in the last few years have accentuated the need for closer ties to state counterparts and improved access to real-time data from a variety of sources.

The California Food Emergency Response Team ("CalFERT"), a joint effort by the FDA, the California Health and Human Services Agency, and the California Department of Public Health, whose employees work and train together, has become a model for demonstrating the success of cross-discipline teams and training in ensuring rapid and joint outbreak responses. Resources to create rapid response teams such as CalFERT in other states across the country are included in ORA's FY 2008 budget to ensure more rapid traceback of food-related outbreaks and to improve capacity to quickly determine the root cause of an outbreak. ORA has contracted with the Western Institute of Food Safety and Security, University of California at Davis, to aid in the development and ongoing maintenance of rapid response teams to include training for FDA and state personnel.

ORA's Revitalization Effort

ORA's revitalization effort, bolstered by an understanding of its current status, will create a foundation for the organization to develop and evolve so it can effectively implement the Action Plan for Import Safety, the Food Protection Plan, and FDAAA. This foundation will also enable ORA to more proactively meet its regulatory challenges, especially those posed by the dynamic global environment in which it operates. The most recent initiative to change ORA was the Transformation initiative or TLT (Transformation Leadership Team). The initiative engaged in a year-long research effort, but its proposed organizational changes were ultimately rejected. During the time period that concerns were being raised about the TLT recommendations, the

President's Interagency Working Group on Import Safety was established, and Congress was considering the legislation that ultimately became FDAAA. Although the TLT's recommended organizational changes were not put into effect, the realization that ORA needed to energize, renew, and prepare itself for both current and future challenges remained.

An Inclusive and Transparent Process

A more inclusive and transparent effort was undertaken to take a fresh look at the challenges confronting ORA as well as the specific plans to address those challenges. This examination was begun in the context of the new initiatives, legislation, FDA's Strategic Action Plan, and resources under consideration at the time it was initiated, and to determine an effective response to those factors. There was a commitment to offer the opportunity for all employees in ORA, as well as other offices throughout FDA, to engage in the effort. The ACRA pledged to visit each district to introduce the new planning process and discuss employee concerns, as well as ideas about the future. By the middle of January of 2008, the ACRA had visited 13 districts with five co-located regions and nine co-located or nearby laboratories, as well as ORA's headquarters staff; the remaining visits are continuing in 2008.

Employees were encouraged to raise any topics for discussion with the ACRA during the visits, and an open, engaged dialogue was achieved. In response to concerns expressed about the importance of open and clear communication, several avenues for disseminating information and receiving input were put into place: 1) a web site was established that would provide ORA employees with the ability to make anonymous comments and suggestions; 2) the comments and suggestions were made available for all employees to view; and 3) the notes from the ACRA visits were posted so employees across the nation could learn about the discussions occurring in those specific venues. Also in early November, 2007, ORA launched "ORA Corner" on its intranet site to provide employees with access to information about the revitalization effort, and to serve as a mechanism for employees to provide feedback on the planning process as it evolved. The notes from the ACRA visits and the comments from ORA Corner were posted for all employees to view and for use throughout the revitalization process.

There was extensive discussion during the ACRA visits about ensuring that the process was widely inclusive, and that a cross-section of ORA employees was engaged to provide input and advice relevant to respective areas of expertise. In October of 2007, the ACRA issued a Call to Action for all ORA employees interested in the future of ORA to volunteer to become part of the process, and to nominate individuals who would best reflect employee interests during the planning efforts. In addition to the Call to Action issued to employees, both the National Treasury Employees Union (NTEU) and the American Federation of Government Employees (AFGE) were invited to submit their recommendations for nominees. A Steering Committee was created to select employees to participate in the process. Consisting of 11 members representing a cross-section of both bargaining unit and non-bargaining unit employees, the Steering Committee had four members from NTEU, one from AFGE, two managers from compliance and investigations, one manager from the laboratories, one manager from leveraging, and one manager from headquarters. The 11th member was a manager from headquarters who was designated as the Steering Committee Chairman. The Steering Committee was charged with selecting nominees who embodied the following:

- Widely respected by their peers and ORA staff,
- Dedicated to the mission of FDA and moving ORA forward,
- Open and not afraid to share their opinions,
- Thoughtful and respectful of others' opinions,
- Fair and even-handed when addressing issues,
- Known for their ability to collaborate with others both inside and outside ORA, and
- Willing to dedicate three months to the process.

The Future Search Conference

Ultimately, 110 individuals were chosen to come to FDA headquarters in Rockville, Maryland in November of 2007 to participate in a Future Search Conference, guided by facilitators and consultants, to help determine a course for ORA. Future Search Conferences are designed to engage a cross-section of stakeholders who are asked to actively participate in planning for the future. The conference is a useful mechanism for guiding institutions facing a wave of social, economic, and technological change. This approach has been used in a wide variety of settings involving both public and private organizations. Throughout ORA's three-day conference, attendees, including external stakeholders such as participants from the FDA product Centers and the Office of the Commissioner, were guided through processes and tasks to help them examine the accomplishments of the past, the internal and external trends apparent in the present, and scenarios for an ideal future. Using the scenarios for an ideal future, the group identified areas of common ground or themes that were agreed to by all in attendance. The areas of common ground were used to create corresponding work groups tasked with development of business plans and action steps for ORA.

A video crew was on hand to capture the work of the November, 2007, Future Search Conference. The footage from the three days was condensed into a 40-minute DVD that was shared with ORA staff in January of 2008 and posted on the FDA intranet site, "FDA Presents". The video was intended to familiarize the staff who did not participate in the Future Search Conference with the process used to create a common vision and identify areas of common ground for further study.

Simultaneously, an unprecedented effort to secure input from ORA's stakeholders was taking place. Representatives from the Office of the Commissioner were asked to provide input, and a telephone conference call was conducted with all fifty states to solicit their feedback about ORA. The week preceding the Future Search, representatives from FDA's Centers (Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), Center for Drug Evaluation and Research (CDER), Center for Biologic Evaluation and Research (CBER), and Center for Medical Devices and Radiological Health (CDRH)) were gathered for two separate meetings with facilitators to participate in several exercises to elicit their perspective and ideas for revitalizing ORA. The Centers provided their input about global and other challenges confronting all of FDA, and ORA in particular. The exercises also yielded a set of ORA strengths, weaknesses, opportunities and threats that were provided to Future Search participants for their consideration and use during the process.

In addition to these activities, stakeholders were asked to participate in the Future Search Conference. At its conclusion, many of the stakeholders chose to dedicate their time and attention to these work groups as Agency stakeholder interviews continued. The seven work groups established were: Inspections/Compliance, Laboratories, Information Technology, Leveraging, Imports, Administrative Support, and Training/Career Development. Over the next few weeks, the work groups developed proposals based on common ground and shared views about ORA that they organized into templates to further focus their ideas. An eighth work group was formed from the Steering Committee to help coordinate the proposals and identify overlap and gaps.

The workgroup proposals were presented to the group of 110 individuals at a subsequent meeting in December, 2007. The eighth work group completed their task by reviewing the proposals and using them to develop the Strategic Frame, which set out the guiding principles and strategic objectives to structure discussions during the December, 2007 meeting. Also in December, a ninth work group was formed to guide the implementation of Quality Management Systems throughout ORA. As part of this process, the original seven work groups were asked on the first day of the meeting to analyze the essence of their proposals and develop new names for their groups to help further focus their visions. The names chosen were: Focused Inspections and Better Compliance; ORA's National Laboratory Resource; ORA Revitalization: We Make IT (Information Technology) Happen; Collaboration and Leveraging; Imported Product Safety; Mission Support; and Training and Career Development. During the December meeting, the work groups began to develop business cases to further explain and support their proposals. The business cases, which reflect these working group names, were further refined by each workgroup throughout the month of December.

During a third meeting in January, 2008, the group of 110 reconvened to reflect on the process, review a draft report, and help shape the course for implementation. Each of the members was asked to reflect on their four months of hard work and dedication to help determine those activities and techniques that were most effective and should continue in the future. In order to ensure the final product reflected the experience, ideas, and hard work of the 110 individuals, an early draft report was presented to the group with time for members to read, digest, and comment on the content and substance of the draft. Reflection on the revitalization process framed the discussion of implementation of the proposals. Both diversity of membership and transparency were key elements in the proceeding months and would therefore be carried forward into the new implementation plan.

Primary Challenges Identified

Ultimately, the revitalization process and the exploration of the current realities facing ORA yielded three primary challenges to ORA currently and in the future for further consideration: environment, workforce and tools.

Environment. Trends like globalization, shifting demographics, and development of increasingly complex products and processes means that the environment in which ORA performs its work has dramatically changed. Where ORA previously concentrated much

of its efforts within U.S. borders, the changing world requires a new and more aggressive approach: ORA must regulate globally.

Workforce. ORA's workforce has shifted, and institutional knowledge has been lost. Such knowledge cannot be rebuilt overnight, but must be cultivated through the span of a career. ORA must develop its workforce and recruit new employees with needed skill sets to ensure that the right skills are embedded in the foundation of its employees in the right geographic locations. ORA must then provide training and mentoring to new staff to cultivate its talent pool and encourage their career at FDA. ORA must identify talented leaders to cultivate management for the future.

Tools. The tools on which ORA currently relies to fulfill its mission are insufficient in the global environment. ORA must invest in its information technology and communications infrastructure; state of the art laboratories and rapid screening tools; risk management capability; and all areas of mission support. ORA must also have the tools necessary to implement new regulatory responsibilities and authorities.

These challenges must be evaluated and fully understood to effectively plan for the future.

ORA's Revitalization Vision for the Future

The three primary challenges have a dramatic impact on ORA's Revitalization Vision for the Future, which builds upon the themes developed at the Future Search Conference held in November of 2007. The environmental realities confronting ORA drive the need for examination of workforce and tools. As the manufacture and trade of increasingly complex regulated products has become a global phenomenon, it has had a dramatic impact on ORA's efforts to protect consumers and enhance public health. ORA cannot be complacent in the face of such challenges, but must address them with careful planning, thoughtful preparation, and determined execution:

- 1) ORA must proactively evaluate, adjust and enhance its investigative, analytical, and enforcement tools, plus its methods and skills, to meet the changing environment and challenges of a dynamic global marketplace to maximize compliance of FDA regulated products and minimize risks associated with those products in this new world. (*Environment, workforce, tools*)
- 2) ORA must take a proactive, global approach to regulating products to succeed in fulfilling its mission since globalization is a phenomenon expected to continue and likely accelerate into the future. This must include the design and implementation of new approaches to the regulation of imported products, and must proactively address their safety and efficacy at every point in the product life cycle from manufacture to consumption by U.S. consumers. This approach will include:
 - partnering with other Federal agencies with responsibilities at the borders,

- holding domestic manufacturers responsible for the safety of ingredients used in their products,
 - positioning ORA employees in countries of interest that export a high volume of regulated product to the U.S., and
 - providing additional training to industry, and developing and implementing incentives for voluntary compliance, such as audited certification programs. (*Environment*)
- 3) ORA must proactively ensure that its efforts have global as well as domestic impact; it must multiply its effectiveness by partnering with other regulatory bodies around the world, and with other federal, state, and local agencies in the U.S. These partnerships would promote exchanges of:
- data, methods, and training opportunities,
 - mutual acceptance of laboratory and inspection results,
 - a seamless regulatory system for food, and
 - certifications pertaining to FDA regulated products. (*Environment, workforce, tools*)
- 4) ORA must enhance compliance of regulated products by developing and processing effective and timely enforcement actions aligned with agency priorities. (*Environment*)
- 5) ORA must bolster its ability to deter noncompliance through strategic and risk-based deployment of its inspection and enforcement resources. (*Environment*)
- 6) ORA must commit to continuous improvement and Quality Management Systems at all levels of its organization. (*Environment, workforce, tools*)
- 7) ORA must acquire and retain needed and specialized skill sets through recruitment, training, certification, and strategies for retaining skilled employees. In addition, ORA must proactively develop and implement an effective succession plan, especially to cultivate supervisors and managers to ensure continuity of mission, leadership, and the talent pool necessary for the future of the Agency. (*Workforce*)
- 8) ORA must provide critical mission and administrative support to its employees. (*Tools*)
- 9) ORA's global workforce must be supported by global communication and data tools. (*Tools*)
- 10) Together with other Agency components and federal partners, FDA must develop and utilize integrated IT systems to increase efficiency and effectiveness. (*Tools*)
- 11) With stakeholder input, ORA must conduct a strategic assessment of its analytical capabilities and invest in its regulatory laboratories to enhance its capacity to rapidly analyze regulatory and surveillance samples, and to support outbreak investigations, enforcement operations, and emergency response. (*Tools*)

12) ORA must proactively enhance its ability and capacity to respond to outbreaks, natural disasters, threats posed by terrorism, and other public health emergencies involving FDA regulated products. (*Tools*)

13) ORA must incorporate risk management in its operations by:

- identifying emerging risks through strategies such as surveillance sampling and data analysis,
- using risk management tools in collaboration with the Centers to determine public health risk and set priorities for resource allocations, and
- developing data systems and analytical capabilities to support its risk-based approach that are supported by customer driven, modern regulatory software applications.
(*Tools*)

14) ORA must identify changes and additions to current regulatory authorities needed to address the increasingly complex products and processes it regulates and the global marketplace in which those products are manufactured and used. (*Tools*)

15) ORA must communicate and collaborate effectively with the Centers and other Agency components to ensure coordination of efforts, such as development of proactive enforcement strategies, to protect and promote public health. (*Environment*)

Analysis of External Environment

Regulatory Challenges

ORA must analyze and understand its external environment to fully realize the potential of its Revitalization Vision for the Future. In this context, the regulatory challenges facing ORA cannot be understated. The primary backdrop for these challenges is the changing world in which ORA must operate. Technological innovations such as the internet have led to instantaneous communication around the world, providing a global marketplace for consumers. Ease of access to shipping mechanisms, such as overnight services, has made delivery of products to the U.S. market more efficient and widely available. The surging global economy has led to more FDA regulated products being manufactured overseas. World economies have a greater interdependence on one another, so events that occur in one nation may impact many others. It is no longer enough to have a robust system focused on regulating domestic production of food and medical products: ORA must have the capacity and capability to establish, maintain, and continually improve a regulatory system designed to succeed in an era of globalization.

Globalization and the interdependence of the world's economies have led to several factors that impact ORA's regulatory structure. The volume of imported products entering the U.S. has increased dramatically. Approximately \$2 trillion worth of imported products enter this country

each year; experts project that volume will triple by 2015.⁶ In the last five years, the volume of imported products has doubled, and 60 percent are food or food-related.⁷ Products that were once manufactured domestically are now being produced abroad; it is more difficult and costly for FDA to directly oversee production at such facilities. Advances in technology have made products more sophisticated and manufacturing processes, both in the U.S. and overseas, more complex.

Additional challenges have emerged in food safety and other arenas. Changing demographics, such as the aging U.S. population, means that more citizens are susceptible to food-borne illness. Consumers have also changed their eating habits, exerting preferences for more convenient items and minimally processed and healthier foods. This trend has an impact on the number of people who may be exposed to food-borne illness since, for example, produce from one farm can be processed and distributed across the nation into thousands of different pre-packaged salad bags affecting thousands of households. Additional challenges, including natural disasters such as Hurricane Katrina; continued awareness of the threats posed by terrorism; and discovery of emerging pathogens associated with food-borne illness, have demonstrated the need for ORA to be flexible in its emergency response and to have effective crisis management systems.

Institutional and Business Process Challenges

ORA's institutional and business process challenges also must be assessed to fully analyze the impact of ORA's external environment on the process of planning for the future. The changing nature of FDA's regulated industries, both in complexity and in location, requires significant flexibility in ORA's staff. Currently, ORA has offices in 49 of 50 states and Puerto Rico and the Virgin Islands, which helps ORA retain needed flexibility to respond quickly to emergencies. However, the global nature of the development, production, and distribution of FDA-regulated products requires ORA to regulate foods and medical products from many locations across the world, not just across the country. The geographic distribution of ORA's staff, while a strength unique to ORA within the FDA structure, presents special challenges regarding effective communication and management throughout the organization, and in obtaining appropriate coordination and consistency across multiple locations.

Because of the increasing sophistication and complexity of FDA-regulated products, ORA's workforce needs to be highly skilled, with scientific and technical expertise in numerous areas, to effectively regulate its industries given the climate of emerging technological innovation. ORA must also be able to continually evaluate and update the technical and professional skills of current employees while simultaneously developing plans for obtaining any skill sets lacking. In addition, mission and administrative support are critical to ORA's structure so operations run smoothly and personnel can dedicate full attention to their assigned duties.

ORA's success depends on having an adequate number of staff with the necessary education, skills, abilities, and experience. Succession planning is a critical challenge for ORA because 20

⁶ Statement of Randall Lutter, Ph.D., Deputy Commissioner for Policy, FDA, before the Committee on Energy and Commerce, Subcommittee on Health, U.S. House of Representatives, on "Regulation of Imported FDA-Regulated Products," September 26, 2007.

⁷ Ibid.

percent of ORA's workforce is eligible for retirement currently with another 15 percent eligible in the next five years. This expected loss of institutional knowledge and expertise necessitates greater focus on recruiting and training new staff and the development of succession planning for a continuance of leadership.

ORA must also enhance its collaboration with the Centers in the face of Agency structural challenges. Overlapping and sometimes poorly defined roles present difficulties in many different contexts, such as case development and processes for clearing documents within the Agency. In some areas, Center and ORA responsibilities may not be clearly defined, and communication and partnerships must be relied upon to overcome these structural challenges.

FDA has initiated a Business Process Improvement Initiative to critically evaluate and improve core business processes throughout the Agency. FDA leaders selected ten processes to evaluate through collaboration of Agency components and study by external management consulting firms. ORA will be directly involved in four of the studies: Risk-based Workplanning for Foods and Feeds Programs; Import Alerts Issuance; Warning and Untitled Letter Issuance, and Implementation of the Food Protection Plan and Action Plan for Import Safety. These four studies examine significant aspects of ORA operations and create potential opportunities for ORA to evaluate current processes with participation of the Centers and Office of the Commissioner, while engaging business consultant expertise. Once the studies are completed, the results will be incorporated into ORA operations as appropriate.

New Initiatives, Authorities and Resources

Import Safety

Another pivotal consideration in fully understanding ORA's external environment is the impact of new initiatives, authorities, and resources. In recognition of the changing world in which the U.S government operates, the Interagency Working Group on Import Safety was formed by President Bush. Led by Health and Human Services Secretary Leavitt, the working group submitted its initial report in September of 2007. That report outlined an Import Strategic Framework to build upon existing efforts to improve the safety of imported products:

- Ensure all federal agencies work together with shared objectives,
- Improve accountability by developing better tools for linking products to manufacturers, distributors and retailers, and verifying supplier and producer compliance with safety standards,
- Focus on risks over the life cycle of an imported product,
- Build interoperable data systems across government agencies,
- Foster a culture of collaboration among federal agencies as well as with external partners (state, local and foreign governments and the importing community), and
- Develop and apply new technologies to identify and mitigate risks.

The Action Plan for Import Safety that followed was issued in a Report to the President in November of 2007.⁸ It is organized under three key principles: prevention, intervention, and response. By focusing on the life cycle of a product from its creation to use by the consumer, all aspects of the Action Plan serve to bolster these core principles and improve the safety of imported products. Although many of the recommendations either involve or have an impact on ORA, some have a more direct impact than others, and may require dedication of resources for effective implementation. Examples include the following:⁹

Prevention

- *Recommendation 2, Verify Compliance of Foreign Producers with United States Safety and Security Standards Through Certification*, impacts ORA's import operations. For instance, mandating certifications based on risk for products coming from particular countries, regions or producers, as well as encouraging voluntary certification programs through incentives or other means, would enable ORA to focus attention and resources on other products being offered for import that may be of greater risk to consumers. (*See Revitalization Proposal 8*)
- *Recommendation 3, Promote Good Importer Practices*, is designed to encourage importers to ensure that the products they bring into the country meet U.S. standards. Development of risk based, concrete guidelines for importers to use in evaluating products, based upon due diligence and preventive control principles, would result in more compliant products being offered for import so that ORA can dedicate its efforts to products of greater risk.
- *Recommendation 4, Strengthen Penalties and Take Strong Enforcement Actions to Ensure Accountability*, includes provisions to permit FDA to refuse admission of imported products where access to manufacturing records has been denied, for example, and to provide destruction authority for refused medical products. Both of these tools would be valuable to ORA's import operations and would serve to prevent potentially unsafe or dangerous products from reaching consumers.
- *Recommendation 5, Make Product Safety An Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities*, which cites establishment of an FDA presence in foreign embarkation ports as an example of how this recommendation could be achieved, would provide ORA personnel with expedited access to foreign sites linked to injury or illness reports in the U.S. (*See Revitalization Proposals 2 and 7*)

Intervention

- *Recommendation 6, Harmonize Federal Government Procedures and Requirements for Processing Import Shipments*, would enable ORA to work more cohesively with its

⁸ This Report can be found in its entirety at www.importsafety.gov.

⁹ The Action Plan for Import Safety is generally supported by ORA Revitalization Proposals 1 – 9, found on pages 30 to 35. Links to specific recommendations contained in the Action Plan are noted as appropriate.

partners in border ports and other import operations to increase efficiency and leverage available resources, for example, by co-locating employees to enhance targeting and risk-management decisions, and by cross-training and cross-utilizing employees to improve coverage at remote or small volume ports of entry.

- *Recommendation 7, Complete a Single-Window Interface for the Intra-agency, Interagency and Private-sector Exchange of Import Data*, would, for instance, create a data service to centralize relevant establishment data, an effort of tremendous help to ORA field operations since research about firms would be streamlined and more detailed information about imported products would be available from a single source. (See *Revitalization Proposal 9*)
- *Recommendation 9, Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards*, which includes enhancing ORA's laboratory capacity for testing and development of analytical tools for rapid screening of products. Rapid test methods would enable the laboratories to protect public health by providing tools to more quickly detect risks, permitting more rapid action against problematic imports. (See *Revitalization Proposals 3 and 6*)

Response

- *Recommendation 11, Maximize the Effectiveness of Product Recalls*, would authorize mandatory recalls for food products when voluntary recalls are ineffective or unreasonably delayed, and thus provide ORA with an effective tool to assist with its recall activities.
- *Recommendation 12, Maximize Federal-State Collaboration*, involves greater use of cooperative agreements with state counterparts, plus increased information sharing and review of policies regarding state laboratory results to improve their use as evidence. ORA will play a major role in executing this recommendation since the organization enters into these agreements with our state partners on behalf of the Agency, and engages in evidence development in its compliance and enforcement activities. (See *Revitalization Proposals 5 and 6*)
- *Recommendation 14, Expand the Use of Electronic Track-and-Trace Technologies*, involves the ability to track imported products throughout their life cycle, from their source through manufacturing and distribution to consumers in the U.S. Track and trace technologies would be a valuable tool for ORA in conducting trace backs of harmful products, stopping further distribution, and coordinating product recalls.

Food Protection

Similarly, FDA's Food Protection Plan is organized around the central themes of prevention, intervention and response, yet is focused on the specific challenges posed by food safety and defense. Nevertheless, the two efforts are intertwined, and ORA's plan for revitalization must be assimilated to ensure that all move forward in a cohesive manner. Although ORA has a vested

interest in all aspects of the Food Protection Plan,¹⁰ those of particular impact in the integrated plan include the following:¹¹

- *Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses* by analyzing food import data for trends, then using a risk-based approach to integrate data and to focus inspection resources. (See *Revitalization Proposals 1, 2, and 9*)
- *Focus Inspections and Sampling Based on Risk* through identification of real-time diagnostic instruments and methods for on-site screening of samples; training of investigators on new and technically complex manufacturing processes; and collaboration with foreign authorities. (See *Revitalization Proposals 1, 4, 5, and 6*)
- *Enhance Risk-based Surveillance* by conducting inspections with tools that target high-risk firms, and using advanced screening technology at the borders. (See *Revitalization Proposals 3, 4, 8, and 9*)
- *Improve Immediate Response*, including recommendations to provide FDA with mandatory recall authority for food products when voluntary efforts are ineffective, and enhanced food record access during emergencies. (See *Revitalization Proposals 3, 4, and 6*)

Food and Drug Administration Amendments Act of 2007

In addition to the plans put forth by the Executive Branch, the Legislative Branch has engaged in activities that have an impact on ORA. There are and will continue to be legislative initiatives offered to address the challenges frequently encountered by FDA and ORA, such as those that have arisen in the context of food safety and imports. During 2007, Congress passed the FDAAA, which was signed into law on September 27, 2007. This new law represents a significant addition to FDA authority. Similar to the initiatives outlined above, FDAAA will have an overarching impact on ORA.¹²

In addition to re-authorizing prescription drug and medical device user fees, FDAAA also contained provisions with a direct connection to ORA operations. One example is *Section 1003, Ensuring Efficient and Effective Communications During a Recall*, a process in which ORA plays a pivotal role for FDA as the focal point for information, advice, and recall operations in the field. This section requires FDA to work with companies and others to collect and aggregate information about recalls; to enhance quality and speed of public communications using existing networks, including electronic forms of communication; and to post information on FDA's website about human and pet food recalls in a single, searchable database that is accessible and

¹⁰ The Food Protection Plan can be found in its entirety at www.fda.gov/oc/initiatives/advance/food.html.

¹¹ The Food Protection Plan is generally supported by ORA Revitalization Proposals 1 – 9, found on pages 30 to 35. Links to specific recommendations contained in the Food Protection Plan are noted as appropriate.

¹² ORA Revitalization Proposals 1, 4, 5, and 6, found on pages 30 to 33, are in alignment with FDAAA. Links to specific provisions are noted as appropriate.

easily understood by the public. Another example is *Section 1004, State and Federal Cooperation*, which directs FDA to work with the states to improve the safety of food, including fresh produce, so that food safety programs and activities are coordinated and cost-effective. It also encourages FDA to provide advisory, technical, and financial assistance to the states for planning and implementing their food safety programs. (See *Revitalization Proposals 5 and 6*). ORA, in collaboration with Center colleagues, will be primarily responsible for implementing these programs.

Many other provisions of FDAAA will have an impact on ORA, including:

- *Section 228, Inspections by Accredited Persons*, which enables medical device firms to submit International Organization for Standardization (ISO) audit reports to FDA.
- *Section 913, Assuring Pharmaceutical Safety*, which calls for development of standards for identification, validation, authentication, and tracking and tracing of prescription drugs; development of a standardized numerical identifier for drug products; and expanded and enhanced resources for enforcement, all of which will assist ORA with counterfeit drug and related investigations.
- *Section 1005, Reportable Food Registry*, under which ORA will respond to reports of adulterated food, including inspection and investigative activities involving such reports. (See *Revitalization Proposal 4*)
- *Section 1006, Enhanced aquaculture/seafood inspections*, under which the inspections for aquaculture and seafood, conducted largely by ORA personnel, are to be enhanced, and which further requires submission of a report to Congress that includes a description of the aquaculture and seafood inspection program that ORA administers. (See *Revitalization Proposal 1*)
- *Section 1008, Sense of the Congress*, which recognizes that FDA needs additional inspectors to improve its ability to safeguard the food supply and additional resources to ensure food safety.
- *Section 1009, Annual Report to Congress*, which requires a yearly submission of data to Congress about food products offered for import, numbers of inspectors, and findings of inspections that will be primarily prepared by ORA.

ORA will play a leading role in implementing these major initiatives. Under the Food Protection Plan and the Action Plan for Import Safety, as well as FDAAA, ORA will be instrumental in the development and implementation of many of the recommendations and action steps, and will collaborate with other federal agencies and components of FDA in this process.

Congressional Appropriation

The FY 2008 Omnibus Appropriation provided ORA with its first substantial budgetary increases in four years. As directed by Congress, a significant portion of the increase will

support State and federal rapid response teams by awarding new cooperative funding agreements to approved States in order to support infrastructure and develop teams as well as ORA Emergency Response Coordinators. In addition, the appropriation act enables ORA to increase both operational and support staff, which will result in increased numbers of inspections, sample collections, sample analyses, and import entry examinations ORA is able to conduct. Risk-based import information technology and increases in outbreak trace back for FY 2008 were also included in the appropriation.

Analysis of Internal Environment

Stakeholder Themes and Issues

Similar to its external environment, ORA must analyze and understand its internal environment to plan effectively for the future. ORA therefore engaged its stakeholders to an unprecedented degree during its revitalization efforts. As previously noted, two meetings were held in November, 2007 with the Centers, and the information gathered was used to inform the Future Search. The Centers were asked to identify major trends that either were already having or would have a major impact on ORA in the future. The medical product centers identified globalization of commerce, technological innovations, information management, resources, and communication as themes to be considered by ORA during its revitalization efforts. Similarly, the food and feed products stakeholders discussed how the world was changing in several ways, including: increased imports and movement of regulated industry offshore; increased ease with which disease and outbreaks spread; terrorism; emerging or re-emerging pathogens; and increased types of contaminants, both chemical and environmental, encountered by FDA. They also identified technological innovation, resources, and higher public performance expectations with a lower tolerance for risk as issues confronting ORA.

States were likewise consulted during a 50-state telephone conference call in November 2007, and generally expressed the view that governments must engage in more proactive and less reactive approaches to public health protection. The states identified communication between the states, districts, and regions as a common concern, and expressed the need for improved website and database access. Information and data sharing were also highlighted. In addition to requesting points of contact for timely inquiries and access to expertise, the states encouraged increased use of available data. For example, one idea was to use import data to develop a national sampling scheme in which states could participate. States expressed a willingness to share their data, and encouraged development of a framework for state competency or setting standards so that ORA could utilize and rely on state findings in its compliance and enforcement activities. This framework would apply to state laboratory analyses as well as inspectional and compliance data. States also expressed interest in improved risk assessments, and encouraged ORA to have an oversight and verification role over state risk management capabilities. Development of risk profiles for imported products destined for various states, and supplemental testing by states of imported products, was likewise encouraged. States further highlighted the need for increased resources to enhance leveraging partnerships, and for additional training opportunities from ORA.

In addition to the state call and the November 2007 meetings, ORA gathered extensive information during follow up interviews with each Center and additional interviews with representatives from various components of the Office of the Commissioner, such as the Office of Chief Counsel, Office of Legislation, Office of Policy and Planning, and three Deputy Commissioners. Stakeholders were encouraged to speak freely and openly; no topic was excluded. ORA probed these internal stakeholders for information about its current state and sought direction for the future.

ORA Strengths

Although each entity viewed ORA from a different perspective, several common themes emerged when queried about ORA's strengths:

- Crisis management and emergency response;
- Dedication and active engagement of ORA employees to their public health mission;
- Quality, professionalism, experience and accessibility of employees;
- Geographically dispersed, flexible workforce;
- Depth of knowledge about FDA, regulated industry, and respective regions; and
- Relationships built both inside and outside of FDA, including with state and federal agency regulatory partners.

There were some differing opinions about ORA's successes. For example, there were mixed views on the laboratory work products. Some stakeholders emphasized the excellent laboratory work done, especially in emergencies, while others identified opportunities to improve lab practices, throughput, and quality. While the fact that ORA offices were spread across the country was lauded, it was also identified as a source of management challenges. Further, although relationships with outside entities were viewed as a strength, it was mentioned that relationships with the states should be more comprehensive, such as by sharing inspectional data to eliminate duplication of work and to enhance risk-based planning.

Areas for Improvement

Areas for improvement were also discussed by stakeholders. Resource constraints were a compelling factor for stakeholders since ORA must function with limited resources in the face of ever increasing demands on its time, and competing priorities for its attention. It was expressed that ORA should have a national strategy for resource allocations to encourage flexibility. ORA's position within FDA was also discussed: some stakeholders expressed the opinion that ORA should be more engaged in policy development and take a more active role in leading compliance and enforcement activities within the Agency, but other stakeholders appeared to take the opposite view, stating that ORA should narrow its portfolio to focus more on its core work of inspection operations and management of those operations. The stakeholders were generally in agreement in expressing the following areas for improvement:

- Need for better communication, coordination, and consistency between and among:
 - Districts and Regions,
 - Districts and ORA Headquarters,

- ORA Investigations and Compliance Branches, and
 - ORA and the Centers.
- More consistent management, business processes, and work quality across districts;
- Improvement of management accountability and systems to ensure the quality and consistency of inspections and related work products;
- Engagement of a wider range of personnel rather than depending on a small group of key personnel for interacting with stakeholders;
- Increase direct contact between the Centers and field personnel, enhanced communication between the Centers and ORA at the working level, and less ORA headquarters control over such communication;
- Increase consensus and shared understanding of the application of risk-based approaches to ORA's work;
- Examination of performance goals and work plans which emphasize inspectional numbers that may not adequately capture public health outcomes;
- Greater investments in enforcement, because strategies vary by district, case numbers are down, and expertise in building and presenting cases has declined.
- Need to increase quantity of foreign inspections and proportion in relation to domestic inspections, for example, by creating a dedicated foreign inspection cadre;
- Need for FDA-wide IT system improvements that support integration throughout Agency components;
- Expand and increase leveraging with federal, state, and foreign regulatory counterparts, and in some cases third parties, including greater reliance on state data;
- ORA is perceived as being too rigid, resistant to change, and unresponsive to new or different ideas, and too concerned with losing its span of control or turf; and
- ORA should shift away from a reactive approach which leaves insufficient resources for strategic investment and longer-term proactive activities (e.g. prevention).

Current and Future Opportunities for ORA

ORA also asked stakeholders for their input on opportunities currently presented to ORA or envisioned for the future. Stakeholders generally perceived opportunities in the following areas:

- To improve work planning and long term strategic planning, balanced against the need to maintain daily operations;
- To support ORA's workforce by:
 - obtaining people with needed expertise to regulate the industry most effectively,
 - ensuring that new hires understand the job and are motivated to succeed,
 - planning for future retirements,
 - providing needed training, and
 - retaining employees through enhanced grade structure and salary;
- To improve the use of technology throughout the organization;
- To develop meaningful changes as a result of new initiatives, such as the Food Protection Plan and ORA revitalization effort;
- To focus on prevention and how that focus will change operations;
- To more fully invest and engage in risk management;

- To engage in rigorous data analysis to identify risks and target priorities;
- To foster collaboration, building partnerships within and outside of FDA from management through all levels of employees;
- For employee details and exchanges between the districts and headquarters (including the Centers);
- To conduct more surveillance work to better inform future prioritization and targeting;
- To improve communication through strategic planning and more proactive outreach;
- For FDA to have a presence abroad; and
- To reinvigorate FDA's reputation.

Current and Future Threats to ORA

Finally, stakeholders were asked to provide their perspectives as to threats posed to ORA. The following ideas were shared:

- Loss of institutional knowledge with retirements, difficulties in training new hires, and succession planning;
- Possibility of being shortsighted and maintaining the status quo instead of planning for the future and being proactive;
- Interventions from outside sources;
- Increasing sophistication of regulated products which requires greater expertise;
- Impact of the internet;
- Rise in imported products and ORA's corresponding role in border work;
- Emergency response activities that leave other work uncovered; and
- Lack of public trust in government, and increasing external demands.

Ideas for the Future

During the course of the stakeholder interview process, many consulted offered specific ideas for consideration by ORA as it plans for the future, such as:

- Development of a SWAT team to respond to emergencies;
- Increasing specialization of investigators, including creation of inspectorates dedicated to particular product areas to increase expertise (although other stakeholders recognized the need to maintain flexibility to respond to crises);
- Utilizing contractors for recall effectiveness checks;
- Creating an international affairs office or liaison within ORA;
- Changing processes to encourage collaboration with Centers as work is performed, or development of a triage system that includes the Centers;
- Development of mechanisms to evaluate and implement new detection technologies and to streamline validation;
- Development of systems that encourage consistency and accountability for performance, and to ensure that work products and inspections meet basic standards outlined in policy documents;

- Development of mechanisms to ensure feedback from and between the Centers and ORA; and
- Development of a list of experts within each Center for quick access by ORA personnel when needed.

Institutional and Business Process Issues

ORA's institutional and business process challenges also must be assessed to fully analyze the impact of ORA's internal environment on the revitalization planning process. Stakeholders articulated a wide variety of thoughts and concerns, yet there was significant overlap despite their diverse perspectives. These commonalities not only demonstrate what is right and good about ORA, but also present strong arguments for needed improvements. The areas of consensus cannot be overlooked as ORA plans its future course. In fact, many of the concerns raised by stakeholders fit squarely under the three primary challenges identified by ORA during the revitalization process: environment, workforce, and tools. The stakeholders expressed strong views about the changing world, and how ORA must adapt to the impact of globalization on its operational structure. Further, workforce issues such as loss of expertise and succession planning were highlighted, as were improvements needed to ORA's tools, including IT systems and data analysis capabilities.

In addition, a recurring theme that emerged among many of ORA's stakeholders was concern that the roles and responsibilities of the Centers and ORA are not clearly defined, resulting in a lack of shared understanding about them. This lack of clarity causes tension and discord between ORA and the Centers and decreases efficiency of business processes related to inspection, laboratory analyses, compliance, and enforcement. Achieving greater clarity in this area would allow ORA to more effectively collaborate with Agency stakeholders and improve its operations.

Performance goals also warrant further examination since ORA's impact on public health cannot be adequately captured under the current system. ORA's performance goals focus disproportionately on outputs, such as numbers of inspections, which do not necessarily reflect the broader priorities of compliance, risk management, and public health protection. These outcome focused performance goals have been difficult to measure, as has showing increased performance each year. ORA's ability to shift its investigative workforce to meet newly identified needs is also hindered as many resources are already committed to meet existing performance goals. Nevertheless, ORA continually responds to all public health emergencies regardless of performance goals. The changing world requires a more meaningful measurement of public health protection outcomes that reflect proactive approaches based upon assessments of risk. To adequately articulate these outcomes, ORA must consider and pursue other metrics to measure success in the future.

Fulfilling the Vision and Meeting the Challenges: **ORA's Revitalization Strategy**

Revitalizing ORA for the Future

As a result of this in depth internal examination and assessment of external factors impacting its future, ORA concluded that it must revitalize and commit to several improvements to confront the primary challenges presented by its environment, workforce, and tools:

- ORA must proactively anticipate and plan for its operating environment to ensure readiness of its workforce and tools. ORA must view its mission and operations in the context of a thriving global economy with increasingly complex products and production technologies, and use this perspective to develop strategies for meeting these challenges. The increase in imports requires an approach that is responsive to globalization and recognizes that ORA must focus on the entire life cycle of products it regulates. Collaboration and leveraging with federal, state, and foreign regulatory partners will be a key aspect of this approach since such partnerships will enhance coverage of these products to tackle the global breadth of this task.
- ORA must develop a skilled workforce to meet the demands of increasingly complex products. Expertise may be needed in the following areas: epidemiology; risk and data analysis; statistics; emergency response; analytical and microbiological laboratory instrumentation; food technology; nanotechnology; industrial, electrical, pharmaceutical, and biomedical engineering; medical imaging technology; and veterinary medicine. To fill these voids in expertise, ORA must not only recruit skilled employees, but simultaneously cultivate and advance existing employees to encourage them to build their careers in ORA. Succession planning must ultimately be the cornerstone for building ORA's talent pool and leadership in the face of continued challenges in the future. As ORA moves forward with these plans, it may be advisable to conduct a more formal skills assessment of its workforce.
- A commitment must also be made to improve the tools ORA uses to perform its work. ORA laboratories must be state of the art and at the cutting edge of new technologies and science. Laboratories must have enhanced high volume rapid throughput capacity, flexibility, and enhanced capability to meet the demands of the changing world. ORA's information technology infrastructure must be modernized, and data systems must support risk-based analysis and regulatory decision making. ORA must adapt its tools and approaches to the changing global regulatory environment and to support its workforce operations.

The Strategic Objectives that form the ORA Revitalization Strategy

Of paramount importance is ORA's ability to shift from being reactive to proactive: preventing harmful products from reaching U.S. consumers is the ultimate goal. The revitalization effort revealed strategic objectives that helped to formulate and guide ORA's strategy for the future. In order to achieve the Revitalization Vision for the Future previously outlined in this report, ORA

utilized the Strategic Frame and five strategic objectives developed at the December 2007 meeting. When combined, the Strategic Frame and five strategic objectives form the ORA Revitalization Strategy for the future. This Strategy addresses ORA's environment, workforce, and tools, and engages these challenges in a proactive manner. The five strategic objectives, which evolved from the Strategic Frame, are to:

1) Ensure continuity of mission and leadership.

To achieve this objective, ORA must have a highly skilled workforce that has sufficient mission support to operate efficiently. ORA must retain its employees by emphasizing professional development and quality of work life, providing opportunities for advancement, and cultivating its leadership for the future. Where skill sets are lacking in the workforce, efforts must be made to fill such voids by recruiting professionals with needed expertise, and through training and certification opportunities offered to current employees. (*Workforce*)

2) Foster regulatory compliance throughout the life cycle of imported and domestic products.

ORA must be proactive to foster industry compliance for all products regardless of their point of origin. Surveillance plays a fundamental role in proactively targeting resources, establishing risk models, and determining the current state of compliance within industry. Effective domestic and import enforcement promotes voluntary compliance in the domestic arena. A strong enforcement program is necessary to maintain a credible deterrent and maximize voluntary compliance. For both domestic and imported products, compliance can be encouraged by holding domestic manufacturers accountable for the safety of ingredients used in their products and by developing incentives for voluntary compliance such as audited or verified certification programs. Additional efforts to address imports include partnering with other federal agencies with responsibilities at the borders and increasing capabilities to inspect foreign establishments. (*Environment*)

3) Enhance tools and scientific resources.

Critical mission and administrative support is vital to ORA's workforce, as are improvements to IT systems and equipment. Investments in regulatory laboratories to increase capacity and capability to rapidly analyze regulatory and surveillance samples, and to ensure responsiveness to outbreaks and other emergencies, would further enhance ORA's response to its dynamic environment. Global communication and data tools are also necessary to ensure successful international and domestic operations. ORA should further identify changes and additions to current legal authorities that would enhance responsiveness to the increasing sophistication of regulated products and the complexity of manufacturing processes in the global marketplace. (*Environment, workforce, tools*)

4) Embed scientific risk-based assessments and approaches.

ORA must identify emerging risks through strategies such as surveillance sampling and data mining, and use risk assessment tools in collaboration with the Centers to determine public health risk and set priorities for resource allocations. Data systems and analytical capabilities must be developed to support ORA's risk-based approach, and which encompass customer driven, modern regulatory software applications. (*Environment, tools*)

5) *Encourage collaboration and leveraging to maximize regulatory impact.*

ORA must leverage resources with its federal, state, local, and foreign counterparts to ensure it has the breadth of coverage necessary to regulate in the new global environment. Memoranda of Understanding and Agreement with federal or foreign regulatory counterparts are useful tools in such partnership efforts. In addition, industry must play an active role in ensuring that its products are safe and must be held accountable for that responsibility. Development of industry guidance to encourage best practices, for example, among importers, fosters corporate responsibility to protect public health. Third party certification with verification programs also provide opportunities for industry to ensure compliance. (*Environment, tools*)

ORA's Revitalization Strategy Implementation

Throughout December of 2007, the work groups developed numerous proposals and further refined 28 specific proposals into business cases that address the primary challenges of environment, workforce, and tools. To guide the development of these business cases, each of the workgroup leaders were asked to monitor comments received on ORA Corner and from the ACRA office visits, and to review the new initiatives and legislation. These detailed business cases (Appendix 1) included goals that support the ORA Revitalization Strategy, and included multiple action steps and milestones to reach full implementation. The proposals are in general alignment with ORA's Revitalization Vision for the Future discussed previously in this report. Moreover, all of the proposals contain elements that address one or more of the five strategic objectives above.

Some of the business cases contain preliminary assessments of the resources needed to move forward with each proposal. These resource considerations were developed by the work groups in the context of their particular area of expertise. Since ORA is responsible for a broad array of activities, it must engage in a systemic approach to resource allocation to ensure the appropriate balance and distribution for its varying responsibilities. It is the responsibility of ORA managers to ensure that this distribution is achieved in a manner that aligns with identified Agency priorities and appropriations commitments, and to identify the sequence of funding allocations.

The Congress enacts annual appropriations that set out the parameters in which ORA must operate. The FY 2008 appropriations cycle emphasized a Congressional directive to reverse the decline in ORA staffing. As such, the FY 2008 Omnibus Appropriation provided funding increases for ORA that have been targeted to increase the number of employees. ORA must plan appropriately for this large scale hiring initiative to ensure that employees with the right mix of skill sets in the right geographic locations are hired while bearing in mind ORA's three primary challenges of environment, workforce, and tools.

Implementation Staging

Accordingly, since resources are not unlimited, a mechanism was developed by ORA management to stage the 28 proposals for further analysis, development and implementation (Appendix 2). The proposals were first examined for degree of alignment with the five strategic objectives. The 15 proposals identified as having the most immediate and significant alignment with the strategic objectives were then further analyzed. The Food Protection Plan, Action Plan

for Import Safety, and FDAAA demonstrate the federal government's commitment to addressing the changing world and global environment in which ORA must operate. They also served as a driving force for the revitalization effort, and the work groups were tasked with explaining how each of their proposals addressed provisions of these initiatives or the legislation in their businesses cases. Accordingly, ORA focused next on evaluating the business cases to determine which proposals most actively and fully support ORA's efforts to implement these initiatives and legislation. Staging these particular business cases for further analysis promotes synergy between ORA's revitalization and previously identified Agency and federal priorities as implementation efforts proceed.

In addition, several business cases were identified as key enablers that address overarching operational needs essential to successful implementation of the new initiatives and FDAAA, and to ensuring that ORA is responsive to appropriations mandates. ORA must have a skilled workforce, critical administrative support for its mission, and Quality Management Systems throughout its organization. Without these components, any plan for ORA's future will be incomplete.

Implementation Considerations

Although the work groups dedicated substantial time and effort throughout December 2007 to their development, largely due to the time pressures faced by the work groups in completing their assignments, all of the business cases require additional work and study to ensure effective implementation. In addition, some of the proposals and action steps identify new authorities that would enhance ORA's ability to achieve the Revitalization Vision for the Future. The new authorities identified will be referred to the Office of Legislative Affairs and other FDA components for their consideration as they analyze Agency legislative needs and priorities. Agency legislative initiatives are further reviewed and analyzed in accordance with the legislative development process, which involves the Department of Health and Human Services and the Office of Management and Budget, to systemically assess legislative needs and priorities both at the Department level and across the federal government.

Ultimately, 13 proposals were initially identified for stage one analysis and further development towards implementation based upon the above staging criteria. Although ORA's focus will first be on these 13 proposals, the remaining 15 proposals will be analyzed in a similar manner as the revitalization process moves forward since all of them may contain ideas of merit that are worthy of further consideration, or ideas that may support other Agency initiatives. The analyses of both the first and later stage proposals will help ORA determine the aspects of each proposal that it is able to pursue given resource considerations and competing Agency priorities, and the sequence in which they will be implemented. It will also assist with identification of specific action items in one proposal that could be combined with action items contained in another proposal. In addition, there may be some action items within a given proposal that have little or no cost, make sound business sense, and can be easily achieved within a short period of time. Others may require more careful planning and assessment before they can be fully implemented, and there will be some that ultimately are not pursued or adopted. Nevertheless, each business case has components that will be used to chart ORA's course for the future.

Proposals Recommended for Stage One Analysis, Further Development, and Implementation Based upon Alignment with Five Strategic Objectives and New Initiatives and Legislation

Proposal 1: ORA Deploys its Resources Efficiently and Effectively Using a Scientific Risk-based Approach (Business Case 1.3).¹³

The goal of this proposal is to deploy resources efficiently and effectively using a scientific risk-based approach, and to ensure that ORA's highly skilled workforce has the support and resources it needs to accomplish the Agency's mission, as measured by a favorable five year trend in compliance outcomes across program areas. It addresses ORA's environment and the need for improved communication and consistency. The proposal is designed to ensure that compliance programs are current and complete; that performance goals and work plans are improved; and that more effective methods to encourage various aspects of internal and external communication are developed. The aim of the proposal is to use well planned approaches to various activities, including resource allocation; employee recruitment and retention; work planning; tracking ORA accomplishments; and communication, that are appropriately risk-based and make the best use of available resources to carry out ORA's public health mission. (*Environment, workforce; Strategic Objectives 2, 4, and 5*)

This proposal addresses Section 1006, "Enhanced aquaculture/seafood inspections," of FDAAA. It also supports Principle 2 of the Strategic Framework developed by the Interagency Working Group on Import Safety, intervention, which requires the federal government, among others, to adopt more effective techniques for identifying potential product hazards, and Building Block 2 of the Action Plan for Import Safety, "Increase Accountability, Enforcement and Deterrence." The proposal will further assist with implementation efforts of Core Elements 1 and 2 of the Food Protection Plan, specifically Core Element 1.1, which includes strengthening FDA actions by focusing foreign inspection on high-risk firms and products, and Core Element 2.1, "Focus Inspections and Sampling Based on Risk." It simultaneously addresses stakeholder concerns about communication, consistency, performance goals, work planning, and employing risk-based approaches to ORA's work.

Proposal 2: ORA Deploys its Highly Skilled Foreign Inspection Workforce (Business Case 1.5).

The goal of this proposal, which is closely linked to Proposal 7, is to deploy a highly skilled foreign inspection workforce with timely, necessary information and appropriate resources so that significant risk-based investigational issues are targeted; its achievement will be demonstrated by reduction in public exposure to unsafe and ineffective goods of foreign origin. This proposal serves to enhance the current foreign inspection process through more effective integration of the planning process with risk-based principles, and by increasing access to tools for investigators on foreign inspection trips. It serves to address the increasingly global nature of the production of FDA regulated products and the need for enhancement in the communications and information technology tools for investigators. The application of risk-based principles to the planning process for both foreign and domestic inspections will ensure greater public health

¹³ Each business case received a number that referred both to the work group that created it, and a sequential number for tracking purposes. For example, work group 1, "Focused Inspections and Better Compliance," submitted businesses cases that were ultimately numbered 1.1 through 1.5.

protection by focusing ORA's finite resources on areas of highest risk. (*Environment, tools, workforce; Strategic Objectives 1, 2, 3, and 4*)

This proposal, similar to Proposal 7, aligns with Recommendation 5 of the Action Plan for Import Safety. The Food Protection Plan specifically highlights risk-based foreign inspections in Core Element 1.1, "Promote Increased Corporate Responsibility to Prevent Foodborne Illness," which includes the action "Focus foreign inspections on high risk firms and products." As further analysis of the business cases are conducted and implementation plans developed, Proposals 7 and 2 may be viewed in concert as part of an overarching plan to provide public health protection in light of ORA's global regulatory environment.

Proposal 3: Strengthen the Scientific Support of ORA Laboratories (Business Case 2.1).

The goal of this proposal is to strengthen the scientific support offered by ORA laboratories to investigations, imports, and enforcement operations to reduce risk and maximize compliance along the entire life cycle of FDA regulated products. This proposal addresses the rise in imported products and the need for increased surveillance sampling to help identify and evaluate risk. It recognizes the need to maintain and enhance science across FDA to maximize compliance and thereby further advance ORA's public health mission. Since the laboratories provide critical scientific support to ORA operations and other FDA stakeholders, the aim of this proposal is to ensure that the FDA has access to the best data, technology and information necessary to support regulatory science. (*Environment, tools; Strategic Objectives 2, 3, 4, and 5*)

This proposal supports Recommendation 9 of the Action Plan for Import Safety to "Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards." Moreover, it is in alignment with the Food Protection Plan since it recommends the use of advanced screening technology at the border, and implementation of an action plan for trace-back process improvements and technologies to track the origin and destination of contaminated foods, feed and ingredients. This proposal also aligns with FDA's Strategic Action Plan, including Objective 2.1, "Strengthen the science that supports product safety;" Objective 4.1, "Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution;" and Objective 4.3, "Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication." Moreover, the proposal directly supports stakeholder desire to increase surveillance efforts to better inform inspection choices.

Proposal 4: Enhance ORA's Risk Management Capability and Capacity (Business Case 3.3).

The goal of this proposal is to establish an IT enabled ORA Office of Risk Management to collaborate with the Centers in the development, establishment, and implementation of a systemic process for the assessment, control, communication, and review of risks regarding quality of regulated products. This proposal addresses the impact of globalization on the volume of imported products, changes in complexity of products, and the resulting increase in ORA's workload. Risk management is a proactive approach that relies on science and modern information technology to systemically identify potential hazards and thereby prevent harm to consumers. The aim of this proposal is collaborate with the Centers to focus available resources on high risk products and firms to maximize public health impact; to employ useful data analysis tools to prioritize and focus ORA's inspection and compliance work (both foreign and domestic);

and to enhance import screening capability. (*Environment, tools; Strategic Objectives 3, 4, and 5*)

This proposal supports FDAAA implementation efforts. Section 1002, “Ensuring the Safety of Pet Food,” requires that FDA create an early warning system to identify adulterated pet food products and outbreaks of illness, and Section 1005, “Reportable Food Registry,” mandates creation of a registry to receive reports that will permit a determination of probability that a food will cause serious harm or death to humans or animals. Risk management tools will support FDA efforts to meet these statutory requirements. In addition, the Cross-Cutting Principles of the Food Protection Plan include focusing on risks over a product’s life cycle and targeting resources to achieve maximum risk reduction. Core Elements of this Plan include focused inspections and sampling based on risk; enhanced risk-based surveillance; and improved risk communications. This proposal also acknowledges stakeholder feedback to be proactive, to more fully invest and engage in risk management, and to conduct rigorous data analysis to identify risks and target priorities.

Proposal 5: Acceptance of Inspection, Investigation and Surveillance Information from Other Sources (Business Case 4.1).

This proposal supports entering into reciprocal agreements with state, local, and foreign counterparts to accept and use information to focus surveillance activities or take appropriate regulatory action, and by developing a system for data and information sharing. The goal of this proposal is to create a seamless system whereby ORA does not expend critically needed resources duplicating work of other competent regulatory authorities. This proposal encourages data sharing among authorities so state and local regulatory efforts are factored into national safety assessments to target resources more effectively. It also aims to establish standards for food regulatory programs and thereby encourage uniform enforcement of food safety requirements nationwide; to create interoperable data systems to streamline sharing of inspection and analytical data; and to obtain data and information from foreign regulatory sources. (*Environment, tools; Strategic Objectives 2, 3, and 5*)

As previously stated in this report, Section 1004 of FDAAA encourages federal cooperation with states by directing FDA to work with the states to improve the safety of food so that food safety programs and activities are coordinated and cost-effective. It also encourages FDA to provide advisory, technical and financial assistance to the states for planning and implementing their food safety programs. This proposal is responsive to that Congressional directive. In addition, the proposal furthers the goals of the Action Plan for Import Safety since it helps to achieve “Building Block 5: Foster a Culture of Collaboration,” which encourages all parties, including federal, state, local and foreign governments, involved in the import life cycle to work together to prevent unsafe products from entering the U.S., and to take action when such products do enter domestic commerce. More specifically, it addresses Recommendation 12 of the Action Plan, “Maximize Federal-State Collaboration,” which encourages consideration of cooperative agreements between federal and state inspection agencies. It likewise supports Core Element 2.1 of the Food Protection Plan, “Focus Inspections and Sampling Based on Risk,” by encouraging the use of reliable information from other sources to leverage resources and improve product knowledge and communication with all regulatory partners. This information will help FDA target resources to achieve maximum risk reduction. This proposal recognizes stakeholder

concerns regarding the need for improved and increased leveraging with federal, state, and foreign regulatory counterparts, and in some cases third parties, including greater reliance on state data.

Proposal 6: Obtain Additional Information from Untapped Sources to Make Risk-based Regulatory Decisions (Business Case 4.3).

The goal of this proposal is to obtain additional information from untapped sources to make risk-based regulatory decisions. It addresses the impact of globalization and the need to increase the breadth of ORA's knowledge about regulated products in this new environment. This proposal aims to gather data from local, state and other federal regulatory laboratories about FDA regulated products to enable ORA to analyze and process the information to make risk-based decisions that are better and more thoroughly informed. Other possible sources include foreign regulatory authorities and academic institutions. Since FDA currently relies on data primarily from its own laboratories and sources, this effort would encourage collaboration, leverage resources and foster partnerships to advance public health. (*Environment, tools; Strategic Objectives 2, 3, 4, and 5*)

Similar to Proposal 5, this proposal is responsive to Section 1004 of FDAAA; Building Block 5 and Recommendation 12 of the Action Plan for Import Safety; and Core Element 2.1 of the Food Protection Plan. It also supports Recommendation 9, as does Proposal 3, specifically action step 9.4, "Increase the quantity and quality of data submitted by participating laboratories to eLEXNET." Moreover, it is responsive to Core Element 3.1 of the Food Protection Plan, "Improve Immediate Response," which encourages FDA to work with other federal, state and local testing labs to communicate testing results. It also addresses stakeholder concerns regarding improved and increased leveraging.

Proposal 7: FDA Foreign Presence (Business Case 5.1).

The goal of this proposal is to locate ORA liaisons in foreign countries to provide support for development of regulatory capacity, promote information sharing and regulatory collaboration, administer certification and verification programs, and to facilitate and coordinate foreign inspections within a given country. It addresses the rising number of imports, the increasing complexity of foreign products, and the shift to manufacturing and sourcing of products abroad. The proposal also engages ORA early in the life cycle of regulated products from particular countries. By obtaining useful information and intelligence from foreign regulatory counterparts, ORA will be able to more effectively analyze risk to target foreign inspection resources. Those inspections will be easier to facilitate, coordinate and conduct because of the presence of FDA personnel either in or near to the identified country. The proposal aims to support greater harmonization of regulatory requirements, increased ability to respond to emergencies, and more efficient implementation of international agreements. (*Environment; Strategic Objectives 2, 3, and 5*)

As previously noted in this report, the Action Plan for Import Safety specifically highlights establishing an FDA presence in foreign embarkation ports as a mechanism to achieve Recommendation 5 of the Plan, "Make Product Safety an Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities." In addition, since this proposal enables ORA to enhance its focus on the life cycle of

imported products, it is in alignment with both the Action Plan for Import Safety and the Food Protection Plan since both emphasize the need for obtaining information about foreign production and manufacturing in support of this focus. Further, the proposal supports Objective 4.3 of FDA's Strategic Action Plan, "Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication," since it will encourage collaboration with foreign regulatory counterparts of strategic importance because of exports to the U.S. It also recognizes stakeholder input that ORA should be proactive, have a presence abroad, and leverage with foreign counterparts.

Proposal 8: Private Laboratories (Business Case 5.2).

The goal of this proposal is to improve the reliability and validity of data FDA receives from private laboratories regarding imported products. Ultimately, this proposal builds upon the current ORA-led initiative to draft and issue guidance by mid 2008 that would set the standards for the sampling and testing of imported products, including the use of third party accredited private laboratories submitting data to FDA. Globalization of the economy has increased the number and complexity of imported products. With this increase in imports, there has been an increase in submissions from private laboratories seeking to demonstrate the absence of an appearance of violation associated with an article offered for import. Additional information or data provided through the accreditation program will assist ORA by providing greater assurance of the reliability and validity of data on which regulatory decisions are based. (*Environment, tools; Strategic Objectives 2, 3, and 5*)

Increasing confidence in private laboratory analytical results was highlighted in the Action Plan for Import Safety list of current plans to protect American consumers. Further, this proposal is in alignment with Recommendation 2, "Verify Compliance of Foreign Producers with United States Safety and Security Standards through Accreditation." The data obtained through enhanced relations with private laboratories supports Recommendation 2.2 of the Food Protection Plan, "Enhance Risk-based Surveillance."

As this proposal also includes a request for new legislative authority, ORA will be forwarding it to the Office of Legislative Affairs and other FDA components for further evaluation. ORA will continue to develop the private laboratory guidance referenced in the Action Plan for Import Safety while the proposal for greater legislative authority is being evaluated.

Proposal 9: Information Technology(IT)/Operations and Administrative System for Import Support (OASIS) (Business Case 5.4).

The goal of this proposal is to develop and implement a fully integrated IT system to analyze data on FDA regulated products offered for import. The system would utilize risk-based, active surveillance, and integrate seamlessly with all key FDA import data systems as well as those of other government agencies. This proposal addresses globalization and the increase in production and manufacturing of regulated products overseas. It is designed to incorporate more data to enhance risk-based product evaluations and thus improve the effectiveness of import entry reviews, and make them more efficient. This proposal aims to create an IT-based "targeting system" that would help reduce the number of unsafe products entering U.S. commerce by providing information on risk level; determining the need for sampling and laboratory analysis to

ascertain safety; and guiding further investigational and enforcement activities. (*Environment, tools; Strategic Objectives 2, 3, 4, and 5*)

This proposal supports Recommendation 7 of the Action Plan for Import Safety, “Complete a Single-Window Interface for the Intra-agency, Interagency and Private-sector Exchange of Import Data,” since it involves development of risk-based screening technologies to more effectively target high risk products, and because development of an implementation plan for the integration of the Standard Establishment Data Service (SEDS) module (which would create a centralized service to provide information about the import supply chain) would be encouraged. It is also in alignment with the Food Protection Plan, specifically Core Element 1.1, “Promote Increased Corporate Responsibility to Prevent Food borne Illnesses,” since it will permit analysis of food import trend data and integrate it into a risk-based approach to focus resources on imports of greatest risk; Core Element 1.2, “Identify Food Vulnerabilities and Assess Risks,” because it will enable enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize risks; and Core Element 2.2, “Enhance Risk-based Surveillance.” It further supports concerns of stakeholders that ORA improve its IT systems and engage in rigorous data analysis to identify risks and target priorities.

Proposals Recommended for Stage One Analysis, Further Development, and Implementation as Key Enablers Based Upon Overall Operational Needs

Proposal 10: Modernize ORA’s Regulatory Software Applications (Business Case 3.1)

The goal of this proposal is to modernize ORA’s regulatory software applications so they facilitate, enhance, and streamline ORA’s operations. Real-time, integrated data from throughout the Agency and beyond is needed for more efficient, reliable, and informed ORA operations. Modernization of the software applications will respond to the need for real-time, integrated data across the globe; for processing of increased data available through partnerships; and for implementation of better tracking, targeting, and decision-making processes. Further, this modernization will focus on utilizing a customer driven approach to achieve success so systems continually meet the needs of users. (*Environment, tools; Strategic Objectives 1, 3, and 5*).

This proposal supports the Action Plan for Import Safety’s Recommendation 7 which emphasizes standardizing data elements captured and facilitating data exchange among partners. The Food Protection Plan includes a section on the need for enhancement of FDA’s IT systems to help FDA better maintain, update, and search records. In addition, this proposal supports the FDA Strategic Plan Objective 1.4, Modernize FDA’s IT Platform, and Strategic Goal 4, Improve the Quality and Safety of Manufactured Products and the Supply Chain. It further addresses concerns of ORA employees and stakeholders for integrated IT systems.

This proposal serves as a key enabler to ORA’s Revitalization as well as all of ORA’s operations. One of the main concerns expressed by ORA employees during the revitalization process was the need for seamless and integrated IT to improve productivity and enhance the informed decision-making process.

Proposal 11: Adequate Resourcing of Mission Support Components (Business Case 6.3).

The goal of this proposal is to adequately resource mission support components throughout the organization to efficiently and effectively service operational programs. This proposal addresses the need for uniformity and consistency of both the mission support structures; operating procedures of these structures; and evaluation of quality of work life alternatives for all staff. With continuing changes and implementation of new Agency travel, financial management, and other administrative information technology systems, employees with limited training must dedicate additional time to their work to learn to use these systems. Through adequate staffing and training of mission support components, ORA will seek to eliminate the use of other employees, such as investigators or managers, to complete mission support work. Those not dedicated to mission support will be able to focus their time on duties such as investigations, inspections, analyses, and supervision which will more efficiently promote public health. (*Workforce; Strategic Objectives 1 and 3*)

This proposal, while not substantially linked to the Food Protection Plan or the Action Plan for Import Safety, aligns with the principles of greater protection of the public health through risk-based allocation of resources. Further, mission support is a key enabler and critical in the accomplishment of both of these initiatives, the FDAAA, and the revitalization proposals.

Proposal 12: Highly Skilled Workforce (Business Case 7.1).

The goal of this proposal is to find, train, and retain a highly skilled and motivated work force for ORA and to work collaboratively with partners to meet ORA's public health mission in a highly technical and changing world. It addresses the need for ORA to critically evaluate current and needed skill sets throughout the organization, and to develop a plan for hiring or training individuals with expertise lacking in ORA's workforce. Training is also essential to effectively regulate increasingly complex and technical products. Further, this proposal emphasizes the need for an evaluation of developmental opportunities, such as certification programs, training curricula, and work exchange programs (e.g. details) that could be made available to ORA employees to help with retention of employees and build skills for the future. Moreover, succession planning to address the leadership and technical knowledge and skills needed to compensate for the large percentage of employees eligible for retirement is essential to this proposal. The aim of this proposal is to strengthen and enhance ORA's workforce and prepare that workforce to respond to the challenges of ORA's future with a plan for ensuring continuity of skills, knowledge, and leadership. (*Environment, workforce; Strategic Objectives 1, 3, and 5*)

As previously noted, this proposal directly aligns with Congressional directives and appropriations for increases in ORA staff. Hiring new staff and training of both staff and supervisors is essential to the implementation of the FY 08 appropriations bill. In addition, FDAAA further highlighted the commitment of Congress to increase field staff in Section 1008: "It is the sense of Congress that ... additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States." This proposal also supports the Food Protection Plan's Recommendation 2.1 which includes elements of training FDA and state investigators to respond to new technology. Capacity and capability building in the laboratories; collaboration with other federal, state, local, and foreign regulatory partners; strengthening investigation and enforcement actions; and focusing resources on risk-based priorities, which are elements of all the initiatives and legislation referenced throughout

this report, are supported by this proposal's goal of a highly skilled and motivated ORA workforce.

Proposal 13: Quality Management Systems Implementation (Business Case 9.1).

This goal of this proposal is to fully implement a robust Quality Management System (QMS) that will be embedded into all operational, program, and support functions to ensure the quality of ORA's work and work products. Further, QMS will foster a culture of continuous improvement, utilization of all available tools and resources, and collaborative work, both within ORA and jointly with Agency partners, to protect the public from unsafe and ineffective FDA regulated products. Doing the right work in the right way is paramount to the success of all ORA operations, and implementation of robust QMS throughout the organization will further enable ORA to meet the challenges it faces and to implement the initiatives, legislation, and revitalization proposals. (*Environment, tools, workforce; Strategic Objectives 1, 2, 3, and 5*)

Current Activities and Immediate Actions

In addition to further analyzing and implementing the above business cases, ORA has already initiated certain activities that support the ORA Revitalization Strategy. For example, ORA is involved in the China Office initiative with the Office of International Programs and the other FDA Centers. Experience gained in that initiative should assist in developing strategies for determining the appropriate locations and interactions with other foreign countries that supply regulated products to the U.S. (*Revitalization Proposals 2 and 7*).

ORA is also actively engaged in exploring a foreign inspection cadre of investigators that will be dedicated to conducting foreign inspections for a specified time, such as a period of one to three years. The increasing demand for risk-based foreign inspections confirms that the current largely voluntary foreign inspection cadre may not meet stakeholder needs. This process, while serving ORA well in the past, may not provide sufficient resources for a more robust foreign inspection program. (*Revitalization Proposal 2*).

Other actions that are underway include:

- ORA involvement in Agency-level Steering Committees working on the implementation of the FDAAA, the Action Plan for Import Safety, the Food Protection Plan, and the MOAs with China. (*All Revitalization Proposals*)
- ORA participation in the Business Process Improvement Initiative, including the evaluation of the Foods and Feeds Risk-Based Work planning; Import Alerts and Bulletins; and Warning Letter Issuance. (*Revitalization Proposal 4*)
- ORA co-chairs the Agency-wide workgroup to harmonize registration and listing systems across all product areas. (*Revitalization Proposal 9*)
- ORA led the working group that developed the first draft of a Private Laboratory guidance that is currently under review. (*Revitalization Proposal 8*)
- ORA is engaged in an analysis of missing skill sets and beginning development of plans to recruit these skill sets in new and unique ways. (*Revitalization Proposal 11*)
- ORA will convene Course Advisory Group meeting in late January to develop courses for ORA supervisors. (*Revitalization Proposal 11*)

- A new ORA emergency response process has been drafted and is under review within the organization.
- ORA hosted a Laboratory Managers Workshop in November of 2007 to discuss the ORA Science Strategic Plan goals and objectives. An outcome was the establishment of three working groups; Drug Chemistry, Food Chemistry, and Microbiology which are using a best business practices approach to streamline laboratory processes, and enhance laboratory operations and sample throughput in ORA laboratories. (*Revitalization Proposal 3*)
- ORA's Analytical Tools Initiative (ATI) reviewed multiple commercial scientific instruments and procured two for use with field investigators and laboratory analysts to enhance ORA's scientific capabilities. (*Revitalization Proposals 1 and 3*)
- The National Sample Distributor (NSD) was initiated in October of 2007 and has successfully routed over 10,000 domestic and import samples to the FDA ORA field laboratories based upon available testing capacity ensuring samples are processed in a timelier manner. (*Revitalization Proposal 3*)
- ORA is engaged in a hiring initiative to balance the current workforce in expertise, location, and job series (e.g. investigator, support staff, and management).
- FDA has scheduled an IT Summit for March of 2008 to foster open communication, gather customer needs, and identify opportunities for improvements. (*Revitalization Proposal 10*)

The Implementation Plan

ORA Revitalization: Implementation Process

The revitalization effort has provided ORA with fundamental knowledge of current operations, and insight about future challenges involving its environment, workforce and tools. The process has afforded ORA the opportunity, together with its stakeholders, to craft a vision for the future and strategic objectives worthy of investments in time, energy and resources. The revitalization process culminated with the selection of 13 proposals for stage one analysis and development which further those objectives in light of the new initiatives and legislation impacting our operations, and which provide the support necessary to achieve those objectives. Because of time constraints facing ORA and the work groups, none of the business cases is completely and fully developed. ORA will put in place a process to manage further analysis and implementation of the 13 proposals identified for the first stage of analysis and further development, to examine and analyze the later stage proposals, and to ensure that its revitalization effort continues its forward momentum. (Appendix 3). Because the future is always dynamic, the plan must also have flexibility to respond to emerging issues and newly identified priorities.

The ACRA is therefore recommending these 13 proposals to the FDA Commissioner along with a robust implementation plan that will revitalize ORA and better position it to rise to the challenges presented by the future. The recommendation focuses initially on the 13 proposals and supporting business cases identified as aligning with the strategic objectives developed through the revitalization process and providing the most support for FDAAA, The Action Plan for Import Safety, and the Food Protection Plan. The analysis and implementation of the

business cases in the first stage will begin with creation of revitalization action groups to be led by managers from throughout the organization. Each of the leaders will be in upper management at the level of District Director or above. The leaders will be asked to gather a group of dedicated professionals with appropriate subject matter expertise to begin the process of further analyzing the 13 business cases identified for the first stage of development and implementation.

Action group membership will have a cross-representation of ORA personnel at various levels and components of the organization. The unions will also be consulted during this process. A chair from each of the work groups (which were initially selected by their respective groups) will be asked to participate in each revitalization action group to provide continuity. In addition each leader will select their action group membership to ensure subject matter expertise, to engage a variety of perspectives, and to enable staff who were not part of the revitalization process to participate. To continue the spirit of collaboration and communication developed during the revitalization process, the leaders will also seek Center, Office of the Commissioner, and state representatives, as appropriate, to participate.

The initial task of the leaders will be to convene, by telephone, the original work group that developed their assigned proposal and obtain a full briefing on the work group's findings and supporting business case. Within each business case, the leaders will need to decide which action items to schedule for immediate implementation, which to analyze more carefully, and which will ultimately not be pursued or adopted.

Revitalization Implementation: Immediate Action Steps

The 13 business cases, and some examples of the action steps on which ORA should be able to move forward immediately, include the following:

Proposal 1: ORA Deploys its Resources Efficiently and Effectively Using a Scientific Risk-based Approach (Business Case 1.3)

- Establish risk-based inspection priorities in collaboration with the Centers that take into consideration both high risk and low risk firms to ensure compliance in all parts of industry.
- Establish a formal mechanism to enhance communication between ORA and the Centers and for ORA to advise the Centers of developing enforcement cases for appropriate guidance and feedback.
- Establish procedures and time frames for compliance programs to be routinely updated.

Proposal 2: ORA Deploys its Highly Skilled Foreign Inspection Workforce (Business Case 1.5).

- Explore the establishment of a separate foreign inspection cadre of investigators that will be dedicated to conducting only foreign inspections for a specified period of time.
- Review and update standard operating procedures for scheduling and coordinating foreign inspection assignments to optimize foreign inspection resources and to provide flexibility to react to situations on the ground.
- Establish a standard operating procedure for preparing and providing the foreign inspection cadre members with timely and useful inspection related preparation material.

Proposal 3: Strengthen the Scientific Support of ORA Laboratories (Business Case 2.1).

- Develop a system to obtain feedback information from inspection, imports and compliance staffs, and from the Centers, to identify analytical technologies needed to support their regulatory operations.
- Identify a cadre of ORA national laboratory experts in program areas to support inspection and enforcement work.
- Establish a database of lab scientists, identifying experience levels and availability to participate in foreign and domestic inspections.
- Leverage laboratory data from other regulatory partners by expanding the use of eLEXNET.

Proposal 4: Enhance ORA's Risk Management Capability and Capacity (Business Case 3.3).

- Establish an ORA-wide, systematic process for the assessment, control, communication, and review of risks associated with FDA regulated products and establishments.
- Determine whether FDA's current data systems capture the appropriate and necessary data for risk-based decision making, including data from external partners and stakeholders.
- Work with CVM to establish an early warning surveillance system and notification during pet food recalls to identify adulteration in the pet food supply and outbreaks of illnesses associated with pet foods. (Requirement of FDAAA Section 1002).
- Work with CFSAN to establish a reportable food registry through which responsible parties may submit reports that there is a reasonable probability that the use of or exposure to such reportable food will cause serious adverse health consequences to humans or animals. (Requirement of FDAAA Section 1005).
- Develop a reporting mechanism to provide annual reports to Congress on imported food by country and type of food, and a listing of the number of FDA inspections performed on imported products. (Requirement of FDAAA Section 1009).

Proposal 5: Acceptance of Inspection, Investigation and Surveillance Information from Other Sources (Business Case 4.1).

- Continue Manufactured Foods Regulatory Program Standards (MFRPS) pilots with states. The MFRPS describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury.
- Establish MOUs or other agreements with other federal, state, local, and foreign regulatory authorities or third parties to share inspection and analytical data.

Proposal 6: Obtain Additional Information from Untapped Sources to Make Risk-based Regulatory Decisions (Business Case 4.3).

- Develop and implement strategic sampling and surveillance plans with state partners and other sources.
- Identify existing successful partnerships, initiatives, and projects; advance their implementation to other areas.
- Create an ORA risk-based planning team that mines external regulatory data sources in conjunction with internal data to help plan strategic sampling, inspection, and enforcement priorities.

- Promote advancement of level 1 and 2 training and certification for FDA and state personnel. A candidate, such as a new hire, becomes level 1 certified after completing broad based training (including on the job experience and classroom attendance) and after successfully passing an audit. Level 2 is more specialized training in a particular regulated product area; the candidate must likewise pass an audit before receiving certification.

Proposal 7: FDA Foreign Presence (Business Case 5.1).

- Create an ORA presence in countries that routinely export to the U.S. a high volume of FDA regulated commodities, have high refusal rates, and/or offer significant opportunities for collaboration and regulatory capacity building.

Proposal 8: Private Laboratories (Business Case 5.2).

- Produce a guidance document to increase the reliability of private lab data submitted to FDA for use in making import entry decisions, including new controls on sample collections.
- Identify the accreditation criteria and standards for entities that accredit private laboratories.

Proposal 9: Information Technology(IT)/Operations and Administrative System for Import Support (OASIS) (Business Case 5.4).

- Develop and implement ORA-wide standard operating procedures for import entry review.
- Implement the proposed Mission Accomplishment & Regulatory Compliance (MARCS) import entry review software system, with user identified enhancements.
- Enhance ORA access to Center databases via the proposed MARCS import entry review software system by fully implementing Center Views.
- Explore creation of a data-link in OASIS, an ORA database, to capture from CBP's data the time of arrival for cargo at truck ports.

Proposal 10: Modernize ORA's Regulatory Software Applications (Business Case 3.1)

- Perform a gap analysis to ascertain software deficiencies and areas that need to be changed to meet critical user needs.
- Establish and implement policies and procedures for a structured approach to software systems and applications that uses input from representative users at all levels within the organization throughout the entire development process.

Proposal 11: Adequate Resourcing of Mission Support Components (Business Case 6.3).

- Review and modify ORA's Table of Organization and allocate adequate support positions to meet mission support needs.
- Develop, approve, and fill new position descriptions that reflect the changing nature and essential contribution of mission support.

Proposal 12: Highly Skilled Workforce (Business Case 7.1).

- Identify skill sets that are currently needed by ORA and develop a process to be used to assure that ORA recruitment and training keep pace with advancements in technology.

- Develop a five year succession plan for ORA that addresses the leadership and technical knowledge and skills that will be needed due to anticipated retirements.
- Establish a base line of training approaches and technologies currently being used and design a process that could be used to identify and utilize appropriate new technologies.
- Identify needed improvements to ORA recruitment and hiring procedures.
- Identify developmental opportunities for ORA employees, such as internships and details that could be available to provide training opportunities to meet future work force needs.
- Prepare a list of incentives currently available to retain employees and identify additional incentives that could be utilized to retain ORA staff.

Proposal 13: Quality Management Systems Implementation (Business Case 9.1).

- Recruit a dedicated cadre of QMS experts to lead the design and ORA-wide implementation of a comprehensive QMS program.
- Identify, design and implement IT infrastructure needs for implementation of an ORA-wide program.
- Review and revise ORA's QMS infrastructure.
- Recruit, hire and train ORA Quality Assurance and QMS Managers.
- Communicate directives, guidelines, and policies that are necessary to initiate a uniform QMS throughout ORA:
 - Review, revise and publish ORA quality policy,
 - Publicize renewed commitment to QMS, and
 - Review and revise as needed the quality systems internal documents.

Business Case Analysis and Implementation Considerations

In addition to those action items listed above, a further examination of the business cases may identify additional action items and milestones from each of the 13 proposals for full implementation and may determine that some of the already identified items need to be modified or postponed to later stages of implementation. The examination may also determine that some of the action items should not be pursued. Once selected, the action group will develop a plan for achieving those milestones, including creation of timelines with detailed deliverables. The analysis and implementation will include continued consultation with stakeholders, focusing on collaboration with the Centers regarding their priorities and needs.

Each leader will also have a point of contact at headquarters to provide advice and assistance, and project management support to assist with their analysis and implementation efforts. The action group leaders will have frequent communication among themselves to ensure that, where overlap in the business cases is identified, their plans eliminate duplication, and to promote a systemic and strategic approach to implementation. The leaders and action groups may also refer to the later stage business cases to ascertain whether there are any supportive action steps that can be identified to further round out their respective approaches to implementation. The revitalization action groups will be overseen by the Deputy ACRA for Field Operations, who will have overall responsibility for ensuring that the action steps chosen for implementation are tied to the needs of ORA and Agency priorities.

Business Case Staging Considerations

The staging criteria used to establish the sequence of the business cases provided a mechanism by which they could be sorted. Staging decisions are not a reflection of whether one business case is superior to another, but rather provided a method for determining where to start the revitalization implementation. These decisions reflect the fact that the new initiatives and legislation have a fundamental impact on ORA operations, and are priorities for the federal government. The remaining 15 business cases have been identified for later stage analysis and implementation efforts. Those proposals are:

- Streamline reporting operations (Business Case 1.1).
- Timely, effective, and appropriate regulatory actions (Business Case 1.2).
- Obtain FDA food commodity embargo authority (Business Case 1.4).
- Respond more quickly and effectively to emerging public health safety problems (Business Case 2.2).
- Strengthen and enhance ORA laboratories (Business Case 2.3).
- IT quality management program to improve customer service and application performance (Business Case 3.2).
- Develop and implement a comprehensive IT training plan for ORA strategic applications and basic PC skills for ORA field staff (Business Case 3.4).
- Provide easy, world-wide data and communication access to improve mobility and efficiency of ORA field staff (Business Case 3.5).
- Urgent health information is widely distributed to better protect public health (Business Case 4.2).
- Designate and utilize experts in the leveraging of voluntary compliance and industry training activities (Business Case 4.4).
- Expand cooperative programs to cover high-risk ready to eat foods (Business Case 4.5).
- Import operational structure (Business Case 5.3).
- Import enforcement authority (Business Case 5.5).
- Administrative support communications (Business Case 6.1).
- Training and position descriptions for administrative support (Business Case 6.2).

Some examples of action steps from these 15 Business Cases that might be immediately pursued include:

- Develop a new Mission Support Work Group that consists of headquarters components, regional management analysts and district mission support personnel.
- Initiate regular conference calls between headquarters and mission support personnel.
- Begin to develop and implement standardized paperless and abbreviated laboratory worksheets for surveillance analyses.
- Determine an optimum laboratory management reporting scheme.
- Explore the feasibility of expanding the use of model or template warning letters or other regulatory actions.
- Establish metrics to demonstrate and evaluate the effectiveness of compliance and enforcement actions.

- Through already established field committees, work with the Centers and investigational branches to establish and coordinate priorities for analytical and sampling efforts.
- Assess commercially available rapid analytical technologies for application to ORA laboratory programs, and develop a listing of these technologies as well as procedures to ensure that this listing remains up to date.
- Review and revise the national yearly laboratory equipment purchasing process (FMD-81).
- Develop with ORA management a list of core IT training requirements for field staff.
- Develop partnerships and grants to increase recall effectiveness of FDA regulated products using existing models.
- Determine the food commodities best suited for a Cooperative Program with national uniform standards from farm to table.

A comprehensive review and analysis of the remaining business cases will be undertaken once this and the first stage analyses have been conducted. As part of the Implementation Plan, a reporting mechanism will be established to track progress at regular intervals on analyses, development and implementation of the first stage of business cases, and to identify opportunities, resources permitting, to phase in later stage business cases for analysis and development. Action group leaders will be responsible for the development of timelines and deliverables for the implementation of their area and will be held accountable for the achievement of those set goals. In addition, action groups may include in their analyses proposals previously submitted by the revitalization workgroups at the December 2007 meeting that were not ultimately developed into business cases.

ORA's revitalization must continue to address the five strategic objectives, the new initiatives and legislation, stakeholder concerns and employee interests as it moves forward. As part of the implementation of the selected proposals, ORA will develop metrics, to be used at regularly scheduled intervals, to measure progress toward achieving the five strategic objectives. ORA will reassess its established performance goals and, where appropriate, develop new or modify existing goals to better reflect ORA's public health mission and its move to a proactive approach. To the stakeholder concern regarding the need for clarifying the roles and responsibilities of ORA and the Centers, ORA will refer this issue to FDA's Management Council or other appropriate Agency body for further discussion, analysis, and resolution.

As previously noted, all legislative proposals will be forwarded, with a requested timeline for a response, to FDA's Office of Legislative Affairs and other appropriate Agency components for review as they analyze Agency legislative needs and priorities. Some of these authorities are in alignment with the Action Plan for Import Safety, such as destruction authority for medical products refused admission into the U.S., which supports Recommendation 4.6 ("Provide authority for the destruction of medical products refused admission in the United States") and authority to permit refusal of admission to imported products if access to records or facilities has been delayed, limited or denied, which supports Recommendation 4.5 ("Authorize FDA to refuse admission of imported products if access – including access to all applicable records, equipment, finished and unfinished materials, containers and labeling – to any factory, warehouse or establishment in which a product for export to the United States is manufactured, processed, packed or held is unduly delayed, limited or denied"). In addition, proposals and action steps

involving IT will be referred to the Chief Information Officer for consideration as part of comprehensive Agency approaches to IT systems development.

Continued Revitalization Process Transparency

Communication and transparency will be key components to the success of this new phase of the revitalization process, implementation, and existing mechanisms for ensuring communication will be utilized and new ones developed as needed. Communication among action group leaders is also essential since ORA must have a plan that recognizes both the value of the proposals developed, and the need to balance resource allocations across the organization. To ensure that the revitalization work groups had wide latitude to identify ORA needs and develop their visions for the future, they were encouraged to develop their proposals without considering ORA's overall budget picture in the process. They were not privy to the resource components of other work group business cases under development. Accordingly, each of the action groups must include a review of available resources and proposed expenditures in their analyses of the business cases, and ORA management must develop the appropriate balance of resource allocations. Management must also monitor implementation efforts of the FDAAA, the Action Plan for Import Safety, and the Food Protection Plan to ensure that the revitalization implementation supports and moves in concert with the strategic initiatives and legislation.

As implementation proceeds, communication and transparency must extend to all ORA employees so they continue to be engaged in the process and ultimate outcomes. ORA employees remain an integral part of the revitalization implementation, so efforts will continue to update staff on the progress of the plans and to solicit feedback. Informal communication is also encouraged as action groups identify others within ORA who may have an interest in specific developments. ORA Corner and the eRoom will remain available for use as communication tools, and all action group leaders will be encouraged to regularly post articles about their progress toward implementation. The comments section of the intranet will likewise be a place for ORA employees to anonymously provide feedback on their understanding of the current plans and suggestions for improvements. Throughout FY 2008, the ACRA will continue her visits to field offices and rely on other methods of communication, such as all hands emails and video conferences, to update employees about ongoing implementation efforts, especially after progress reports are received from the action groups once that reporting mechanism is established.

Conclusion

The revitalization process has provided ORA with great insight. It has offered a mechanism to explore the current status of ORA, to examine the impact of both internal and external environmental factors, and to identify a vision for the future of a revitalized ORA. The process has enabled the organization to articulate strategic objectives and a strategy for meeting the challenges posed by globalization. It has also provided the opportunity to reinvigorate professional ties both within and outside of the organization.

The dedication of ORA staff, all of FDA, and state partners to the revitalization process has provided ORA with a strong foundation for its future. As ORA moves into the implementation phase of this effort, this energy, spirit, and professionalism will no doubt continue. As a result of the revitalization journey, ORA is positioned to meet the challenges of the future with enthusiasm and determination, and to continue its dedication to public health protection far into the 21st Century.

APPENDIX 1

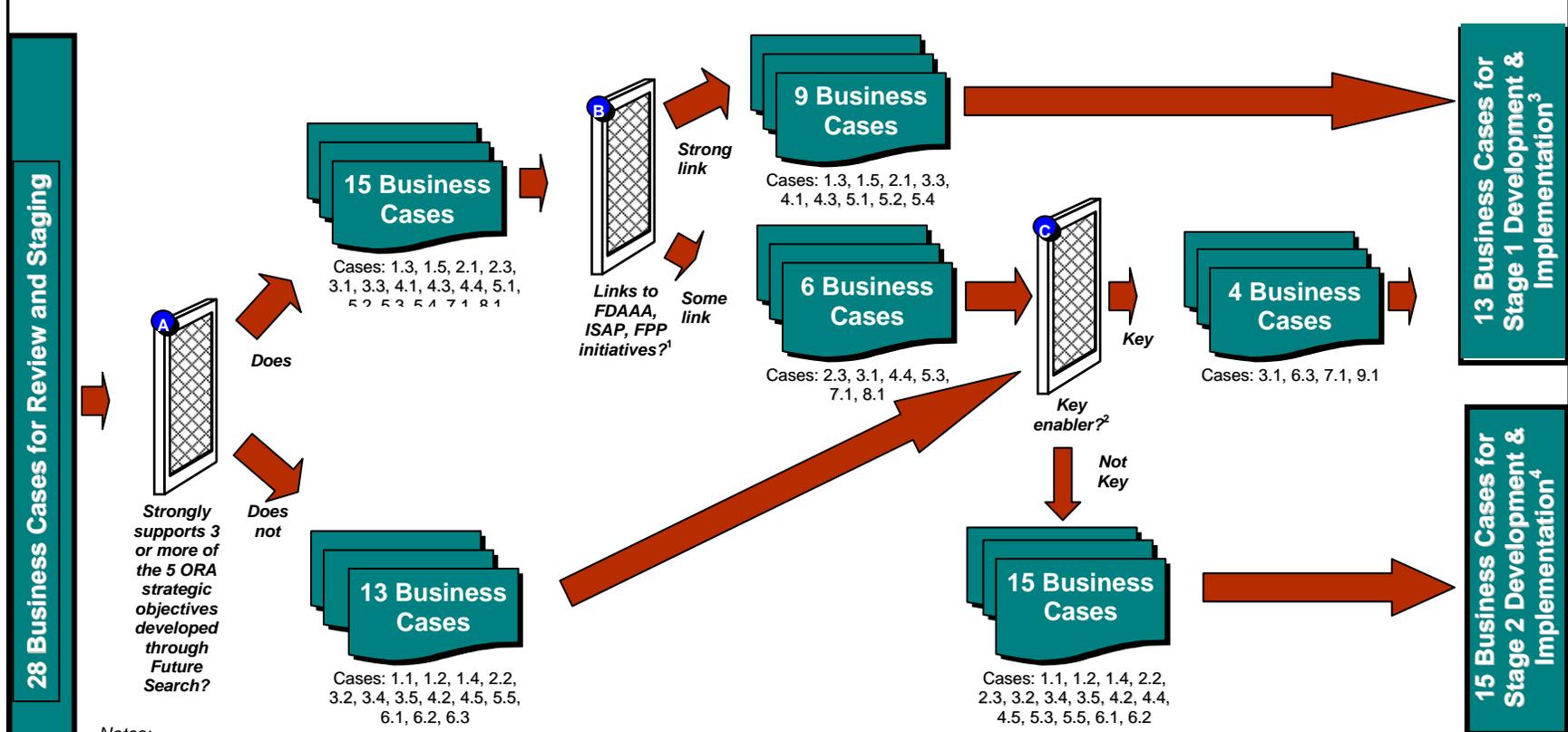
All 28 business cases are attached in this Appendix or, can be found in the FDA eRoom “ORA Revitalization Report and Business Cases” at <http://eroom.fda.gov/eRoom/ORA3/ORAREvitalizationReportandBusinessCases>.

Instructions on accessing the eRoom:

- Click the above link
- OR:
 - Open the intranet browser to Inside FDA <http://inside.fda.gov>
 - In the left-hand blue column, there should be a link to "My eRooms." Click on that link.
 - This will bring you to the eRoom site. Click the OK sign.
 - Click on the link to the appropriate eRoom name “ORA Revitalization Report and Business Cases.”
 - Pdf copies of the business cases and report are posted within the eRoom.

APPENDIX 2

28 business cases were reviewed to determine which to consider in detail now – 13 will move to further development and implementation in stage 1



Notes:

- (1): "Links to FDAAA, ISAP, FPP initiatives" denotes that business case supports work group(s) that ORA is either leading or with which ORA is substantially involved or is aligned with the core intent or specific language from one or more of the initiatives
- (2): "Key enabler" denotes case has substantial indirect, cross-cutting impact
- (3) Stage 1 business cases require reconciliation with each other and sequencing – items from stage 1 and stage 2 business cases should be considered to help fill gaps
- (4) Stage 2 business cases contain items that could be used to fill gaps in Stage 1 cases

APPENDIX 3

Implementation of the business cases should include an analysis of the relationship among cases; a master schedule and budget; and performance metrics to determine success



- ▶ Review cases to reconcile overlapping goals or action steps
- ▶ Combine cases with similar goals or action steps
- ▶ Redesign cases, as necessary



- ▶ Create a Master Schedule for the implementation of each stage
- ▶ Determine cases that provide necessary prerequisites for other cases
- ▶ Select cases for “easy wins”



- ▶ Inventory existing metrics/external expectations
- ▶ Identify key outcomes and activities for each business case
- ▶ Develop performance measures and catalogue the measures



- ▶ Develop budget for each stage of implementation
- ▶ Apply resources to the stages and implement business plans