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0. Executive Summary

Overview: This report provides a comprehensive review of the current status of CFSAN’s research, support programs, and alignment with regulatory responsibilities, along with recommendations that are intended to guide these areas moving forward. The CFSAN review was initiated under the auspices of the FDA Science Board, with the CFSAN Research Review Subcommittee (hereafter referred to as CRRS) charged to address the following six objectives within the context of the broad categories of scientific expertise and technologies that are necessary for CFSAN to fully support its regulatory functions and decision-making:

- Identify any important gaps or imbalances in scientific expertise and technological capability in which CFSAN should increase efforts to ensure that it can address the current and future demands of its regulatory role.
- Review and recommend research areas where CFSAN might reduce, maintain or expand its current levels of research effort;
- Identify opportunities to better leverage the Center’s scientific programs through partnerships with institutions and organizations of the broader scientific community;
- Determine if CFSAN is doing what is needed to recruit, develop, and retain the professional expertise needed to address current and future challenges to food and cosmetic safety, and nutrition;
- Assess and recommend management and review practices for setting priorities which will guide the direction of resources to the highest priority activities;
- Identify the most important future challenges facing the Center scientific research enterprise as well as the major institutional and systemic barriers to addressing them.

The CRRS strongly recommends that the Report be read in its entirety, and discourages against selected focus being given to particular sections (e.g. Executive Summary, Conclusions). Key findings and observations from the CRRS are contained throughout the Report and the attachments, with focus on the SWOT (Table 2, page 37, and separate attachment for more detail). The observations and recommendations can best be understood and acted upon when considered in context of the entire Report.

CRRS Members, Process and Methods of Assessment: The CRRS was composed of experts in the fields of food science, food processing, food safety, nutrition, and consumer and science communication. The multi-disciplinary composition of the CRRS, as well as the number of experts selected, were deemed necessary due to the broad scope, roles, responsibilities, and research areas within CFSAN. (See page three of the Report for further details on CRRS Members).

The CRRS carried out its work through weekly, one-hour conference calls and electronic communications, both prior to and post a two-day site visit at CFSAN (January 14-15, 2010). The CRRS took particular interest in the development of a Strategic Plan for CFSAN Science and Research, which it was notified was occurring at the same time. The CRRS did not want to duplicate the Strategic Plan work but rather sought to have its report ensure alignment,
understanding and awareness of activities, competencies and demands of the Center, where necessary. Further, the CRRS strove to keep those involved in generating the *Strategic Plan* informed of its activities.

The two-day CFSAN site visit involved an in-depth series of meetings, reviews and updates that resulted in a better appreciation of the competencies, workload, integration and focus of the scientists at CFSAN. The review of information and discussions were extensive and required additional dialogue with CFSAN lead scientists following the site visit. Details are provided starting on page 7 of the Report.

**Findings and Observations:** Findings and observations by the CRRS fell into six general categories:

- **Staffing:** The CRRS was highly impressed by the staff’s dedication to CFSAN’s mission, the quality of science demonstrated by the CFSAN staff, as well as the modern and well-maintained research facilities. However, the CRRS observed that there was insufficient support staffing in administrative and technical positions. The ratio of scientists to support staff was unbalanced and inefficient at best. Also, with respect to staffing, it is essential more effort be given to nurturing CFSAN’s ‘people pipeline’ to ensure the necessary skills, experiences and expertise are provided for legacy/succession planning, among the science functions.

- **Research:** Both laboratory and non-laboratory research are essential to the mission of CFSAN, but they need to be better integrated and fully aligned, without one being given priority over the other. Based on observations, it appears that non-laboratory research, especially in areas where food science, nutrition and consumer areas integrate and connect, receive lower priority and attention. Applied research areas related to food science, food processing, food technology and nutritional science with regulatory implications must also be given higher priority.

- **Communication:** In the current environment, where the investigation, development of scientific understanding and resolution of a problem/crisis can take significant time, it is critical that risk, regulatory science and consumer communication, including evaluation of the impact of communication on consumer understanding and behavior become an integral component of CFSAN regulatory action. This area appears to lack the attention and resources required for the challenges at hand.

- **Increased Connectivity, Interaction, Alignment and Visibility within CFSAN and with other key external and/or professional organizations, at the national and international level are essential, but insufficient within the current structure and focus.**

- **Research Prioritization:** The key to ensuring successful programmatic and regulatory outcomes related to CFSAN’s role and responsibilities is the use of science-based risk assessment, a system of prioritization, and management protocols that ensure issues and incidents of highest concern and potential impact are given the necessary resources and attention. It is critical that project outcomes support strategic outcomes. These areas do not have sufficient focus.

- **Resources.** Resources (number, depth, and subject matter expertise) are lacking at multiple levels, and will likely become more acute as the demand grows for expertise in
areas of cutting-edge science. Sufficient resources are essential, whether for research, for relationship-building, or for developing people. To this point, the number of research FTEs at CFSAN has remained essentially the same since 2002 (Chart 1).

- **Office of Cosmetics.** In light of limited review and with recent questions raised by the Campaign for Safe Cosmetics, it is recommended that a separate review be done of the Office of Cosmetics to address any outstanding issues/concerns (e.g. regulatory authority, framework).

**Recommendations:** The summary of the recommendations provided below follows the findings and observations, as listed above, and are not intended to be in rank order.

**Internal**
- Implement a system for research project management that includes tracking of progress and measurement of progress toward goals, with information provided in an annual research report.
- Provide flexibility to improve recruitment and retention of research personnel and improve the ratio of support staff (administrative and laboratory) to research personnel. The latter should be a priority.
- Strive to maintain a balanced portfolio of mission-relevant research which is responsive to stakeholders’ needs for regulatory science and that is cognizant of, and adapts to, the changing external environment.
- Give laboratory and non-laboratory research equal attention, including regulatory science research relating to food safety, food science, nutrition and communications. Please review the list that addresses existing gaps (page 23), recommendations for expansion (page 25), and recommendations to improve/enhance the situation (page 26) in both areas of research.
- Carry out separate reviews/assessments within the other Offices of CFSAN, including the Office of Cosmetics, and the Centers of Excellence to better understand roles and responsibilities and to ensure alignment and optimize efficiencies, effectiveness and productivity across the organization as a whole.
- Establish a routine process for establishing the identification of emerging issues/risks utilizing environmental scans, emerging issues maps, and networks—internal, external, national and international.
- Institute internal and external advisory panels to CFSAN’s various Offices/Centers, and use them to perform regular reviews and to implement a structured procedure for developing research priorities.

**External**
- Further develop CFSAN’s extramural research program. The ‘return on investment’ (ROI) will be 1000 fold.
• Develop a public face and communicate the value of CFSAN’s efforts in public health.
• Adopt a global approach to education, outreach and information sharing.

Conclusions: It is of paramount importance that CFSAN continue to be viewed as a leader in food science, food processing, nutrition and consumer science and communication, with its data and insights used to inform regulatory decisions, worldwide. A thrust toward “cutting edge” science is laudable but to maintain this status, CFSAN must provide the anticipatory, fundamental and applied regulatory research that is integral to its mission. In doing so, the focus of CFSAN research cannot ignore the applied/practical/technology-oriented side of food science, nutrition and consumer science and communication, nor can it ignore the importance of contact between CFSAN scientists with colleagues in other countries. To maintain and build its stature, CFSAN’s planning process needs to be more open and inclusive, actively seeking engagement with leading scientists and organizations in academia and industry, and benchmarking against other organizations.

CFSAN’s role and responsibilities will continue to revolve and evolve around its ability to mitigate today’s problems AND anticipate and act on tomorrow’s crises. It cannot succeed based on the status quo, not if it is to be the “best in class” upon which all food regulatory agencies model themselves. As an organization, CFSAN must adapt to continuously changing and increasing responsibilities, at the same time that science is more advanced and complex, the range of foods and cosmetics continues to expand, imports continue to increase dramatically, and there is an ever more complex regulatory and risk environment in which to operate.

In light of the above, it is the collective opinion of the CRRS that CFSAN must:

• Create opportunities for their research scientists to meet with and participate in scientific exchanges with world experts.
• View itself as both a national food regulatory agency, and an expert body with international influence. To be effective CFSAN staff must integrate and collaborate with their international counterparts.
• Establish a formalized process for identifying and prioritizing emerging issues. Utilization of environmental scans, emerging issues map and internal and external panels will be essential.
• Review in detail the SWOT conducted by the CRRS (Table 2), and undertake its own SWOT that includes the views and insights of representatives of all key stakeholder groups.
• Undertake a benchmarking study of the Center to be done by an independent 3rd party organization with expertise in benchmarking.
• Build capacity to advance and lead in those areas that are key to its mission—risk analysis, food safety, food science, food processing, nutrition, communication science and regulatory science

Limitations of the Report: This review was unable to cover several programs and offices within CFSAN and these must be reviewed since they are important in the total assessment of the Center. Areas of particular concern include consumer studies and nutrition, as well as food science, food processing, food technology and the consumer science underpinning such activities.
as labeling, dietary supplements, etc. A complete assessment of the practical work/needs required for food safety, food processing, and food science in general was also not complete. To that end, a deeper dive of the COEs is highly recommended to: 1) fully understand roles and responsibilities of the COEs; and 2) gain the requisite benefits the COEs are intended to provide.
1. Introduction

The Center for Food Safety and Applied Nutrition (CFSAN) is a science-based regulatory organization responsible for carrying out the food and cosmetic safety mission of the U.S. Food and Drug Administration (FDA). CFSAN’s Mission states:

**The Center for Food Safety and Applied Nutrition, in conjunction with the Agency’s field staff, is responsible for protecting and promoting the public’s health by ensuring that the nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.**

CFSAN operates nationally and globally in a challenging environment with an ever changing array of consumer products and complex supply chains. To accomplish its mission, CFSAN has responsibility for the safety, nutrition, and labeling accuracy of these products and processes. This responsibility necessitates that CFSAN builds and sustains vigorous, high-quality intramural and extramural scientific research programs. The information and data from these programs provide the foundation for sound regulatory policy, compliance and enforcement programs. With evidence-based science at its core, the FDA can ensure that it is, and will continue to be, best positioned to carry out its statutory responsibilities.

1.1 Roles, Responsibilities and Staffing

CFSAN roles and statutory responsibilities can be summarized as follows:

- It is a science-based regulatory organization addressing the food and cosmetic safety mission of FDA.
- It operates on a global stage dealing with complex, expanding supply chains, working to ensure safety, nutrition, and labeling accuracy.
- Its focus is to build and sustain vigorous, high-quality intramural and extramural programs through regulatory policy, compliance and enforcement programs.

As of September, 2009 CFSAN employed 837 people. The staff includes professionals that are highly specialized with various areas of expertise including lawyers, compliance and enforcement experts, chemists, epidemiologists, food technologists, toxicologists, microbiologists, molecular biologists, nutritionists, pharmacologists, physicians, sanitarians, mathematicians, statisticians, and communications experts, as well as support personnel. Among the professional staff, approximately 32% (267) are classified as researchers engaged in the collection of original scientific data (distinguished from the analysis and interpretation of data/information routinely collected by the agency). An additional 31 are classified as research managers and directors.

Center researchers also perform regulatory functions when they are required (e.g., petition/compliance/guidance/policy reviews, risk assessments, training, etc.), in coordination with programmatic counterparts in the areas of regulatory policy, compliance and enforcement. As stated above, the Center’s research programs should provide the scientific foundation to ensure sound public policy, as well as services provided to consumers, the industry (domestic and foreign) and other groups both within and outside the Center.
It is important to also consider CFSAN’s roles and responsibilities in light of those of the FDA, which include:

- Protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

- Advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Underscored sections are directly related to the work of CFSAN.

1.2 Research Areas

To support its regulatory programs, CFSAN has developed an integrated research program plan that has the goal of directly supporting, through effective problem solving, food safety, and applied nutrition concerns that FDA faces daily. This is a work in progress that has not yet been realized, although there are signs of progress after many years of limited action due to attrition and other reasons (e.g. inconsistent leadership).

CFSAN’s research capacity consists of three integrated programs designed to meet the food safety, food defense, applied nutrition, and cosmetic safety regulatory needs of the agency. This includes a strong intramural research capability, a small extramural research program and four “Centers of Excellence” (COEs). The Center leverages its research capabilities and outreach opportunities through support of the four COEs in focused program areas (see page X for more information):

- The Joint Institute for Food Safety and Applied Nutrition (JIFSAN);
- The National Center for Food Science and Technology (NCFST);
- The Western Center for Food Safety (WCFS); and
- The National Center for Natural Products Research (NCNPR)

CFSAN research is divided into two categories, laboratory and non-laboratory research. For laboratory research, which is traditionally the largest research area for CFSAN, the research program has been devoted to food safety (chemical and microbiological hazards). There have been a significant number of accomplishments, including but not limited to development of analytical methods, method validation, risk assessment techniques, and microbial forensics.

Non-laboratory research is also a critical part of CFSAN’s research program, and is an area that is growing in importance (e.g. research into consumer understanding). FDA’s ability to communicate to the public through effective labeling, messaging, education programs and overall risk communication activities — even in the absence of complete information concerning a real or perceived health risk — is essential (see pages 24-26 for more detail).

2. Members of and Charge to the CFSAN Research Review Subcommittee (CRRS)

2.1 Members of the CRRS
In view of the broad scope, roles and responsibilities, and research areas of CFSAN, it was deemed necessary from the outset of this review that a multi-disciplined group of experts would be asked to serve. To that end, in addition to the Chair, Dr. Rhona Applebaum and Co-Chair, Dr. John Floros, (both members of the FDA Science Advisory Board), the following seven (7) experts were asked to participate. All but two completed the assessment. Dr. Larry Sasich (the consumer representative and member of the FDA Advisory Board) and Dr. Sam Godefroy (Director General of the Food Directorate, Health Canada) each stepped down due to personal schedules and other competing commitments. The CRRS members and their areas of expertise are shown in Table 1.

Table 1. CFSAN Research Review Subcommittee Membership

<table>
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<tr>
<th>Name</th>
<th>Title</th>
<th>Expertise</th>
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<tr>
<td>Rhona Applebaum</td>
<td>VP, Chief Scientific &amp; Regulatory Officer</td>
<td>Food Microbiology, Food Safety, Nutrition and Regulatory Science</td>
<td>The Coca-Cola Company</td>
</tr>
<tr>
<td>John Floros</td>
<td>Professor and Head, Dept of Food Science</td>
<td>Food Science &amp; Technology</td>
<td>Pennsylvania State University</td>
</tr>
<tr>
<td>Christine Bruhn</td>
<td>Director, Center for Consumer Research</td>
<td>Consumer Food Marketing Specialist, Consumer Behavior / Food Safety, Risk Communication</td>
<td>University of California-Davis</td>
</tr>
<tr>
<td>Fergus Clydesdale</td>
<td>University Distinguished Professor and Director of Food Science Policy Alliance</td>
<td>Food Science, Nutrition Science, Regulation</td>
<td>University of Massachusetts – Amherst</td>
</tr>
<tr>
<td>Johanna Dwyer</td>
<td>Senior Nutrition Scientist</td>
<td>Clinical Nutrition Science and Food Composition</td>
<td>Tufts University / National Institutes of Health</td>
</tr>
<tr>
<td>John Sofos</td>
<td>University Distinguished Professor, Center for Meat Safety &amp; Quality</td>
<td>Food Microbiology, Food Safety, Animal Science</td>
<td>Colorado State University</td>
</tr>
<tr>
<td>Tom Trautman</td>
<td>Fellow, Toxicology &amp; Regulatory Affairs</td>
<td>Toxicology, Food Safety, Regulatory Science</td>
<td>General Mills</td>
</tr>
<tr>
<td>Larry Sasich</td>
<td>Stepped down</td>
<td>Consumer Representative</td>
<td>LECOM School of Pharmacy</td>
</tr>
<tr>
<td>Sam Godefroy</td>
<td>Director General of the Food Directorate</td>
<td>Food Analytical Methods, Risk Assessment, Food Standards</td>
<td>Health Canada</td>
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2.2 The Charge to the CRRS

The CFSAN review was initiated under the auspices of the FDA Science Board, which charged the CRRS to review CFSAN’s research, support programs, and alignment with regulatory responsibilities. Within this scope, the CRRS viewed its work as encompassing two basic areas:

- Conduct a review of CFSAN research and support programs;
- Report on the alignment of the research endeavor with the regulatory responsibilities of CFSAN.

In addition, consideration was given to the broad categories of scientific expertise and technologies needed to fully support CFSAN’s regulatory functions and decision-making in relation to the six objectives outlined in the Charge (Appendix):
• Identify any important gaps or imbalances in scientific expertise and technological capability in which CFSAN should increase efforts to ensure that it can address the current and future demands of its regulatory role.

• Review and recommend research areas where CFSAN might reduce, maintain or expand its current levels of research effort;

• Identify opportunities to better leverage the Center’s scientific programs through partnerships with institutions and organizations of the broader scientific community;

• Determine if CFSAN is doing what is needed to recruit, develop, and retain the professional expertise needed to address current and future challenges to food and cosmetic safety, and nutrition;

• Assess and recommend CFSAN management and review practices for setting priorities which will guide the direction of resources to the highest priority activities;

• Identify the most important future challenges facing CFSAN scientific research enterprise as well as the major institutional and systemic barriers to addressing them.

2.3 How the Review was conducted

The CRRS carried out its work through weekly, one-hour conference calls, both prior to and post a two-day site visit at CFSAN (January 14-15, 2010). Of particular interest to the CRRS was the on-going Strategic Plan for CFSAN Science and Research. It was the goal of the CRRS to not duplicate the activities underway in the development of the strategic plan, but rather to ensure alignment, understanding and awareness of activities, competencies and demands of the Center, as necessary. To that end, the information that was shared by CFSAN Staff and their consultant, Dr. Bern Hapke, was invaluable (see page 13 for more information regarding the Strategic Plan)

The two-day CFSAN site visit involved an in-depth series of meetings, reviews and updates. The “Fact Finding Mission” resulted in a better appreciation of the competencies, workload, integration and focus of the scientists at CFSAN. The complete agenda and information received is included in the appendix. A synopsis of the two-day meeting is summarized below, with a more detailed overview to follow:

• Tour and discussions with the laboratories for the Office of Regulatory Science (ORS) and the Office of Applied Research and Safety Assessment (OARSA). This involved 12 different research areas/labs:
  o Spectroscopy and Mass Spectrometry Branch
  o Method Development Branch
  o Microbial Methods Development Branch
  o Molecular Methods and Subtyping Branch
  o Bioanalytical Methods Branch
  o Chemical Contaminants Branch
  o Molecular Genetics Branch
  o Molecular Virology Team
  o Immunobiology Branch
  o Virulence Mechanisms Branch Developmental, Reproductive,
  o Toxicology and Immunotoxicology Branch
Neurotoxicology & In Vitro Toxicology Branch

- CFSAN poster session, with the opportunity to discuss and review 40 studies with the relevant researchers.
- Briefing on the Office of Cosmetics and Colors
- Briefing on the CFSAN Research Strategic Plan
- Q&A with the CFSAN Research Office and Division Directors

The need for, and importance of, CFSAN research extends to all CFSAN Offices, to other CFSAN operations, and to other agencies and departments outside of FDA. However, the CRRS assessment was limited to the principal research offices, ORS and OARSA.

To avoid any confusion regarding this report, the following CFSAN Offices were not directly included in the CRRS review:

- Office of Food Defense, Communication and Emergency Response
- Office of Compliance
- Office of Food Safety
- Office of Regulation, Policy and Social Sciences
- Office of Nutrition, Labeling and Dietary Supplements
- Office of Food Additive Safety

It was the conclusion of the CRRS that limiting the review to the research to ORS and OARSA (as outlined in the scope of the Charge given to the CRRS) meant that findings were only limited to these two offices. It was the consensus of the CRRS to recommend that the other offices within CFSAN be reviewed in the future to provide CFSAN and FDA a total assessment.

3. Details of the January 14-15 CFSAN site visit

3.1 Overview:

As a construct for the review, the CRRS focused their attention on assessing the CFSAN Mission in parallel with the Charge to ensure that what was presented and reviewed was in alignment, and to guard against “mission creep.” The 2009 State of Science Report on CFSAN (hereafter “2009 Report”), was used as an important reference for the CRRS. Specific note was taken of the following:

- CFSAN scope of responsibility:
  - 75% of budget spent on foods--$417MM domestic, $49MM imported;
  - 377M registered facilities—154M domestic, 223M foreign;
  - Importance of foods to the U.S. economy.
- Why CFSAN does research:
  - To support its food and cosmetic safety and nutrition mandates.
To identify, detect and control hazards through communication of findings and appropriate information and implementation of methods articulated in policies, compliance guidance, and enforcement directives.

- To address existing, emerging and potential hazards.
- To serve as the basis for regulations and guidance issued by FDA; critical to justify costs/benefits of regulation.

**Difference between CFSAN and NIH:**

- NIH conducts basic biomedical research (NIH, a non-regulatory institution has stated that translational research required by CFSAN is outside its scope, mission and expertise;
- FDA/CFSAN conducts applied and translational research.

**CFSAN takes advantage of research capabilities of other Federal research agencies:**
CFSAN utilizes its four COEs to leverage its scientific and regulatory needs in food safety, food defense, applied nutrition and cosmetic safety. The COE program allows CFSAN to leverage research funds with research efforts in chemistry, microbiology, molecular biology, food science, toxicology, immunobiology, epidemiology, social sciences, education and risk assessment. COEs and their areas of concentration:

- NCFST--Food safety and technology with Illinois Institute of Technology,
- JIFSAN--Food safety and applied nutrition with the University of Maryland,
- NCNPR--Natural products research;
- WCFS--Food safety research at University of California-Davis.

Additional information was requested by the CRRS and received (Appendix).

### 3.2 Non-Laboratory Research

- The CRRS took specific note of the emphasis given to the importance of non-laboratory research in the 2009 Report, “Non-laboratory research is also an important part of CFSAN’s research program. FDA must be able to communicate to consumers through effective labeling, education programs, and risk communication.” At present there is little evidence that this area of research has received targeted emphasis.

- CFSAN’s ability to achieve its mission of ensuring that consumers have confidence in the safety of foods, supplements and cosmetics and have the knowledge and tools to make informed dietary choices is dependent on having unimpeded access to the scientific community.

- The statements contained in the 2009 Report were critical in supporting our position to review/assess consumer research and the importance of consumer communication in today’s environment (despite this focus having been initially questioned at the outset of the review process).

### 3.3 General questions that remained with the CRRS following the site visit
• What relationships exist with other organizations and agencies to deliver the intended results and drive leveraging of resources and research?

• How work/research is prioritized. Is there a ‘Decision Tree’ for priority setting? What are the criteria for setting priorities and weighing decisions?

• What isn’t being done? Where and when does CFSAN have to step in and get the work done?

• Is the focus more on “prevention” and ‘being proactive’ vs. “being reactive?”

• Where is the emphasis on ‘classical’ food science, food technology, food safety, and nutrition (practical)?

• Where do the newer technologies fit (e.g., nanotechnology)? Safety of new technologies? Cross-cutting technologies (e.g., omics, etc.)?

• What is the response time/execution/communication? What does the sequence, with times, look like?

• Is there a central source for routine activities (e.g. administration, ordering, the basics required to operate a laboratory efficiently and effectively)? This is essential for the productivity of the research staff.

• Are ‘think tank’ models being used to assess what’s been done to build on what’s known and therefore avoid unnecessary duplication/redundancy?

• Can more be leveraged from the COEs?

• Is there legacy/succession planning for the next generation of CFSAN scientists (people pipeline). The CRRS voiced concern with retirements and losing institutional memory.

3.4 Specific findings from the two-day site visit

The CRRS received scores of documents, including decks from various laboratory leads, 40 posters with key research examples, listings of 2009 accomplishments, and an overview and update from the Strategic Plan.

3.4.1 Summary of observations/highlights from various groups:

• Office of Regulatory Science (ORS) Laboratories (Introduction by Dr. Musser)
  
  o Primarily reviewed laboratory capabilities. Well equipped, state of the art equipment. Key need is for software developers/IT which should increase capacity, efficiency, effectiveness and ultimately productivity.
  
  o Evidence of collaboration, e.g., molecular detection. To avoid work duplication, there is a sharing of work, e.g., CDC will target top 100 pathogens, and FDA fills in the gaps.
  
  o A question was raised about the Bacteriological Analytical Manual (BAM), the “bible” for bacterial detection methods and updating of same. The response provided was that though this is important to do, it is not the highest priority in light of other competing priorities. This response concerned the CRRS since FDA’s ability to take effective regulatory action is limited without isolates, so
Summary: Overall ORA is doing excellent, needed work and has excellent instrumentation. The equipment and caliber of scientists are top notch. They not only have the tools, but the know-how to use them. They have little secretarial or other support and appear to be doing these functions as scientists because otherwise they will not get done. This is unacceptable and a misuse of talent.

- Office of Applied Research and Safety Assessment (OARSA) (Introduction given by Dr. Wekell)
  - State of the art laboratories/specialized facilities. Space shared with CVM. Questions arose re: cross-over and duplication of effort/resources.
  - In response to queries re: leveraging scale/knowledge, the CRRS learned there are meetings to allow for critical mass and knowledge sharing (e.g., Virology and Allergy Symposia). It was agreed this was a valuable process and should be duplicated and become a ‘best practice’/SOP within the Center.
  - Concern with deliberate acts of terrorism and how to prevent. It appears CFSAN goes to OARSA to assess same. Quote by CRRS member—“As a citizen, it is comforting to know CFSAN has this yet no one knows they exist.”
  - Need more technicians and support staff (GS6, 7, 8 level)
  - Microbiology
    - Work being done on *Listeria* (sero-typing, growth under refrigeration), *E.coli* O157:H7 and use of micro-array, basically to interrogate unique strains, or outbreak strains with focus on specific attributes and to assess virulence since not all the same.
    - Looking at gene expression and typing to assess virulence; Staph enterotoxin work, other pathogens as well as beneficial organisms.
    - Other areas in micro visited: cell culture enrichment, development of multi-virus DNA microarray
  - Toxicology
    - Looking at developmental/reproduction as well as nano-toxicology for dermal absorption (use of scanning microscope purchased two months ago—overall excellent equipment.
    - Other toxicology areas discussed: Melamine and male reproduction; confocal microscopy and dermal projects; high through put screens for heptotoxins; assessment of inflammation as a co-effector of toxicity; rapid detection methods to toxin identification.
  - Question raised: If have NCTR, why is there a Division of Toxicology in OARSA? Response: “For the niche areas that NCTR doesn’t do. For example, the work on melamine and male reproductive toxicology was not done at NCTR.”
Other areas: Mushrooms (source of Vitamin D and use in disease prevention)

Office of Cosmetics (Review given by Dr. Pat Hansen)

- Limited time for discussion, despite many questions by CRRS.
- Appeared there was no pre-market approval required so questions arose related to adequate oversight. Voluntary registration?
- Time spent finding problems and then target research needs.
- More emphasis given to guidance. Significant changes in last 5-7 years.
- Utilizes a ‘quad’ approach to identify/mitigate/resolve problems.
  - Partners include EU, Canada, US, Japan, with international ‘consensus’ meetings to help set priorities.
  - CRRS was impressed with this example of collaboration and leveraging expertise and experience and “intelligence” of emerging issues.
- Regulatory framework was not clear.
- Point person for cosmetics on the team, Larry Sasich, had to step down due to scheduling and other work.
- CRRS recommends that in light of limited review, their lack of familiarity with the Office of Cosmetics and the recent questions raised by the Campaign for Safe Cosmetics, that a separate review be done of the Office of Cosmetics to address any outstanding issues/concerns (e.g. regulatory authority, framework).

3.4.2 CFSAN Strategic Plan

- Detail presented by Bern Hapke.
- Update on the Strategic Plan provided during the March 1, 2010 CRRS conference call (see page 20).

3.4.3 Poster Session

- Staff presented 40 posters from a variety of research areas (Appendix).
- Range and scope of work demonstrated the skill, competency, expertise and capability of CFSAN.
- Of special interest were those projects that allowed for a direct link to regulatory oversight (e.g. the work on seafood safety).

3.4.4 Meeting with CFSAN Office Directors and Lab Branch Chiefs –Panel Discussion

- Observations by CRRS (not priority ranked)
  - CFSAN is too inner-focused. More outreach and external engagement is necessary. They need to “cultivate” old/new contacts/relationships; “collaborate” in more areas; “communicate” what they are doing and learn what others are doing.
  - More clarity is required on how data gaps in research needs are identified, how priorities are set, and the importance of leveraging. How can CFSAN best leverage/collaborate with others?
  - There is need for a shared vision for 2020 and beyond.
- Consumer research is needed to ensure appropriate consumer communications. Discussed why communications are critical (see assessment on communications on page 22).

- Biggest obstacle to doing research is personnel: not enough support staff (staff/admins); ratio of technicians to scientists is unbalanced and inefficient; there is need to focus on legacy and succession planning to ensure their ‘people pipeline’ is as robust as possible for the future.
  - Scientists (like all scientists) want to feel their work is important, that what they do has significance, but they lack understanding of the larger role of the agency, or where their work fits in. Thus they are driven to make such connections on their own, which may or may not be as efficient and/or effective.
  - When asked what the gaps are, what kinds/types of scientists and science are needed, the response given was “best to wait for the Strategic Plan.” The CRRS concluded that this made sense since you need to know what the work is, before deciding on the competencies and the organization. However, the CRRS was surprised to see that there were no suggestions.
  - CRRS raised questions on the practical work/needs required for food safety, food processing, and food science in general. Response was NCFST. CRRS recommended more is needed, especially since NCFST does not ensure regulatory compliance. CRRS feels this is too critical an area and requires a deeper dive to fully understand roles and responsibilities of the COEs.
  - Need more time/resources for relationship building.
  - Need to better leverage academics, build partnerships.
  - Need to improve processes to increase efficiencies and effectiveness.
  - Need support services. Hiring the basics; need to fix the basics in the organizational design. Situation is overstretching current staff capacity to do the work required.
  - Need for better IT systems. Lack thereof is impacting the effectiveness, efficiency and overall productivity of the Center Research.
  - Research needs to be driven by risk.
  - Need to raise the public’s awareness of what CFSAN does, i.e., basic public relations outreach is required.
  - Better communication and connectivity is needed across all stakeholders, both internal and external.
  - There needs to be a time for celebrations, which doesn’t appear to be the case. To maintain morale, need to focus on improving relationships, capacity, connectivity, and camaraderie.
  - What is the relationship with the Field? The Field units seem at best to be viewed as limited in their ability to contribute, and at worst to be ignored. Important to raise understanding in tandem with closer collaboration and information sharing.
  - How best can CFSAN capture best practices? This is important.
Better communication.
Better networking.
Develop creative, workable solutions to increase harmony between program and research staff, e.g., a meeting similar to what USDA does with Ag Outlook. It is important to raise awareness of what CFSAN/FDA does, as well as to increase collaboration internally. Panel preferred increasing camaraderie internally first.

4. Interim report to the FDA Science Advisory Board

An Interim report was provided to the FDA Science Advisory Board on February 22, 2010. The Report underscored the importance of CFSAN in fulfilling its mission in an environment where the public’s expectations of the Center are essentially two-fold:
- Mitigate/eliminate today’s problems
- Anticipate/act/resolve tomorrow’s crises

This dual expectation on the part of the public, as well as the government, is challenged by the enormity of the facts facing the Center, including but not limited to the following:
- 75% of food supply and 100% of the cosmetics sold in the US are under its regulatory authority.
- >377,000 registered food facilities
- Economic importance of the American food supply.

4.1 General observations and recommendations for improvement

There were six initial, general observations identified by the CRRS that have transcended to the final report, along with four recommendations for improvement. These include:

Observations

- **Staffing:** The CRRS was highly impressed by the dedication to mission and quality science demonstrated by the CFSAN staff we met with, and the ORS and OARSA scientists who participated in the site visit. The preparation for the site visit and the on-site briefings and tour were very informative and professionally done, but disjointed and many arrangements were made and carried out by higher level scientists and other high level personnel, rather than by the “support staff.” The research campus is modern and well-maintained, providing a pleasant atmosphere for researchers and staff. The CRRS felt an esprit de corps, founded on mutual respect, among the leadership team. Where it is appropriate, researchers strive to (and frequently succeed in) publishing research results in top tier journals in relevant disciplines.

- **Research:** Both laboratory and non-laboratory research are essential to the mission of CFSAN but they need to fit better together, and nonlaboratory research especially in areas where food science, nutrition and consumer areas integrate and connect, needs to be given a higher priority and attention.

Communication: In the current environment, where the ‘truth’ and resolution of a problem/crisis can take significant time, it is critical that risk communication and communication of the science be an integral part and standard practice of the Center’s operations and mandate. It is vital that
appropriate communication be provided to the public for two principal reasons: a) to raise their awareness and knowledge of the situation to help them in making the appropriate decisions for themselves and their families; and b) to maintain/enhance their confidence in the Agency. As shared with the FDA Science Advisory Board, in the February 17, 2010 Interim Report, communications with stakeholders must be viewed as a continuum during the resolution of a crisis/problem (see Figure 1). Communication must be done so that it informs and doesn’t scare or raise concerns needlessly. To leave a void is unacceptable since experience shows the void is often filled with misinformation.

**Figure 1. Communication as a Continuum with Stakeholders**

- **Increased Connectivity, Interaction, Alignment and Visibility within the following:**
  - FDA Leadership Offices/Centers
  - CFSAN Centers of Excellence
  - Field
  - Within CFSAN itself
  - Other agencies, both national and international
  - Other stakeholders

- **More Clarity on Research Prioritization:** Key to ensuring successful programmatic and regulatory outcomes related to CFSAN’s role and responsibilities is the use of science-based risk assessments, a system of prioritization, and management protocols that ensure issues and incidents of highest concern and potential impact are given the necessary resources and attention. It is critical that project outcomes support strategic outcomes:
• Use of external panel experts for advice/guidance on overall direction and setting priorities in regard to research areas, gaps, competency needs, and staff development.
• Use of special panels for independent scientific peer review and advice on targeted issues.
• Use of environmental scans to help identify emerging scientific and technical issues. This would include allowing CFSAN scientists to actively participate and attend external meetings to engage with leading scientists in academia and industry.

- Sufficient resources to ensure all of the above and other recommendations herein are implemented.

Opportunities for improvement
- Implement a system for research project management, the tracking of projects and progress toward goals and include this information in an annual research report.
- Provide flexibility to improve recruitment and retention of research personnel and allow for support staff (administrative and laboratory). This can include allowing for growth opportunities for development, cross-training programs, part-time assistance, summer internships, staff assignments and short term visits with universities. Allowing for less bureaucracy and paperwork, to the extent possible, will be of great benefit.
- Develop a public face and communicate the value of CFSAN work in public health. Let the country and others know what they do, and the impact of what they do, using traditional as well as new media (e.g. websites, Facebook, Twitter, other media).
- Strive to maintain a balanced portfolio of mission-relevant research responsive to stakeholders’ regulatory science needs and cognizant of the changing external environment. Science-based risk assessment to ensure success of this process is essential.

5. Specific Topics Addressed by the CRRS

5.1 Strategic Plan for CFSAN Science and Research (hereafter the “Strategic Plan”):
The following observations and recommendations were the result of conversations with CFSAN Staff and Dr. Bern Hapke:

- The CRRS applauded the efforts underway in the development of the Strategic Plan. The CRRS questioned how the Plan would be aligned with that of CFSAN/FDA leadership teams. Awareness by the Center’s leadership is important, but of greater importance is to have alignment with the leadership’s vision so that the Strategic Plan’s outcomes and conclusions will be championed, resourced and executed.
- The CRRS was in strong support of the Strategic Plan’s goals to have project outcomes support strategic outcomes, i.e., research directed to fill data gaps for known hazards (e.g., activities underway with fresh produce),
  - Research relates to regulatory goals;
• Regulatory goals identify knowledge gaps which serve to direct research tasks and outcomes.

• It was pointed out that the types of processes being assessed (e.g. prioritization) is the type of process that can benefit from Six Sigma (business management strategy designed to improve the quality of process outputs by identifying and removing the causes of ‘defects’) and can be used as a process for all other Science and Research Groups (SRGs) within CFSAN.

• The CRRS asked if priorities have been established and what are the criteria used to set research priorities.
  
  o Dr. Hapke: Currently, three areas of prioritization are on-going within SRGs:
    
    • From a research need
    • From a regulatory need
    • Across all research projects

  o Dr. Hapke: Specific to the criteria, there is a balance among the importance of the rule, quality of the research and impact. Specific criteria used to prioritize are weighted. Examples include:
    
    • Assess the rule making (or guidance) and impact from the rule
    • Implementation of the rule and assessment whether the research will have broad impact
      o Food safety impact
      o Political interest in the rule
      o Quality of the research results
        • Expense
      o Ease of Adaptability
      o Urgency for the rule

• There is a need to better define the process. Specifically the following questions need to be addressed:
  
  o Is science used to make a rule or is the rule used to direct the science?
  o Is it case by case?
  o Should it be?

• Understanding the CFSAN Process in light of the Strategic Plan:
  
  o Does the Strategic Plan include input from FDA leadership and how decisions are made? There has to be an ultimate decision maker/decision making body. Clarity on the decision making process is essential.
    
    • Dr. Hapke: The goal is to have an internal panel from various offices, with CFSAN Leadership involved, to ensure strategic outcomes support strategic goals.
    • Dr. Hapke: Current process is the Science Advisor (appointed by the Center Director), has veto authority with review by the CFSAN
Leadership, (i.e., Center Director, Deputy Center Director, and Office Directors).

5.2 Assessment of the CFSAN Consumer Studies’ Research, 2001-2009

During the January 14-15 site visit there was no presentation/discussion specifically on consumer research. The CRRS found this disappointing for two reasons:

- Importance of consumer research in general, and specifically related to regulatory decision-making and enforcement,

- Non-laboratory research was identified as part of their research program. It was the consensus of the CRRS that consumer research/education must be integral to CFSAN’s Science and Research Program.

CRRS requested from CFSAN a listing of consumer research studies. CFSAN shared with CRRS a 16-page summary of the research undertaken from 2001 through 2009 (CFSAN Consumer Studies’ Research, 2001-2009). The following is an analysis by Dr. Christine Bruhn, a member of the CRRS, and an expert in consumer communications. The CRRS supported and agreed with Dr. Bruhn’s recommendations.

CFSAN has an on-going plan to investigate consumer attitudes, knowledge and behavior in the area of food safety, including food allergens, nutrition, and the impact of food label statements on attitudes and behavior. Both qualitative and quantitative research projects are conducted as appropriate for study objectives. Findings are shared within the FDA, presented at professional society and other meetings, and published in the peer-reviewed literature.

The program would be strengthened if:

- Activities were organized to illustrate a clear progression from identifying an issue to tracking FDA response. These steps would include identifying an issue, exploring appropriate regulatory responses, fine-tuning these responses through qualitative research (such as focus groups), implementation of the response or rule making, then tracking effectiveness through national surveys, and modifying regulations as appropriate. This should be integrated into FDA’s continuing improvement process to that regulatory response is modified as new information evolves from the scientific community and means of communicating are refined.

- Clearly identify how the Agency will utilize information gathered through qualitative and quantitative research to address priorities. For example, how will the Agency respond to information learned from the Infant Feeding Practices Study II 2005-2007? Findings have been reported in the professional literature. Have the findings identified gaps that are within the Agency’s authority? What are the Agency’s next steps for regulatory programs related to infant feeding?

- Topics addressed orally should be published in the peer-review literature. Agency staff has addressed a wide variety of critical topics. It would be beneficial to share the Agency data and perspective in a published form to reach a broader audience. For example, “Educating home food preparers: Where has the message gotten through?” and “How do U.S. consumers handle precut bagged lettuce?” both presented at the 2007 American Public Health Association annual meeting, should be submitted for publication.
Delay due to OMB procedures to clear consumer research studies to proceed should be resolved. OMB procedures appear to prevent the agency from addressing an issue in a timely fashion. For example, the document prepared for our review in 2010 notes that the 2007 Trans Fat Consumer Study has received OMB approval and will soon be in the field (page 8 of review document shared). This suggests a 2 ½ to 3 year delay before the survey moves into the implementation stage. Similarly, the 2007-2008 Health Care Provider Survey is still waiting OMB approval. To address this delay and permit the agency to move in a timely fashion, the CRRS urges OMB regulations be modified for faster approval. We suggest that if OMB does not respond to a request within three months, the request would automatically be approved.

6. Responses to the Charge Given the CRRS

The following responses to the six objectives contained in the Charge are intended to serve as an assessment and evaluation based on our analysis, observations, review and discussions. In addition, constructive advice, constructive criticism and recommendations are provided to assist CFSAN in being a world-class organization, with its work and processes serving as a model for those regulatory agencies with similar missions. It is the intent of the CRRS that the entire report, and not only the responses to the six objectives, be used by CFSAN and FDA as guidance and direction in strengthening what the CRRS believes is one of the best food regulatory systems in the world. Our collective goal is that this review be used to assist and improve CFSAN as an organization. To that end, it is essential that the deliberations, conclusions, recommendations and actions taken by CFSAN are based on the best scientific evidence – derived from both laboratory and non-laboratory research.

6.1 Objectives One and Two

It was the judgment of the CRRS that Objectives 1 and 2 should be considered in tandem due to their interdependence and connectivity. To that end, section 6.1 should be read and considered in its entirety, as all points collectively address the CFSAN research and support programs, and the alignment of the research endeavor with the regulatory responsibilities of the Center.

1) Identify any important gaps or imbalances in scientific expertise and technological capability in which CFSAN should increase efforts to ensure that it can address the current and future demands of its regulatory role;

2) Review and recommend research areas where CFSAN might reduce, maintain or expand its current levels of research effort.

6.1.1 Gaps

Laboratory Research:

- Practical food processing research, with focus on safety. Should include research that is both complementary and fundamental (e.g., processing impacts on micronutrient content and bioavailability). Rationale: FDA has food processing as a “leading area” in its charter (additional commentary below).
• **Nutrition research**, with more collaboration among the other nutrition groups, both internal and external. This would help CFSAN in meeting this important area of the FDA Mission. COEs should be better leveraged for these scientific investigations.

• **Newer technologies**, with focus on nanotechnology, its safety, as well as other cross-cutting technologies, e.g., omics.

**Non-Laboratory Research:**

• **Consumer research.** Many consumer studies involve regulatory science research. Although the research involving consumers is largely social science rather than biological science, it is still scientific research that is important to FDA’s mission. Results must be communicated and debated with other scientists, as well as with regulatory officials. Some of this research involves cutting-edge cognitive science issues that are important to understanding consumer views about risks and benefits. If regulatory measures are to have their intended consequences, it is important to study consumer views, both proactively and reactively. Results should be released and published in a timely manner.

  o **Stakeholder and consumer attitudes**, appear to be neglected and/or not given high priority in current CFSAN plans. Research is needed on consumer behavior and lifestyle as it affects obesity, front-of-pack labeling, labeling of dietary supplements containing nutrients that do not use current DRI levels, and a myriad other issues (please refer to the report on consumer research).

**Staffing:**

• **Lack of technicians and administrative support.** This gap in personnel adversely impacts the efficiency, effectiveness, and ultimately the productivity of senior research scientists, and in fact, the productivity of CFSAN/FDA. Having senior research scientists doing routine or administrative tasks vs. using their expertise to design research and interpret data (to be used to base policy and guidance) is a serious misuse of staff capabilities.

• **Scientists and Succession planning:**
  o Need to develop experienced teams that are bold and interdisciplinary in nature, that together can develop the sound science the agency needs to carry out its mission.
  
  o Need to develop a group of senior scientists who can direct the research through the next decade. In the last decade, many talented individuals left the agency for other parts of government or industry, where career paths seemed more desirable and predictable. Thus the “pipeline” of replacements for the many highly skilled and experienced senior staff who will retire in the next several years needs to be filled with a cadre of qualified candidates. At present the agency relies to an inordinate degree on scientists from other countries who cannot advance to the highest level of the agency because of their visa/residency problems. This is not sustainable.
  
  o Succession planning will be adversely impacted if there is a high level of turnover in the junior positions, due in part to what they perceive as career opportunities—real and perceived. To that end, there may be a large number of qualified young scientists who do not see a future for a number of reasons, including an inability to be promoted (e.g., citizenship status, stagnation plateaus, etc.), inability to be engaged in
and apply their scientific knowledge to regulatory science, compliance issues and policy decisions.

- Need to develop a succession process and plan, utilizing at least three timelines of entry: ready now, ready in 1-2 years, ready in 3-5 years. It is important to provide scientists identified in the succession planning with opportunities for development within the agency, including strengthening of agency career ladders. There is also the need for a strengthened system of peer review of personnel, and projects, to ensure that standards remain high.

6.1.2 Recommendations to Expand

**Laboratory Research**

- The use of science-based risk assessments, a system of prioritization, and management protocols that ensure issues and incidents of highest concern and potential impact should be given the necessary resources and attention. This is critical to ensuring successful programmatic and regulatory outcomes related to CFSAN’s role and responsibilities.

- Basic food processing capacity and capability building and the need to focus on more practical food science and technology issues. This should not be an either/or for CFSAN. It is critical that both the practical (applied) food science/food safety research, as well as the basic sciences/research, be given equal attention. In looking at food as a system, it is unclear who is doing this and it is critical CFSAN have the necessary resources to do same.

- Entire area of “High Risk Food Product Safety.” Within this category seafood safety seems to be very heavy as compared to other areas.

- Scientific capacity in the field laboratories and closer routine communications between field laboratories and the central office. The field laboratories are vital for identifying problems in a timely manner. There is a need for frequent two-way communication between the field and central office, and vice versa.

**Non-Laboratory Research**

- Developing a research program to better understand what motivates dietary choices among consumers. The research should include concentration in the areas of nutrition labeling and nutrition messaging, with focus on increasing consumer awareness, understanding and use of nutrition information to make dietary choices that meet their individual needs for energy and nutrients.

- CFSAN’s regulatory, food, nutrition and consumer science research. Typical research proceeds from discovery to resolution, but it is also important to have research that focuses on ascertaining if, in fact, the problems identified were resolved.

- Risk Assessment. While EPA has asked the National Academy of Science to address risk assessment and decision making at that agency, FDA has an equally important role in conducting risk assessments for microbiological and chemical hazards, as well as nutrition and health issues. FDA has historically been strong in this area, and it is important to its regulatory mission that the agency maintains and strengthens its expertise and credibility, both with domestic and international audiences.
6.1.3 Recommendations to reduce or change

- Change molecular epidemiology to include real time interactions with those in the field.

6.1.4 Recommendations to maintain

- All other programs; however must involve a priority assessment using a risk based approach to assist in setting priorities.

6.1.5 Recommendations to improve/enhance

**Laboratory Research**

- **Resources for both a reactive focus, to mitigate current problems in a more timely fashion, and a proactive focus, to anticipate and act on future problems.**

- Need to improve the processes for updating key tools used, not only by CFSAN, but other Centers and stakeholder groups, e.g., the Bacteriological Analytical Manual (BAM).

- Databases and IT capacity.

- The assurance that pivotal regulatory studies completed within ORS and OARSA are compliant with Good Laboratory Practices (GLP) and an in-house Quality Assurance unit ensures confidence with respect to the integrity of data generated. This will help ensure confidence in conclusions resulting from such research and application to regulatory questions, processes, procedures and outcomes (e.g., rule making) from both a national and international perspective.

- Methods and means for prioritizing research in these areas also need clarification.

**Non-Laboratory Research**

- **Resources for both a reactive focus to mitigate current problems in a more timely fashion, and a proactive focus to anticipate and act on future problems.** The consumer and regulatory science research done within FDA is of high quality, but it is often too little, too late, and not communicated sufficiently to stakeholders in the academic community and elsewhere.

  - Example 1. Consumer science research on the so-called health claims “report card”. It appeared to follow, rather than precede, by months or years, the promulgation of the regulations. Moreover, the research, when published after months/years, suggested that consumers understood the levels of claims differently than regulators thought they did. A science-based agency ideally uses the science prospectively to design regulatory measures, and consumer understanding is key to resolving problems. Thus, post-regulation research is important, but research prior to the promulgation of regulations is equally vital.

  - Example 2. Research on front-of-pack and point of purchase labeling, an issue currently under consideration by a number of organizations including the FDA, the Food and Nutrition Board, the National Academy of Sciences, and others. Focus, as well as contracts, were put in place only after industry and professional association efforts (which FDA was aware of and had participated in as an observer) had been going forward for several years. The resources to conduct
more proactive research on issues such as these are essential. Results from such studies will provide the science necessary for guiding successful regulations and implementation of same.

- Example 3. Need for proactive approaches in assessing the current interest in folic acid fortification of cornmeal/flour. The FDA did groundbreaking work in modeling the likely effects of folic acid fortification prior to the promulgation of regulations in the 1990’s, and it is to be hoped that similar research will precede the other similar work. There is interest by CDC in the fortification of maize flour/products with folic acid. Such a proposal raises many technical questions about the technology of fortification of such products, and the need to assess current FDA resources for answering these questions. There are also questions about the attitudes of the subgroup of consumers who are heavy users of such foods, and what the effects of such consumption might be on folate intakes, and ultimately on health outcomes of interest. The research effort would benefit from more intramural personnel and resources.

6.1.6 Recommendations for timeliness and frequency of communications concerning the scientific basis for regulatory actions

The CFSAN regulatory reviews and rationale for health claims are scientifically sound and add to the body of evidence on these relationships, but they are not always published in the scientific literature. Examples include reviews of various health claims. Also, guidance for development of health claims is of interest not only to industry but to food and nutrition scientists and others with a stake in the regulated products. Resources should be made available to permit this, since it is key to communication with stakeholders.

6.2 Objective Three

Identify opportunities to better leverage the Center’s scientific programs through partnerships with institutions and organizations of the broader scientific community;

The interaction among and between the COEs (JIFSAN, NCFST, WCFS, NCNPR) was not apparent from the research discussed, and in fact there seems to be overlap or competition in some cases rather than cooperative efforts. Addressing this issue could help leverage skill sets and resources, as well as further collaborative efforts and research advancements to assist CFSAN/FDA in their missions. In addition, further leveraging the COEs would represent an excellent growth/development opportunity for junior and senior scientists.

6.2.1 Recommendations

- Establishing formal venues, such as seminars, to create interactions between/among inspectors, overseeing and coordinating staff and regulators to develop real-time research between the fundamental research and its application in the field. This was seen in only one of the poster sessions on seafood that exemplified the benefit of research activities in providing a workable solution to a practical food science/food safety need.

- Consider expanded collaborations/partnerships with government agencies, both national and international. Having dedicated resources (people and dollars) to target and manage
these partnerships can make them both a reality and sustainable. Assuming such efforts can be professionally executed, managed and maintained in the absence of dedicated support/resources is naïve. Such a dedicated program office can also be used to establish, manage, and execute sabbatical programs/fellowships for senior and junior scientists and can work towards both helping to realize both national and international opportunities. In addition to the specific benefits to the CFSAN/FDA and the US, it would also help enhance reputation as an organization/country that ‘walks the talk’ as it relates to training. CFSAN’s working to help educate others also provides a significant ‘ROI” (return on investment) in food safety knowledge practices, as well as economic value to our food chain.

- Extramural Research Programs. CFSAN itself characterizes its extramural research program as ‘small.’ It is important the focus and resources allocated to extramural research programs be increased for the following reasons:
  
  o CFSAN’s research program could be greatly expanded and the quality of its research increased by strengthening its extramural research program and through the creation of an extramural research portfolio. To be of benefit to CFSAN/FDA/public health, the program must be enlarged. As an added benefit, more young scientists can be trained and serve as a recruiting source for CFSAN’s ‘people pipeline” and succession planning. This in addition to all the benefits collaboration brings (enhanced research quality, networks, relationships, emerging issue identification, problem solving, etc). This extends to greater partnering with universities outside the COEs, or in collaboration with same. In particular valuable partners might be found in Food Science Departments.

  o Extramural funding is extremely important for CFSAN/FDA, especially now that the Agriculture and Food Research Initiative (AFRI) is eliminating research funding for food science, food processing, food technology and nutrition (apart from childhood obesity). This dramatic cut in funding will adversely affect research in these areas which are critical to regulatory action and education for consumers and industry. After all, what could be more important to both the missions of FDA and CFSAN than research in these areas which would be admirably done through extramural funding. It is essential that the food supply and the sciences that underpin same (food science, food processing, food technology and nutrition) be developed (and resourced) to continue to address health and safety issues to further advance the health and well being of the consumer. This will not happen without FDA and AFRI support

  o Establishing and/or ‘earmarking’ funds to support a group of extended research projects would add to/leverage CFSAN’s current research program and add value to its portfolio. In addition, such collaborations add further value through intellectual stimulation, professional development, and utilization of national assets to help focus on critical research needs.

- The art of working collaboratively and networking - both nationally and internationally, with a variety of institutions, and stakeholders, including industry - is a skill that must be developed in our global society and especially within an organization like CFSAN/FDA. Such activities must be encouraged, with an emphasis on developing and training junior
scientists in this discipline. Of course, there must always be an outcome of benefit—a rationale and a mutual deliverable. One way to ensure such a competency becomes ingrained and internalized is for CFSAN/FDA leadership and scientists to make it part of their work objectives and performance plans.

- Finally, more attention is needed to foster closer collaboration with other FDA Centers, federal agencies, and external organizations in relevant research programs.
  - Consider a national center for risk assessment in collaboration with EPA and others. Risk assessment and decision making has been identified as an area of concern by NAS and OMB.
  - Consider a program to develop “national” research priorities that places research projects through a competitive process among all Federal agencies.

**6.3 Objective Four**

**Determine if CFSAN is doing what is needed to recruit, develop, and retain the professional expertise needed to address current and future challenges to food and cosmetic safety, and nutrition.**

More needs to be done in developing scientists with a focus on applied food science and communications, in particular communication with consumers. Focus should be placed on establishing collaborations with universities and scientific communications and risk communication organizations/experts to train scientists.

**6.3.1 Recommendations**

- CFSAN research is conducted in the context of rapidly changing technology and new scientific breakthroughs. Researchers could benefit from participating in a series of high-level science forums for the purpose of exchanging ideas, being exposed to new methods, considering new applications, and stretching their intellect and vision toward new possibilities. These forums would be conducted to expand the horizon of regulatory research. Creativity and innovation are critical to all forms of research, but especially where resources are limited.

- As CFSAN research grows in complexity and levels of sophistication, the demand to handle large data sets and analyze complex data greatly increases. Continued focus on IT and informatics support must keep up with research demands.

- An essential part of research planning involves recruitment and retention of researchers themselves and the anticipation of future needs. While CFSAN has incorporated capacity building into its planning, more should be done to prepare for transitions, turnover, and especially recruiting the next generation of researchers and scientists with knowledge and skills reflected in tomorrow’s new science. CRRS has outlined a list of positives that may serve to attract talent, as well as a list of negatives that will pose challenges to recruitment:
  - **Positive**
    - The availability of excellent equipment and facilities is a great recruiting tool as is a budget to conduct research without applying for grants

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- **Negative**
  - The lack of technicians and increased workload due to lack of administrative assistants reduces publication numbers and professional recognition as well as advancement and promotion in grade in the FDA guidelines for scientific advancement
  - The Wiley building in particular had no common areas for scientists to meet and share ideas which might be a disincentive
  - Roadblocks to travel, present papers and meet with peers is a disincentive to personnel as well as to creativity and professional recognition

- CFSAN has some excellent researchers and scientists but, as a Center, is vulnerable because it lacks depth in critical positions and in subject matter experts. This vulnerability is likely to become more acute as the demand for new experts in cutting-edge science such as new food processing and packaging technologies, food chemistry, nanotechnology, “omics,” international food safety, food science and nutrition issues, regulatory science and risk assessment increases. This vulnerability is also compounded in that it may make it difficult to attain a critical mass when structuring research teams.

- ORS and OARSA have an impressive record of productivity in providing important research support for CFSAN. The scientific training of the research personnel is diverse and well suited to address scientific policy and regulatory issues that are relevant to the products that CFSAN regulates. Before filling vacancies, the Human Resources staff must have an understanding of scientific terms, concepts, and/or methods that describe the candidates who will fill these critical positions. A lack of scientific understanding leads to improperly screened applications, with the result of severely limiting the pool of truly qualified applicants. This would greatly facilitate the hiring process for research scientist position. Also, over time, unfilled positions create a perverse incentive not to fill them because the resources are used for instrumentation and other purposes in support of the current research program.

- There is a need for more people/staff interactions and cross-interaction opportunities among the research scientists and regulatory scientists to brainstorm and ideate. Suggestions to increase the cross-fertilization of ideas and brainstorming include scheduling of routine ‘seminar series’ as a means of sharing what is being worked on by various groups/offices in FDA/CFSAN. Planned and periodic opportunities to engage in ‘table top exercises’ (e.g., food safety, crisis issues) are also both an excellent training tool, and fosters enhanced communication, collaboration, and coordination. Such activities must have support from the leadership, and become a routine and disciplined event. Extending such opportunities, interactions, and required activities to the Field and various research Centers (e.g. NCTR), both within and outside FDA, including the States, would foster better collaboration, ideation and reduce potential for redundancy and duplication of resources.

6.4 Objective Five

**Assess and recommend management and review practices for setting priorities which will guide the direction of resources to the highest priority activities;**
CRRS was pleased to find that CFSAN has undertaken a strategic plan to assist them in prioritizing the research planning process to ensure the focus and attention of its research efforts. Yet, CRRS found that there were limitations to the current planning process and opportunities for further enhancement that could both improve the research enterprise at CRRS and help achieve its critical public health missions.

6.4.1 Recommendations for management practices

- The process of setting research priorities needs to be better connected to the needs of reviewers and compliance personnel. It would be helpful to establish more routine and frequent interactions between researchers and those in review and compliance roles.
  - Priority setting would include identifying an issue, exploring appropriate regulatory responses, when appropriate fine-tuning this responses through qualitative research (such as focus groups) with the appropriate audience, implementation of the response or rule making, then tracking effectiveness through national surveys, modifying regulations as appropriate. This should be an integrative procedure in which regulatory response is modified as new information evolves from the scientific community and means of communicating are refined. CFSAN communications with internal and external audiences could address this comprehensive approach. The approach is similar to what is done for new ingredients as related to a post-market surveillance approach.
- Establish a close relationship with the ORA (Office of Regulatory Affairs). Having a close relationship will allow for better research programs/projects to provide the Field with useful information/tools. A ‘best in class’ example was the research utilizing analytical tools on fishing boats.
- The emergency response research is reactive based on crises when they develop. CFSAN research would be improved by establishing a formal mechanism for emergency response research planning or strategy for implementing emergency response research and identification of emerging scientific and public policy issues that impact the mission of FDA. While, it is difficult to achieve specific plans for emergencies, mechanisms such as scenario planning and environmental scanning can add insights and improve preparation for emergencies, unknown contingencies, and emerging issues. The aforementioned recommendation on the use of ‘tabletop exercises’ would be of great benefit in this regard.

6.4.2 Recommendations for changes in the review processes

- CRRS was concerned that the process of setting research priorities was almost exclusively internal without a formal mechanism for obtaining key stakeholder input from the regulated and associated industries. The entire research enterprise at CFSAN would benefit from an exchange of ideas and perspectives from the regulated communities and other external entities such as academic researchers, scientific societies, and other government agencies such as USDA, NIH, Health Canada, etc.
- Consumer and congressional concerns should be addressed in setting priorities for research. For example, with the increasing push for lower sodium content in foods, there should be research to understand and evaluate whether there is any increased risk from the perspective of food safety.
• The review process should include an evaluation of the best scientific and technological predictions you can make from reports from the field as well as changes in food policy or recommendations.

• CFSAN should adopt a more structured procedure for developing research priorities by considering the model used by the National Toxicology Program (NTP) for establishing its research priorities. NTP has two groups that provide advice to the Director on its research programs. One, the NTP Executive Committee, composed of representatives from affiliated government organizations, is responsible for providing advice on policy oversight. The second, the NTP Board of Scientific Counselors and associated scientific committees, is composed of external scientific experts who assist the Director on scientific oversight. NTP benefits from this arrangement through better coordination with intergovernmental agencies, better recognition of emerging issues and greater transparency and credibility of its research programs. See Figure 2. for the format used by NTP.

Figure 2. National Toxicology Program.

6.5 Objective Six

Identify the most important future challenges facing the Center scientific research enterprise as well as the major institutional and systemic barriers to addressing them.

6.5.1 Most important future challenges:

• Maintenance of relevance to, credibility and confidence by the public CFSAN serves.

• Lack of a stable highly experienced staff or succession plans for replacing key personnel as they retire.

• Continuing erosion of budget and resources.

• Falling behind in scientific competencies that are essential to ensure needed regulatory oversight and guidance, due to time constraints and conflicting priorities. Examples include food science and technology, nanotechnology (beyond cosmetics) and increasing
research capability in “omics.” Developing food related nanotechnology expertise should be encouraged.

- Effective communication to consumers and other stakeholders (key opinion leaders) on complex scientific issues of risk, and relative risk.

- Maintenance of scientific research that is relevant to regulatory compliance and oversight, while fostering scientific research that is relevant to emerging regulatory and public policy challenges.

- Ability to identify emerging issues. In order to identify research that is proactive towards developing the science that is essential to addressing emerging regulatory and public policy issues, we recommend that FDA institute a formalized process for identifying and prioritizing emerging issues. The process should be open to representatives from both internal and external stakeholders and include means to systematically capture and evaluate concerns that may arise from scientific, regulatory, or societal challenges. The resulting emerging issues map can be useful to: 1) determine strategic research priorities; 2) illustrate the focus and benefits of FDA research; and 3) serve as a reminder to both internal and external stakeholders of FDA’s strategic priorities. An example of a possible format for an emerging issue map is shown below (Figure 2.)

**Figure 2. Possible Format for an Emerging Issues Map**

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**6.5.2 Systemic barriers**

- A lack of support for CFSAN conducting research. This can best be addressed by insuring the research is clearly seen to be relevant to the mission.
• Competition for research dollars from other agencies as they position themselves as more relevant (yet need to recognize that FDA has a unique perspective and responsibility that is different from EPA and other agencies).
• Inability to identify emerging issues.
• Inability to attract world class scientists due to resources, and available opportunities in cutting edge research/publication.
• Inability to allocate sufficient resources emerging regulatory and public policy challenges due to budgetary constraints.
• Increasing responsibilities with stationary/decreasing staffing. The Chart below shows CFSAN’s continuing increases in responsibilities with stationery/decreasing FTEs. (see Chart 1).

Chart 1. CFSAN Staffing vs. Growing Responsibilities

6.5.3 Institutional barriers
• Critical to remove/address any institutional barriers which argue against research at CFSAN
• Lack of an identity for FDA research and lack of a scientific voice. For example there is no clear “Center of Excellence” to speak for FDA on microbiological food safety, toxicology, food analysis, food processing, etc.

6.5.4 Globalization

In considering the future of CFSAN’s activities and research, globalization will more and more be a driving force. Both regulatory research, to support regulatory science are in growing demand globally and CFSAN’s ability to help train and educate the international community on the methods, techniques problem-solving and related approaches is tied closely to the CFSAN’s Mission. Whether food or cosmetics are produced here or abroad CFSAN’s responsibility remains the same--to protect and promote the public’s health by ensuring that the nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. Thus the CRRS believes that there is real merit in establishing a global research consortium and a shared research portfolio where non-proprietary studies and research findings could be both shared and studies be planned to leverage global resources and experts especially with similar regulatory agencies in other countries.

7. Conclusions

The aim of this review is to provide recommendations and observations to improve and strengthen the current state of CFSAN to make it a ‘best in class’ regulatory body. It is essential therefore that CFSAN’s decisions and policies are based on the best scientific research, evidence and interpretation, which in total, are intended to provide the best guidance and oversight. Information and governance to the industries they regulate results in CFSAN achieving its mission to protect the public’s health.

To provide the anticipatory, fundamental and applied regulatory research that CFSAN needs to fulfill its mission, CFSAN’s planning process needs to be more open and inclusive, actively seeking engagement with leading scientists and organizations in academia and industry, and benchmarking against other organizations. CFSAN science is looked to globally as a source of data and insights to inform regulatory decisions worldwide, yet CFSAN scientists have only minimal contact with colleagues in other countries. Specifically, the following should be considered:

• Create opportunities to meet with and participate in scientific exchanges with world experts from academia, other governmental organizations and industry to consider topics relevant to the research agenda for CFSAN’s regulatory science mission.

• Establish a formalized process for identifying and prioritizing emerging issues. The process should be open to representatives from both internal and external stake holders and include means to systematically capture and evaluate concerns that may arise from either scientific, regulatory, or societal challenges. The resulting emerging issues map can be useful to 1) determine strategic research priorities, 2) illustrate the focus and benefits of FDA research, and 3) serve as a reminder to both internal and external stake holders of FDA’s strategic priorities. (see earlier comment on same) This emerging issues map/environmental scan will also be of value in identifying new technologies, emerging science, the changing policy landscape, trends in the regulated industry and the economy.
and how these developments will affect CFSAN, realizing, of course, that emerging issues do not always follow an exact timeline.

- The CRRS undertook a SWOT of CFSAN Science and research (Table 2). This can serve as a base for one done internally by CFSAN itself by a variety of stakeholders—

### Table 2. CRRS SWOT of CFSAN Science and Research (see attachment for clarity)

<table>
<thead>
<tr>
<th>STRENGTH</th>
<th>WEAKNESSES</th>
<th>OPPORTUNITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>People</strong></td>
<td><strong>People</strong></td>
<td><strong>People</strong></td>
</tr>
<tr>
<td>Scientific leadership</td>
<td>Lack of scientists with specific food science competencies and experience</td>
<td>Current economic challenges have resulted in availability of highly qualified scientists</td>
</tr>
<tr>
<td>Excellent scientific expertise</td>
<td>Limited administrative staff so senior scientists needed for routine tasks</td>
<td>Programs</td>
</tr>
<tr>
<td>Strong core group of senior scientists</td>
<td>Poor training of current support staff uses senior scientists for routine tasks</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>Facilities</td>
<td>Insufficient interaction with external scientists not part of FDA</td>
<td>Communications</td>
</tr>
<tr>
<td>Excellent facilities</td>
<td>Insufficient communication opportunities for cross &amp; within-function disciplines</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>Modern equipment</td>
<td>Management leadership - insufficient people with necessary experience &amp; vision</td>
<td>Tie research to real-time regulatory activities to make a case to Congress &amp; consumers</td>
</tr>
<tr>
<td>Regional centers that address specific topics</td>
<td>Programs (General)</td>
<td></td>
</tr>
<tr>
<td>Large organization with expertise devoted to specific problem areas</td>
<td>Mission creep, lack of focus &amp; unclear mechanism for identifying priority areas</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>Addressing the mission across a wide variety of food commodities and issue areas.</td>
<td>Overlap in research between centers &amp; inadequate budget</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>Large array of topics covered with strong expertise</td>
<td>Few examples of basic research being tied to FDA regulations and policing</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>Research is abreast of the science and in some cases, ahead of the science as it relates to future food safety risks</td>
<td>Delayed reporting of agency findings in the scientific literature</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>The “Quad Approach” used by the Office of Cosmetics to keep abreast of emerging issues (US, Canada, Japan and EU)</td>
<td>Programs (Social Science &amp; Risk Communication)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>THREATS</th>
<th>OPPORTUNITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td><strong>Opportunities</strong></td>
</tr>
<tr>
<td>• Funding threat if agency does not effectively communicate plan, actions, &amp; impact.</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>• Retention of scientific talent and expertise</td>
<td>Tie research to real-time regulatory activities to make a case to Congress &amp; consumers</td>
</tr>
<tr>
<td>• Research is deemed irrelevant for FDA</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>• Food is diminished compared to drugs in the FDA mission</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>• Other organizations recognized as primary food safety &amp; nutrition science resource</td>
<td>Promote programs/research benefits to increase visibility &amp; obtain greater funding</td>
</tr>
<tr>
<td>• Loss of credibility with the public and Congress</td>
<td>Share information among bench scientists &amp; social scientists within the agency</td>
</tr>
<tr>
<td>• Loss of credibility and influence with international trading</td>
<td>Increase communication effectiveness by working closely with social scientists</td>
</tr>
<tr>
<td>• Food policy &amp; regulation not based upon best available science</td>
<td>Implementing the FDA Strategic Plan for Risk Communication</td>
</tr>
<tr>
<td>• FDA is not a food NIH &amp; there are dangers if that notion is perpetuated</td>
<td>Hold periodic planning sessions/table top exercises with agency scientists &amp; stakeholders (e.g., academic, industry, &amp; consumer representatives) to assess/mitigate/learn current &amp; emerging issues</td>
</tr>
<tr>
<td>• Proposed changes to funding mechanism and charter of NACMCF threaten to undermine this prestigious scientific advisory committee</td>
<td>Address how the agency can most effectively complete its mission</td>
</tr>
<tr>
<td>• Loss of relationships/networks/collaborations if skills not transferred</td>
<td>Develop and implement a plan to evaluate research effectiveness</td>
</tr>
</tbody>
</table>

- CFSAN would benefit from the direct advice of a Board of External Scientific Counselors, as recommended in November 2007 by the FDA Science Board in its report to the Commissioner titled “FDA Science and Mission at Risk.” Its main role would be “to provide rigorous, ongoing review of science with the Center”, and among its first assignments could be review and advise on the results of the Strategic Plan of CFSAN’s Science and Research. Again, a model similar to NTP, as discussed earlier, would be helpful.

- CFSAN should develop a list of organizations against which to benchmark its research planning process. Consideration should be given to other FDA Centers like CFSAN, other federal regulatory agencies like EPA, and similar organizations in other countries. However the benchmarking study must be done by an outside professional group in
order for it to be of benefit and utility to CFSAN in implementing improvements and changes in the organization.

- CFSAN’s research program deserves better financial and IT support, to avoid its scientific base from eroding.
  - CFSAN and FDA Leadership should establish a competitive, nationwide extramural research program a priority in the FDA budget request.
  - CFSAN should actively participate in FDA’s IT initiatives to assure its needs are being recognized and addressed.

- Build capacity to advance and lead new regulatory science.
  - Build scientific capacity in critical research areas to ensure the science remains the basis of sound policy. The Strategic Plan, emerging issues map and longer-term research planning can help ensure this occurs.

This review was unable to cover several programs within CFSAN and these must also be reviewed since they too are important. Areas of particular concern include consumer studies and nutrition, as well as food science, food processing, food technology and the consumer science underpinning such activities as labeling, dietary supplements etc.

Finally, it is worth repeating that since 2002, the number of research FTEs at CFSAN has remained essentially the same (Chart 1). This, despite the fact that the Center’s responsibilities have continued to increase, the state of science is more advanced and complex, the range of foods and cosmetics continues to expand, imports have increased dramatically, progress has brought more complexity and significant changes to supply chains, and the regulatory environment and the world at large presents new and different challenges on a daily basis.