# THE NUTRITION REVIEW PROJECT

## REPORT TO THE DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

## DECEMBER 8, 2014

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## Acknowledgements

This report would not have been possible without the efforts of many dedicated, talented, and knowledgeable individuals who made the Nutrition Review Project a reality. It was a large undertaking that was made possible by continued efforts and support of the members of the project's Steering Committee, its Nutrition Implementation Team, numerous nutrition subject matter experts, and "the Doctor," who cured all seemingly intractable report formatting issues.

# Executive Summary and "Road Map" to this Report

## *Executive Summary:*

This report contains the Nutrition Review Project's (NRP) recommendations for enhancing the nutrition and nutrition-related activities within the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration's (FDA). The NRP was commissioned by the CFSAN Director in recognition of the many health problems in the United States (U.S.) that have nutritional causes. The project consisted of staff from FDA's Office of Foods and Veterinary Medicine (OFVM) and the program offices within CFSAN that engage in nutrition and nutrition-related activities

The NRP examined both FDA's goals for its nutrition and nutrition-related activities and the activities themselves. Its threshold recommendation is that FDA reorient its nutrition goals toward the actual achievement of improvements in the health of Americans. As reoriented, FDA's nutrition and nutrition-related activities would have to contribute to improvements in health in order to be successful. FDA's current nutrition goals of ensuring accurate and useful nutrition-related labeling on packaged foods and promoting the healthy reformulation of foods would be ways of achieving those improvements.

This recommendation is made with full appreciation of the difficulties associated with linking improvements in the health status of Americans to FDA activities. Nonetheless, it is not clear how to increase the public health impact of FDA's nutrition and nutrition-related activities if the Agency's stated goals can be met without actually improving public health.

The other recommendations in this report involve ways of enhancing FDA's ability to benefit public health. If adopted, they would likely require a reconsideration of how resources are allocated within the FDA food program.

Most of the recommendations relate to substantive matters rather than to strengthening internal management processes. The NRP concluded that management processes are best left to senior CFSAN leadership and will depend in part on whether the recommendations are adopted. Nonetheless, the NRP does recommend:

- Coordination among all activities: All nutrition-related activities in the various CFSAN program offices should be linked together to form a coherent nutrition component within CFSAN, with clear goals and objectives and an annual plan of work;
- Evaluation against program goals: There should be periodic evaluations of the nutrition component within CFSAN to determine whether it is meeting its goals and objectives and whether any of the activities should be modified, taking into account both costs and benefits;
- Collaboration with other government agencies: FDA should collaborate with other government agencies to develop and implement a government-wide plan with clearly defined roles and responsibilities for each agency;

- Collaboration with the private sector: FDA should collaborate with industry, professional associations, locally-based public service organizations, and consumer-oriented organizations on a range of nutrition-related matters.

The bulk of the remaining recommendations address:

- Labeling claims: How to enhance FDA's ability to ensure that nutrition and health-related labeling claims on foods are understandable to consumers, and are truthful, and not misleading;

- Product reformulation: Fostering and promoting the reformulation of foods to make them healthier;

- Medical foods: How to ensure that foods labeled as medical foods do in fact meet significant nutritional needs associated with certain diseases and conditions and do not defraud consumers;

- Bioactive food components: Ensuring that FDA is knowledgeable regarding emerging science and new products in the marketplace derived from that science to ensure that they are safe and that the claims being made for them are truthful and not misleading;

- Education: How to enhance education to help consumers comprehend nutrition-related labeling and make healthy food choices;

- Behavioral studies: How to enhance behavioral studies and the analysis of data from various public and private databases to better evaluate the impact of FDA's activities on consumer behavior, the nutritional status of Americans, and their overall health;

- Laboratory and clinical research: Ensuring that FDA's own laboratory research and its support for laboratory and clinical research elsewhere supports its nutrition-related goals, objectives, and activities.

## *Roadmap:*

This report is divided into a relatively short main text and nine appendices, as follows:

Main Text

Purpose: This section describes the purpose of the NRP, to make recommendations on how to enhance CFSAN's nutrition and nutrition-related activities. Although the traditional emphasis of the FDA food program has been on addressing safety issues from contaminants, there is a growing appreciation for how many health problems in the U.S. have nutritional causes, either in whole or in part.

Case for Change: This section describes the illnesses, deaths, and costs in the U.S. associated with nutrition-related diseases and conditions such as obesity, cardiovascular disease, and diabetes. It notes that the Institute of Medicine (IOM) of the National Academy of Sciences

(NAS) has advocated that the Federal government play a significant role in support of heathy eating.

Overview of Current FDA Nutrition-Related Activities: This section summarizes the nutrition and nutrition-related activities that CFSAN now conducts. Many activities involve food labeling, such as implementing labeling requirements mandated by law, e.g., Nutrition Facts Labeling (NFL), or educating consumers on the meaning and of nutrition-related labeling and how use it to make healthy food choices, or conducting behavioral studies on how consumers perceive or react to nutrition-related labeling. Other activities not directly related to labeling include ensuring the nutritional sufficiency of infant formulas and reducing *trans* fats in the diet.

Key Questions for the NRP: As described in this section, NRP staff first had to: (1) determine which food activities should be deemed to be "nutrition and nutrition-related" in order to differentiate them from food safety activities that do not involve nutrition; and (2) propose the overarching goals for these activities. Determinations of how best to enhance the nutrition and nutrition-related activities should be made in the context of the goals they are intended to achieve. Finally, NRP staff considered how these goals could form the basis for a new 10 year strategic plan for nutrition to be included in the new FDA 10 year strategic plan for food and veterinary medicine under development.

The Nutrition Review Process: Internal and External Interviews: As explained in this section, the first step in the NRP was interviewing 56 FDA employees and 32 individuals outside of FDA to obtain views on what the FDA nutrition mission should be and how it should be carried out. The NRP took these views into account when developing the recommendations contained in this report. This section provides a brief summary of the interview results. (Appendix C contains the more detailed summaries provided to FDA by the contractor that conducted the interviews).

The Nutrition Review Process: The Steering Committee: As described in this section, the next step in the process was the formation of a Steering Committee to provide broad direction and oversight to the project. This section describes the membership and principal activities of the Steering Committee.

Definition of "Nutrition and Nutrition-Related Activities:" This section contains the definition developed and adopted by the Steering Committee to answer one of the "Key Questions for the Nutrition Review Project" described previously.

A Strategic Framework for Nutrition: As described in this section, the next step involved developing a "strategic framework" for nutrition within CFSAN. The framework contains the results that nutrition and nutrition-related activities should be designed to achieve. Current activities can be evaluated based on whether they contribute to one or more of the results in the framework, and new activities can be designed to contribute to these results. This section provides a brief description of the strategic framework, with a focus on the overarching, i.e., "top level," results that the nutrition and nutrition-related activities should achieve. These overarching, "top level" results should be regarded as the public health-oriented goals for all nutrition and nutrition-related activities, against which their success should be measured. (The actual framework and a narrative prepared for it by the FDA Office of Policy in Appendix G.)

Nutrition Component for the OFVM Strategic Plan 2015-2024: NRP staff then developed a recommended 10 year strategic plan for nutrition. If adopted, it would be included in the next FDA 10 year strategic plan for food and veterinary medicine. The strategic plan would orient the nutrition goals toward achieving public health improvements in keeping with the "top level" results in the strategic framework. This section contains the recommended 10 year strategic plan for nutrition.

Summaries of Recommendations for Improvement: This section summarizes the 10 "white papers" developed by the NRP that contain recommendations for strengthening FDA's nutrition and nutrition-related activities and contains some additional recommendations relating to program management and processes. (The white papers are contained in Appendix A.)

Prioritizing the Recommendations for Improvement: This section contains the NRP's recommendations on how to prioritize the recommendations for improvement. It would not be realistically possible to implement all recommendations simultaneously, assuming they were all adopted.

Appendices:

Appendix A: White Papers Containing NRP Recommendations for Strengthening FDA's Nutrition and Nutrition-Related Activities: Each white paper addresses a specific subject area by describing current activities or a current situation and making recommendations for improvement. Where possible at this time, the recommendations include cost estimates in both additional dollars and "Full Time Equivalents" (FTEs).

Appendix B: Costs and Benefits of FDA Food Initiative Proposals: This is a table showing that the potential annualized net benefits for FDA's recent and contemplated nutrition-related initiatives could be considerably greater than those for its food safety initiatives directed toward contaminants in the food supply.

Appendix C: External and Internal Interview Summaries: The interview summaries provided by the contractor, as described above.

Appendix D: Industry Listening Session Notes: FDA staff were invited to an industry round table-type discussion on topics relevant to the NRP conducted in Burr Ridge, Illinois by the Institute for Food Safety and Health (IFSH). These are the notes from that meeting taken by FDA staff.

Appendix E: Steering Committee and Nutrition Implementation Team Members: The individuals and their office affiliations that served on the NRP Steering Committee and on a larger team that became known as the Nutrition Implementation Team (NIT). The NIT developed the proposed strategic framework for nutrition and was largely responsible for developing the recommendations for how to strengthen FDA's nutrition and nutrition-related activities.

Appendix F: Offices Responsible for Nutrition and Nutrition-Related Activities: A number of offices in FDA engage in nutrition and nutrition-related activities. This appendix lists the offices and the activities performed by each of them.

Appendix G: Strategic Framework Chart and Narrative: The chart containing the recommended strategic framework (as described above) along with a "narrative" that explains the chart in detail, that was drafted by the Office of Planning (OP) within the Office of the Commissioner (OC).

Appendix H: Nutrition Portion of the Current OFVM Plan 2012-2016: This appendix contains the nutrition portion of the current five-year strategic plan for food and veterinary medicine that the proposed 10-year plan (as described above) would replace.

Appendix I: References

## Purpose

This report contains the findings and recommendations of the Nutrition Review Project (NRP). This project was commissioned by the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN) to examine the nutrition and nutrition-related activities within CFSAN and recommend how they could be enhanced to more optimally benefit the public health. The NRP addressed the following question: Within reasonable resource constraints and the current statutory framework, is there more that these activities could be accomplishing to increase their public health effectiveness and if so how?

The traditional emphasis of FDA's food program has been on preventing and responding to illness from contaminants in food. Nutrition and nutrition-related activities have been an important but secondary aspect of the overall program in terms of resources and attention. In recent years, however, there has been a growing appreciation for how many of the health problems in the U.S. have nutritional causes, either in whole or in part. The potential annualized net benefits for FDA's recent and contemplated nutrition-related initiatives could be considerably greater than those for its food safety initiatives directed toward contaminants in the food supply (See Appendix B). This is not to suggest that food safety activities should be de-emphasized in favor of nutrition-related activities. Those activities are directed largely toward different health endpoints – mostly acute for food safety while mostly chronic for nutrition – but the significant potential to benefit the public health does raise the question whether the nutrition part of FDA's program should be examined to determine how and whether it could benefit the public health more than it does now.

## The Case for Change

In the U.S., chronic diseases are a leading cause of death. Poor diet and physical inactivity are major preventable contributors to the leading chronic diseases. Approximately 17 percent (400,000) of deaths in the U.S. in 2000 were linked to poor diet and physical inactivity (Mokdad et al., 2010). Prevalence rates of chronic diseases are high: 37 percent of adults have cardiovascular disease, 34 percent have hypertension, 11 percent have diabetes, and more than two thirds are overweight or obese. About a third of children are overweight or obese (Dietary Guidelines for Americans (2010) (DGA 2010). According to the DGA 2010, "Americans are

experiencing an epidemic of overweight and obesity. Poor diet and physical inactivity are also linked to major causes of illness and death" including "…cardiovascular disease, hypertension, type 2 diabetes, osteoporosis, and some types of cancer." Onset of type 2 diabetes, once known as adult onset diabetes, now occurs during childhood (IOM 2012).

Changes in diet can have tremendous impacts on disease rates and the associated health care costs. Danaei et al. estimated that overweight and obesity are responsible for over 200,000 deaths, high sodium for 102,000 deaths, low omega-3 fatty acids for 84,000 deaths, and high *trans* fatty acids for 82,000 deaths each year (Danaei et al., 2009). Bibbins-Domingo estimated that a reduction in sodium intake by 1,200 mg per day could reduce new cases of coronary heart disease, stroke, and myocardial infarction by upwards of 100,000 cases and save $10 billion to $24 billion in health care costs each year (Bibbins-Domingo et al., 2010). Finkelstein et al estimated that about 9 percent ($147 billion) of annual medical expenditures result from obesity (Finkelstein et al., 2012). The Trust for America's Health estimated that a 5 percent reduction in obesity rates could result in a decline of almost $30 billion in five years. (Trust for America's Health 2012).

The need for the Federal government to support healthy eating was highlighted by an IOM panel charged with identifying mechanisms for reducing the rates of overweight and obesity. Its report stated that there are no simple or single-pronged solutions to address the problem of obesity and overweight and that a "meta-strategy" involving a range of interventions is needed. The panel emphasized the Federal government's role in setting policy for nutrition standards, improving healthy choices in foods and beverages, and providing consumer information and education (IOM 2012). Similarly, an IOM report on "Strategies to Reduce Sodium Intake" emphasized that to be successful, strategies "must embrace an approach that emphasizes the entire food system and emphasizes sodium intake as a national concern." This effort must be "supported by a strong Federal government commitment to sodium reduction."

## Overview of FDA's Nutrition and Nutrition-Related Activities

FDA's nutrition and nutrition-related activities are based on scientific evidence supporting the link between diet and health. Much of the early activity focused on fortification of foods to prevent both nutrient deficiencies and over consumption of certain nutrients. Today, reports from the IOM and other scientific bodies and the recommendations of the Dietary Guidelines for Americans (published every five years) provide a basis for a number of FDA's nutrition and nutrition-related activities. In the last 20 years, many of these activities have been oriented largely toward food labeling. Although Nutrition Facts labeling (NFL), ingredient labeling, and health claim labeling have their own statutory mandates and requirements, the statutory core for much of the FDA labeling program is the requirement that food labeling be truthful and not misleading (section 403(a)(1)**,** Federal Food, Drug, and Cosmetic (FD&C) Act). Many of the FDA nutrition resources exist to support the implementation and enforcement of these and the other labeling provisions in the FD&C Act as they apply to nutrition. Other activities include ensuring that infant formulas are nutritionally adequate and provide for normal physical growth, and taking steps to limit partially hydrogenated oils (PHOs), i.e., *trans* fats, in the food supply.

Principal nutrition and nutrition-related activities include:

- Designing the NFL, including updating the nutrients that must be shown in each serving of food in accordance with the latest science and updating serving sizes based on the latest information on how much consumers actually eat;
- As required by statute, conducting premarket review of "health" claims proposed for food labeling that would link a food to a reduced risk of a particular disease or condition;
- As required by statute, designing and implementing requirements for calorie information on restaurant menus and products in vending machines;
- Establishing criteria for when labeling may claim that a food is "healthy" or a good source of a particular nutrient;
- Enforcing the statutory requirement that nutrition-related labeling be truthful and not misleading;
- Developing and updating new methods of detecting various nutrients in food for purposes of determining whether labeling declarations relating to those nutrients are accurate;
- Analyzing data from various databases to determine, among other things, how FDA labeling initiatives appear to be affecting purchases, the nutritional content of foods, and the nutritional status of Americans;
- Engaging in consumer education to help consumers understand and act on NFL and other nutrition-related labeling to make healthy food choices;
- Engaging in consumer behavioral studies to determine how consumers perceive and act on NFL and other nutrition-related labeling, including their understanding of nutrition and its importance to their health;
- Ensuring that infant formulas contain the nutrients required by statute and regulations for infants to thrive and that these nutrients are bioavailable to infants;
- Taking steps to limit *trans* fats in the food supply;
- Establishing voluntary guidelines for the gradual reduction of sodium in processed foods;
- Providing general principles for fortification of foods to prevent nutrient deficiencies and to prevent over-consumption of certain nutrients.

## Key Questions for the Nutrition Review Project

Although the original mandate for the NRP was to address how FDA could enhance the public health impact of its nutrition and nutrition-related activities, during the course of this project it became apparent that fulfilling this mandate would involve addressing the following specific questions:

1. How to define "nutrition and nutrition-related activities" so as to distinguish them from "food safety activities" in the FDA program? Prior to the NRP, no such definition existed.
2. What should be the overarching goals for FDA's nutrition and nutrition-related activities? Currently, for labeling it is to ensure that nutrition-related labeling is scientifically

accurate and understandable to consumers so that they can act on it to make healthy food choices. Alternatively, the overarching goal could be that consumers actually do act on this labeling and thereby improve or maintain their health to some appreciable extent.

3. What should the nutrition component of an updated FDA strategic plan for the food and veterinary medicine program contain? The strategic plan would describe the overarching goals for nutrition as well as objectives and strategies relating to how those goals would be achieved.

As will be described, the NRP developed recommendations for each of these questions.

## Internal and External Interviews

The first step in the NRP process involved conducting interviews with 56 FDA employees and 32 individuals outside of FDA. The external individuals included leaders in nutrition in academia, other government agencies, former government employees, consumer advocacy organizations, the food industry, and food consultants. The purpose of those interviews was to obtain views on what the FDA nutrition mission should be and how it should be carried out.

The external participants stressed the need for FDA to establish measurable goals, prioritize its activities, define its role in supporting Federal policies, and increase its public visibility on nutrition-related matters. Specific recommendations included addressing front-of-pack (FOP) labeling and communicating the positive aspects of good nutrition. Both of these matters are addressed in this report.

The FDA employees focused on a need to improve internal processes. Recommendations included the creation of internal working groups to foster and improve understanding of all the nutrition and nutrition-related activities that span several different offices in CFSAN and to obtain agreement on the goals, objectives, and scope of those activities. The primary activities the FDA employees recommended for improvement were in the areas of consumer education and outreach and behavioral studies. This report addresses these areas.

Interview summaries are in Appendix C.

## The Nutrition Review Project Steering Committee

Once the interviews were completed, a Steering Committee was convened to provide broad direction and oversight to the NRP. The Steering Committee consisted of representatives from the OFVM, the CFSAN Deputy Director for Regulatory Affairs**,** and the offices in CFSAN that engage in nutrition and nutrition-related activities. A list of individuals, their offices, and the nutrition and nutrition-related activities conducted by each of these offices, is in Appendix E.

The Steering Committee developed a definition for "nutrition and nutrition-related activities" to help distinguish those activities from activities that are food safety-related without also being nutrition-related. It then established a large working group, the "Nutrition Implementation Team," consisting of subject matter experts from the CFSAN offices represented on the Steering Committee. The Nutrition Implementation Team:

- Developed a proposed strategic framework for the program under the direction of the OP. The proposed strategic framework is included in this report.
- Developed recommendations for how to enhance many of the nutrition and nutrition-related activities to better achieve the results for nutrition articulated in the proposed strategic framework.

The Steering Committee authorized the development of this report that contains, among other things, recommendations for a strategic framework, enhancements to FDA's nutrition and nutrition-related activities, and a 10 year strategic plan for nutrition based on both the strategic framework and the recommendations for enhancement.

## Definition of "Nutrition and Nutrition-Related Activities"

Both FDA's nutrition activities and its food safety activities are intended to reduce the incidence of illness and disease. Distinguishing between activities that are nutrition and nutrition-related from activities that are solely food safety-related is not always clear since both may be directed toward reducing risk of a disease or condition. As a rule of thumb, food safety activities are directed toward reducing risk from contaminants in food, while nutrition and nutrition-related activities are directed toward reducing risk or promoting health through healthy eating, i.e., through good nutrition. Also, it is not always clear whether a regulatory action against labeling that is false or misleading is also nutrition-related. To provide clarification, the Steering Committee defined nutrition and nutrition-related activities as follows:

*For purposes of this project, nutrition and nutrition-related activities encompass all activities intended to support growth, maintain health, and reduce the risk of chronic diseases, nutrient deficiencies and other nutrition-related problems through a nutritionally healthy food supply and diet. These activities include assessments, education and outreach, economic analysis, food supply monitoring, research, and compliance.*

Chronic diseases and conditions covered within this definition include obesity, nutrient inadequacy, inadequate growth, heart disease, site specific cancers, diabetes, hypertension, osteoporosis, age-related macular degeneration, neural tube defects, and dental caries.

## A Strategic Framework for Nutrition

Fundamental questions for any FDA program include whether and how its activities and resource allocations align with the Agency's goals for that program. Many FDA nutrition program activities focus on providing "accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity" (FDA Foods and Veterinary Medicine Program Strategic Plan 2012-2016, Goal 4). FDA assumes that if the program is successful in that regard, consumers will make eating choices that will improve or maintain their health. FDA allocates nutrition resources to ensuring that labeling requirements mandated by law are scientifically accurate and understandable, e.g., NFL, health claim labeling, and menu and vending machine calorie labeling. FDA also devotes resources to whether other nutrition-related claims, e.g., the use of the term "healthy" to describe a product, meet criteria established

by FDA through rulemaking. However, structure/function claims – a common nutrition-related claim – remain unsubstantiated with no resources available for them.[1]

Another stated nutrition goal is to foster the development of healthier foods by encouraging food product reformulation (FDA Foods and Veterinary Medicine Program Strategic Plan 2012-2016, Goal 5). The current strategic plan emphasizes reducing sodium content in the food supply although it does not contain a target for either the extent of reduction or a public health impact against which success could be measured.

Alternatively, to succeed, the program should achieve, or significantly contribute to, public health improvements. Providing information that could possibly result in significant improvements would not, alone, be sufficient. Similarly, reformulation efforts would have to lead to improvements in public health.

Admittedly, it would be challenging to evaluate whether such goals were being met. In the case of labeling, for example, success would depend in large measure on consumer choices freely made and on improvements in public health that have multiple causes.

These difficulties notwithstanding, the NRP recommends that nutrition goals focus on achieving public health outcomes. Simply ensuring the scientific accuracy and quality of labeling information is unlikely to be adequate for achieving public health benefits. Although FDA does not have the tools to address all the factors that are needed to ensure healthy diets and improved public health, FDA should continue to assess its authorities and tools related to nutrition with the goal of improving the public health of Americans.

Toward that end, the Steering Committee appointed the Nutrition Implementation Team to develop a first ever "strategic framework" for the nutrition portion of CFSAN's program. The strategic framework that the NRP is proposing articulates the results that program activities should achieve. Under this framework, the "top level results" for the nutrition program would be:

1. Reduce rates of nutrition-related risk factors for chronic disease;
2. Improve rates of optimal nutritional status among adults; and
3. Ensure rates of optimal growth and development in infants and children.

We recommend that these "top level results" form the basis for the nutrition portion of the next 10 year strategic plan for foods and veterinary medicine.

The strategic framework also contains several "lower levels" of results that, if met, would increase the likelihood of achieving the top level results. The framework is presented in its entirety in Appendix G along with a narrative written by the OP that explains the relationships between the lower level and top level results.

Articulating the results to be achieved should enable FDA to evaluate current and future activities and resource allocations in terms of how they contribute to these results. Those that contribute significantly could be prioritized accordingly.

[1] As described in the white paper on structure/function claims in Appendix A, reviewing even a small number of structure/function claims could be resource-intensive because for all practical purposes, the claims may be made until such time as FDA disproves them.

If this framework is adopted, the NRP recommends that the NIT refine it first in collaboration with the OP, since it represents a first effort done with some speed. We would also recommend that the NIT work with the OP to develop performance measures for each result in the framework. These performance measures can be used to help evaluate whether the results are actually being met.

## Nutrition Component for the OFVM Strategic Plan 2015-2024

The NRP recommends that the overarching goal for the nutrition portion of the upcoming 10 year strategic plan focus on achieving public health improvements in keeping with the strategic framework. That goal would include the "top level" results in the strategic framework, i.e., reducing the rates of nutrition–related risk factors for chronic disease, improving rates of optimal nutritional status in adults, and by ensuring rates of optimal growth and development among children and infants. Ensuring accurate and useful nutrition-related labeling and educating consumers about its significance to them would become "objectives" and "strategies" under that goal but would no longer be the goal itself. Likewise, the current goal of encouraging healthy reformulation of foods would become an objective under that new goal. New objectives would include enhancing FDA's database surveillance capacity to track labeling and nutrient changes in foods, including changes associated with FDA initiatives, and how those changes appear to be affecting the nutritional status and health of Americans. They would also include keeping up with emerging nutrition science especially in the area of probiotics and other bioactive food components.

The current five year strategic plan through 2016 is provided in Appendix H. The recommended strategic plan for the following 10 years is as follows:

### OFVM Strategic Plan

**Goal 2**: Nutrition – Optimize health through improved nutrition.

The FVM Program plays an important role in reducing the rates of nutrition–related risk factors for chronic disease, improving the rates of optimal nutritional status of adults, supporting growth and development among infants and children and improving the health of pets to ultimately enhance health by improving rates of optimal nutrition status in both humans and animals. It does so by improving the way human and animal nutrition information is communicated to, and understood by consumers so they can make healthier dietary choices; monitoring the composition of the foods in the marketplace and the nutrition intake of the U.S. population; and facilitating new products and the reformulation of existing products to be healthier and nutritious. As evidence-based approaches for improving the nutrition of humans and animals are strengthened, new strategies will be identified to promote improved health and well-being in humans and animals.

**Objective 2.1:** Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.

The FVM Program will use its best available tools including surveillance, research, education, regulation and other options to best convey nutrition information on food labels, restaurant menus, vending machines, and pet food labels and will continue to work with stakeholders, including industry and consumer and public health groups to implement these strategies.

**Strategy 2.1a** Improve the availability and accuracy of nutrition information provided to consumers by modernizing the nutrition and supplement fact labels, and implementing the expansion of nutrition labeling to menus in restaurants and other retail establishments and to vending machines.

**Strategy 2.1b** Advance regulatory capacity to ensure that nutrition-related claims, including health claims, nutrient content claims, structure-function claims, dietary guidance statements and medical food disease claims are truthful and not misleading.[2]

**Strategy 2.1c** Enhance the FVM understanding of how consumers notice, understand, and act on labeling and nutrition information, including nutrition facts labels, nutrition content claims, and dietary recommendations.

**Strategy 2.1d** Promote collaboration with stakeholders including industry and consumer and public health groups to enhance consumer nutrition education directed towards age groups and demographics with specific needs.

**Objective 2.2:** Monitor emerging nutrition science as well as changes in the nutritional status of foods in the marketplace and their impact on the nutritional and health status of Americans.

The FVM Program will advance its understanding of emerging food technologies, nutrition science, the nutrition-related health status of the U.S. population, and the composition of the food supply in order to evaluate the impact of FVM Program nutrition initiatives.

**Strategy 2.2a** Enhance FVM's food and nutrition analysis capacity to monitor the composition of foods in the marketplace and claims on their labels.

**Strategy 2.2b** Monitor the nutrition intake of the U.S population in collaboration with federal partners, and analyze the effect of FVM initiatives on nutrient intake and actual health outcomes.

**Strategy 2.2c** Enhance FVM's capacity to review and respond to emerging scientific and technological issues in food and nutrition.

**Objective 2.3:** Encourage and facilitate new products and product reformulation to promote a healthier food supply.[3]

The FVM Program will promote and facilitate the reformulation of food toward healthier products. FVM will enhance and support healthful reformulation by using regulatory or other

[2] Front-of-Package (FOP) labeling would be included under this strategy.
[3] Initiatives relating to sodium and *trans* fat reduction would be included under this objective.

mechanisms such as nutrition labeling, voluntary guidelines, research into healthful ingredient substitutes, and stakeholder collaboration.

**Strategy 2.3a** Improve the nutritional profile of processed foods through mechanisms including voluntary industry guidelines, labeling, and expansion of regulatory authorities where appropriate

**Strategy 2.3b** Encourage research into healthful ingredient substitutes to support development and reformulation of healthier food options.

**Strategy 2.3c** Collaborate with industry to increase the number of foods that qualify for nutrient content and health claims.

## Summaries of Recommendations for Improvement

As described earlier, the NRP Steering Committee constituted the NIT, consisting of representatives from OFVM and the CFSAN program offices that engage in nutrition and nutrition-related activities, to develop recommendations for improvement on behalf of the NRP. In addition to their own detailed knowledge of FDA's activities, the NIT considered ideas from various sources, including interviews conducted with FDA staff and individuals external to FDA and to the Federal government. The recommendations adopted by the NRP are summarized here and described in detail in Appendix A.

# EVALUATION

**What:** Determining whether FDA's nutrition and nutrition-related activities are meeting the goals and objectives that the Agency has established for them is an essential part of program management and design.

**Currently:** FDA has never undertaken a comprehensive evaluation of its nutrition and nutrition-related activities. A number of evaluative-type activities occur that primarily involve consumer behavioral studies and analysis of information in various food labeling and nutrient status databases. Consumer studies examine how consumers interpret nutrition-related information and labeling, including the results of FDA labeling initiatives. Database analysis examines associational relationships between FDA labeling initiatives, primarily NFL, and the nutrient status of Americans.

**Recommendations:** As soon as practicable, conduct a comprehensive evaluation to establish a baseline for the program and then conduct periodic evaluations thereafter. These evaluations should focus on how successful the program has been in meeting its goals and objectives and what more needs to be done. In order to determine how FDA activities are affecting health, FDA should consider: (1) enhancing consumer studies by engaging in a longitudinal study to monitor the relationships between nutrition knowledge, food choices, and health outcomes; and (2) enhancing its database analysis by: (a) linking actual health outcomes from the Medicare database to nutrition status from National Health and Nutrition Examination Survey (NHANES); (b) monitoring the extent to which foods are being fortified with nutrients and reformulated to limit or remove nutrients, and linking both to the nutrient status of Americans. Finally, FDA should develop performance measures for each of the results in the strategic framework for the FDA's nutrition program.

## PRODUCT REFORMULATION

**What:** Manufacturers reformulate products by reducing or eliminating nutrients and calories that can contribute to the risk of chronic diseases, including obesity, diabetes, and heart disease. Manufacturers might also reformulate to increase nutrients of public health concern, i.e., that may be lacking in the diet, or to make a health claim.

**Currently:** Reformulation is occurring voluntarily as a result of FDA labeling initiatives and consumer interest in making healthy food choices. FDA can also compel reformulation in some circumstances by determining that a particular nutrient at a particular level in food is not safe. Changing consumer behavior is challenging. Making heathier foods that are desirable and require minimal behavioral change is an appealing alternative. One critically important area for reformulation is sodium reduction. Significant reductions in sodium in the American diet could save thousands of lives every year.

**Recommendations:** FDA should, among other things, (1) encourage voluntary and gradual sodium reduction efforts; (2) increase its monitoring of food databases to determine whether and how foods are being reformulated and to assess any unintended consequences; (3) collaborate with industry and academia to study the net health effects of substituting new ingredients in place of the ingredients being limited or removed; (4) finalize its preliminary determination that PHOs are not Generally Recognized as Safe (GRAS); (5) engage with industry to consider how and whether foods could be reformulated to reduce saturated fats.

## FRONT-OF-PACK (FOP) LABELING

**What:** FOP labeling consists of symbols or numbers displayed on the front of food packages to convey information about the nutritional value and general healthfulness of the food. FOP labeling systems can relate to nutrients or food components to limit, such as calories, sodium, and fats or can provide interpretive information about the healthiness of a food product. The purpose of FOP labeling is to facilitate the consumer's ability to make healthy food purchases.

**Currently:** FDA has not issued regulations or guidance addressing FOP labeling, but it is monitoring the current industry sponsored systems in the marketplace. FDA is waiting until NFL is updated to address FOP issues. The industry FOP systems include the use of symbols, numerical values, quantitative information, and algorithms to provide information and/or indicate that products meet certain healthful criteria. A multiplicity of systems could cause consumer confusion. Different systems can be inconsistent and potentially misleading in terms of overall healthfulness.

**Recommendations:** Even though FDA continues to wait on FOP labeling until it completes its update of NFL, FDA could proceed to consider whether and how it should engage in FOP labeling to ensure that labels are useful to consumers and not misleading regarding the healthfulness of the food. If the decision is to engage, the Agency has options, including

whether to issue regulations to mandate a single national system, or issue guidance to establish basic principles applicable to all FOP labeling.

## MEDICAL FOODS

**What:** A medical food is a food that claims on its labeling that it manages a disease or condition that has a "distinctive nutritional requirement." There is no specific statutory requirement that a medical food undergo premarket review as a prerequisite to making the claim, as would be required for a pharmaceutical making the same claim.

**Currently:** The statutory definition of a medical food is complex, and lends itself to contradictory interpretations. Many products are labeled as medical foods and make "disease" claims without premarket review and approval by FDA. This places the burden on FDA to determine whether the disease or condition really does have a "distinctive nutritional requirement," as required by the statute, and whether the claim of managing the disease or condition is true.

**Recommendations:** FDA should consider how best to expeditiously remove those foods that make false or misleading claims while not unduly impeding the development of medical foods that really make a difference between function and dysfunction. FDA should clarify the definition of medical foods, primarily focusing on when a disease or condition has a "distinctive nutritional requirement," as required in the statutory definition. FDA should also develop a standard of evidence needed to support and substantiate disease claims for medical foods, possibly in collaboration with industry.

## DIETARY GUIDANCE STATEMENTS

**What:** Dietary guidance statements are labeling statements that focus on general dietary patterns, practices, and recommendations that promote health and may refer to either a food "substance" or a disease (or health-related condition), but not to both. An example of a dietary guidance statement that contains a substance but not a disease is: "Drink low-fat milk for a healthy diet", while the statement: "Diets rich in fruits and vegetables may reduce the risk of coronary heart disease" is a dietary guidance statement because it contains a disease but not a specific substance.

**Currently:** Dietary guidance statements have great potential value to help consumers make healthy food choices, but there is concern that they are appearing on products that have negative nutritional attributes, such as high levels of sodium, while others are appearing on products that lack meaningful amounts of the foods to which the statements pertain.

**Recommendations:** In order to ensure that dietary guidance statements are truthful and not misleading, FDA should consider: (1) clearly defining them to ensure that these claims are consistent with Federal dietary recommendations, e.g., the DGA 2010; (2) ensuring that they are substantiated the applicable science; (3) ensuring that they appear only on the labels of foods that

have more positive than negative nutritional attributes; (4) ensuring that foods bearing dietary guidance statements contain meaningful amounts of the nutrients to which the statements pertain; and (5) conducting studies to better understand how consumers are influenced by them.

## STRUCTURE/FUNCTION CLAIMS

**What:** Labeling on dietary supplements and conventional foods including infant formulas often bear "structure/function" claims that, for the most part, claim that the food helps maintain or improve a body structure (e.g., "builds strong bones") or a body function (e.g., "maintains bowel regularity") in a healthy person.

**Currently:** Structure/function claims are a common form of nutrition-related claim on conventional foods and dietary supplements. There is no statutory requirement for premarket review of structure/function claims, nor does FDA have an express statutory right of access to a manufacturer's data in support of its structure/function claims.

**Recommendations:** FDA should consider whether to begin substantiating structure/function claims given their great potential to mislead consumers. Options for doing so include: (1) simply requesting the underlying data from manufacturers; (2) creating incentives to manufacturers for providing the underlying data, e.g., an FDA "mark" signifying substantiation by FDA; (3) conversely, requiring a mandatory disclaimer on conventional foods similar to that already required by statute for dietary supplements that the claim has not been substantiated by FDA; and (4) collaborating with NIH to study the validity of structure/function claims. FDA should also consider whether it could or should require that amounts of the nutrients in question, and the significance of those amounts relative to the claims being made for them, should be mandated on labeling.

## BIOACTIVE FOOD COMPONENTS

**What:** Bioactive food components, such as probiotics (microorganisms) and prebiotics (dietary fiber) are not considered nutrients, but may be beneficial to health. Probiotics and prebiotics have been the subject of increasing marketing and public attention.

**Currently:** Many products with probiotics make structure/function claims that, like all structure/function claims, are not reviewed by FDA. Typical claims relate to general health, the immune system, and improvements in natural gut flora. Also unknown and unregulated is whether the microorganisms survive to achieve their desired effects through the shelf life of the products. FDA has not defined "dietary fiber," so manufacturers are including in the fiber declaration on NFL added fibers that are not known to convey health benefits. This could be misleading, because added fibers may not confer health benefits.

**Recommendations:** FDA should continue monitoring the science and developments in the marketplace relating to probiotics and other bioactive food components. FDA should also consider whether and how it could address the validity of structure/function claims and the survival of the probiotic microorganisms through the shelf life of products. The Agency should

consider collaborating with outside groups to conduct research on the effectiveness of added fibers and other bioactive components generally.

## CONSUMER STUDIES

**What:** FDA engages in surveys, interviews, focus groups, "experimental" studies to test consumers' reactions to different label formats, concepts, designs etc. It also conducts literature reviews to learn about consumers' understanding of nutrition-related matters, including their understanding of nutrition-related labeling, and whether FDA labeling and education initiatives are affecting consumer behavior.

**Currently:** The size of the staff and amount of funding for consumer studies limits FDA's abilities to determine how our nutrition activities affect health. Despite these limitations, studies have been conducted on how various labeling initiatives by FDA and industry (NFL, menu, and FOP labeling) affect consumers' understanding and behavior.

**Recommendations:** Consumer studies can be vital in determining the impact of FDA activities, including how these activities are actually affecting health. FDA should consider conducting: (1) longitudinal studies to measure long term effects of behavior and health; (2) studies of food label use and comprehension among persons from different cultures and incomes; (3) pilot projects to explore how mobile technologies can be used to affect consumer food choices; (4) holding focus group testing in advance of economic analysis to improve the predictive accuracy of FDA's economic models and better inform FDA's regulatory decision-making; and (5) obtaining expedited Office of Management and Budget (OMB) clearance for studies.

## CONSUMER EDUCATION

**What:** FDA engages in consumer education to inform and influence consumers about how to make healthier food choices. FDA consumer education is designed to help consumers read and comprehend nutrition-related labeling and understand why this information is important to them in maintaining good health.

**Currently:** Activities include education for younger audiences and teachers; the use of social and traditional media; and development of materials for continuing medical education.

**Recommendations:** FDA personnel and others interviewed for this project repeatedly cited a need for more consumer education. A well designed program can improve consumers' dietary practices. Toward that end, FDA should consider: (1) developing specific goals for its nutrition education program; (2) expanding collaboration with "multiplier" organizations such as the American Medical Association (AMA) and medical specialty organizations (via continuing education materials), and with local organizations and health departments; (3) increasing its collaboration with industry and other Federal agencies; (4) increasing its use of multimedia and

social media; (5) expanding the FDA school-based food safety program to include nutrition; and(6) targeting special audiences based on age and demographics.

## LABORATORY AND CLINICAL RESEARCH

**What:** CFSAN conducts nutrition-related research in support of program needs. The majority of laboratory research is directed toward methods development and method validation, the latter reflecting the need to develop targeted methods that can be transferred to FDA field laboratories.

**Currently:** Intramural laboratory research activities that CFSAN conducts include improved developments of methods regarding omega-3-fatty acids, phytosterols, vitamin K, and different types of fats.

**Recommendations:** In order to continue improving methods for the analysis of nutrients and to continue monitoring of changes in food composition, FDA should consider: (1) collaborating with external groups on methods development and validation work on new components; (2) ensuring that adequate methods are developed for bioactive food components and structure/function such claims; (3) collaborating with the Illinois Institute of Technology's IFSH to conduct human studies about the functionality of new dietary fiber sources, and (4) developing methods for detecting essential nutrients and other constituents in medical foods.

In addition, the NRP recommends the following:

## COORDINATION AMONG ALL ACTIVITIES

All nutrition-related activities in the various CFSAN program offices should be linked together to form a coherent nutrition component within the FDA food program, with clear goals and objectives, as well as an annual plan of work.

## COLLABORATION WITH OTHER GOVERNMENT AGENCIES

FDA should initiate or participate in a general collaboration with other government agencies to develop and implement a government-wide plan with clearly defined roles and responsibilities for each agency.

## COLLABORATION WITH THE PRIVATE SECTOR

FDA should collaborate with industry, professional associations, locally-based public service organizations, and consumer-oriented organizations on a range of nutrition-related matters.

## Prioritizing the Recommendations for Improvement

The NRP recognizes that its recommendations are extensive and that as a practical matter, they cannot all be implemented or even effectively planned for simultaneously. Consequently, the NRP recommends that, as a first step, implementation plans be developed based on the following levels of prioritization:

First tier:

*Program Evaluation*: This is needed to establish a baseline against which future evaluations can be measured. A number of activities necessary to conduct an evaluation do not exist today. Identifying these activities and initiating them should not wait.

*Sodium and Trans Fats Reduction:* This is an aspect of product reformulation that has the potential to save thousands of lives per year.

*Front-of-Pack Labeling*: Although FDA has waited to engage in FOP labeling until it completes its update of the NFL, planning should start now. FOP labeling has great potential to influence consumer behavior toward making healthy food choices and to influence manufacturers toward healthy reformulation. However, a multiplicity of inconsistent and potentially unsubstantiated FOP labels could undermine that potential.

*Medical Foods*: Resolving what appears to be a growing and sometimes egregious problem of products making unsubstantiated therapeutic drug-type claims by simply labeling themselves as "medical foods" should be an Agency priority. At the same time, FDA should not inadvertently stifle the development of legitimate medical foods that can make a difference between function and dysfunction.

Second tier:

*Dietary Guidance Statements*: These health-related labeling claims have great potential to influence consumer choices toward healthy products. However, they are unregulated and there is a growing concern about their potential to mislead consumers. Many of the regulatory concepts

that could be used to address this concern could potentially apply to unsubstantiated structure/function claims as well. The NRP recommends that FDA first apply these concepts to dietary guidance statements to determine their utility.

*Structure/Function Claims*: These claims appear to make up the preponderance of unsubstantiated health-related labeling claims. Developing a regulatory structure to ensure that structure/function claims are truthful and not misleading could be challenging but potentially of great value to consumers.

*Bioactive Food Components*: Many of the issues with these products involve the validity of labeling claims, including structure/function claims. Other issues involve whether added fibers, rather than naturally occurring fibers, convey health benefits.

Supporting activities:
The following types of activities can be critical to the achievement of many, if not all the activities in both tiers. Consequently, they are listed here as support activities that can be used as needed:

- *Consumer Education*
- *Consumer Studies*
- *Laboratory and Clinical Research*

Deferral:
The NRP defers to senior leadership on the prioritization of the following:

- *Coordination of all nutrition and nutrition-related activities*
- *Collaboration with other public sector agencies and organizations in the private sector*

# Appendix A. White Papers: Recommendations for Improvement

Cost estimates are provided where possible at this time, especially for recommendations that are likely to have relatively significant resource implications. Cost estimates are highlighted in blue.

## EVALUATION

**What:** Determining whether FDA's nutrition and nutrition-related activities are meeting the goals and objectives that have been established for them is an essential part of program management and design.

### Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

Monitoring and evaluating the impact of FDA's programs in improving nutrition could be important in contributing to the achievement of:

- Strategic Framework: "Top level result" #1, " Reduce rates of nutrition-related risk factors for chronic disease," "Top level result" #2, "Improve rates of optimal nutritional status among adults," and "Top level result" #3, "Ensure rates of optimal growth and development in infants and children."
- Strategic Plan: Objective #2.2, Strategy #2.2a

### Currently:

Evaluating success against program goals: The goals, objectives, and "key initiatives" against which the success of FDA's current nutrition and nutrition-related activities should be evaluated are in the Strategic Plan for 2012-2015 for the FDA Foods and Veterinary Medicine Program. The goals are to: (1) provide accurate and useful information so consumers can choose healthier diets and reduce the risk of chronic disease and obesity; and (2) encourage food product reformulation. No single, comprehensive evaluation of the program against these goals has been conducted, although evaluation-type activities do occur.

Some of the "key initiatives" in the strategic plan are relatively easy to evaluate because they relate to specific events, such as publishing menu and vending machine calorie declaration regulations. Likewise, the "key initiatives" under the reformulation goal primarily relate to events associated with sodium and *trans* fat reduction. However, evaluating whether the

"accurate and useful information" goal is being met involves determining whether all information that the program provides is "accurate and useful" rather than whether discrete events have occurred.

Evaluating the accuracy of information: Currently, FDA program experts can evaluate the accuracy of some but not all nutrition-related labeling, including the NFL, the calories listed on menus and for products sold in vending machines, health claims for which premarket review is required by law, and "healthy" claims for which there are criteria established by FDA regulation. The accuracy of FDA's education efforts is also easily evaluated. The accuracy of structure/function claims that make up the vast majority of nutrition-related labeling claims cannot now be evaluated.

Evaluating the usefulness of information: Evaluating usefulness to consumers requires: (1) behavioral studies to learn how consumers understand and act on all this information; and (2) analytical studies of the relationship between labeling and the nutrients Americans are consuming. This relationship can provide insights into how consumers are responding (through changes in their nutrient status) to the information they are receiving from labeling and education. These data can also indicate how their nutrient status is being affected by product fortification (e.g., adding nutrients) and reformulation (e.g., reducing or removing potentially harmful nutrients). The nutrient status of Americans is available from NHANES conducted by the Centers for Disease Control and Prevention (CDC), for which FDA pays $500,000 annually. Food labeling information is purchased from private databases and a database that FDA creates through a contactor.

Consumer studies relating to the usefulness of information: Recent and current consumer studies examine how consumers interpret different versions of NFL; how they understand calorie information on menus; whether they pay attention to existing FOP labeling; how they interpret various labeling claims; and how FDA initiatives have affected consumers' diet-related perceptions, attitudes, knowledge, and behaviors.

Database analysis relating to the usefulness of information: Program staff look for associational relationships between NFL and the nutrient status of Americans. Improved nutrient status associated with changes in that labeling suggests that consumers are finding the labeling useful in making purchasing decisions.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Periodically evaluate FDA's nutrition and nutrition-related activities: This evaluation would measure the success of these activities against the nutrition goals and objectives in the strategic plan and the strategic framework.

The following specific recommendations for evaluation are based in part on the NRP recommendation that FDA's nutrition goals involve actual improvements in public health.

2. Consumer studies: Conduct a multi-year, longitudinal cohort study to monitor and assess relationships between and among health, use of nutrition labeling over time, diet-related knowledge and attitudes, and food choices.

*Estimated Additional Cost: $500,000 for first year, $1,000,000 for second year, and $300,000 per year for years 4-8; 1 additional FTE.*

3. Database analysis: Increase baseline funding for NHANES to assist in analysis of additional biomarkers of nutrient status, beyond the current funding for analysis of red blood cell folate to assess folate status (e.g., potassium, vitamin D, B12). Obtain and link individual Medicare/Medicaid medical and mortality histories to nutrient profiles from NHANES to determine possible cause and effect relationships between nutrient profiles and actual health outcomes. In addition, use the food labeling databases and the nutrient profile database to monitor the extent to which foods are being fortified with added nutrients and reformulated to limit or remove various nutrients as well as the impact of these actions on nutrient status. Use these databases to determine the impact of health and nutrient content claims.

   *Estimated Additional Cost:*
   - *Increasing baseline funding for NHANES: $250,000-$500,000 per year.*
   - *Linking Medicare/Medicaid histories to nutrient profiles: $10,000 per year and 0.5 FTE.*
   - *Monitoring, fortification, and reformulation and linking to nutrient status, plus determining impact of health and nutrient content claims: $400,000 to $500,000 per year and 1-2.5 FTEs.*

4. Monitor changes in composition of food products. Using results of the 2010-2011 survey as a baseline, design and implement an expanded biannual Food Labeling and Packaging Survey (FLAPS) to monitor changes in composition of foods, both in the nutrients that are declared on the NFL and in the ingredients declared on the ingredient list. Products sampled in this survey would continue to be selected based on market share.

   *Estimated Additional Cost: The current survey costs $950,000; an expanded survey would cost closer to $1,750,000.*

5. Develop performance measures: As described in the "Strategic Framework" sections of this report, the NRP's proposed strategic framework for nutrition articulates the results that the program is designed to achieve. If adopted, FDA should consider establishing performance measures for all the results against which the success of each result could be measured. The NIT should be reconstituted in collaboration with the OP to develop these performance measures.

# PRODUCT REFORMULATION

**What:** Manufacturers reformulate products by reducing or eliminating nutrients and calories that can contribute to the risk of chronic diseases, including obesity, diabetes, and heart disease. Manufacturers might also reformulate to increase nutrients of public health concern (e.g., prior standard for enriched cereal grains with the fortification of folic acid to prevent neural tube defects) or to increase nutrients to make a health claim.

## Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

Reducing intakes of calories and nutrients such as *trans* fats, saturated fats, sodium, and sugar through reformulation could be important in contributing to the achievement of:

- The Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease;" "Top level" result #2, "Improve rates of optimal nutritional status among adults;" and "Top level" results #3, "Ensure rates of optimal growth and development in infants and children;" and
- The Strategic Plan: Objective #2.3, Strategy #2.3a and #2.3b

## Currently:

Two major objectives of FDA's nutrition program have been to provide consumers with information to better enable them to make healthy food choices and to provide them with healthier food options from reformulated foods. These objectives are interconnected because consumer preferences for healthier foods can serve as an incentive to reformulate. Some FDA personnel interviewed as part of the NRP questioned whether reformulation should be an FDA goal because it is largely an industry responsibility. While essentially true, reformulation can be an important consequence of FDA labeling and education initiatives. Additionally, under certain unique circumstances, FDA can compel reformulation by determining that a particular nutrient is not safe at any level or above a specified level.

Changing consumer behavior to make healthier dietary choices can be a long-term process that is difficult to measure. Achieving healthier diets through the availability of healthier foods that are attractive to consumers without behavioral change can be an appealing alternative. Although reformulation alone cannot substitute for healthful decisions, it can contribute significantly to reducing risk factors for chronic diseases and improving rates of optimal nutritional status.

Reformulation is not without its own challenges, however. Reformulated foods may be less appealing than the formulations they replace. Also, certain substances, e.g., salt, may be needed in foods for technical functions.

Current FDA activities and initiatives that can affect product reformulation include:

1. Nutrition Facts Labeling (NFL):

a. Sodium: Excess sodium can cause high blood pressure, a leading cause of heart disease, kidney disease, and stroke. Americans eat about 3,400 mgs of sodium every day, while the DGA 2010 recommends intakes less than 2,300 mgs daily. According to the CDC, children and adolescents eat the same amounts of sodium as adults and also risk developing high blood pressure.
b. *Trans* fat: Listing of the amount per serving above 0.5 grams has been required since 2006. The IOM has described how the intake of *trans* fatty acids can raise low density lipoprotein (LDL-C), or "bad" cholesterol, which can increase the risk of developing heart disease, and recommends that Americans limit their intake of *trans* fat. The DGA 2010 made a similar recommendation. The CDC estimates that eliminating intake of *trans* fat from PHOs could prevent up to 20,000 cases of coronary heart disease (CHD) and up to 7,000 deaths annually.
c. Saturated fat: The amount per serving is required. The American Heart Association (AHA) recommends limiting saturated fats. Saturated fats can raise 'bad" cholesterol and increase the risk of heart disease. Replacing saturated fats with similar amounts of unsaturated fats may reduce that risk. The Harvard School of Public Health recommends keeping intakes of saturated fats as low as possible. It would not be prudent to eliminate saturated fat completely, however, because foods that are good sources of healthy fats – olive oil, peanuts, and salmon – also contain some saturated fats. According to the DGA 2010, reducing saturated fat to less than 10 percent of calories will help lower blood cholesterol levels.
d. Calories: FDA proposed in 2014 to increase the prominence of calories per serving on the NFL.
e. Added sugars: FDA proposed in 2014 to add a listing for the amount of "added sugars" per serving. Sixteen percent of Americans' calories come from added sugars. The DGA 2010 recommends reducing intakes of calories from added sugars because high intake can decrease the intake of nutrient-rich foods. The IOM reported that many foods and beverages that are major sources of added sugars have low levels of nutrients such as vitamins. The AHA, the American Academy of Pediatrics (AAP), and the World Health Organization (WHO) also recommend decreasing the intake of calories from added sugars.

2. <u>"Healthy" labeling incentives</u>: Manufacturers may make "healthy" claims if their food contains at least certain amounts of beneficial nutrients and no more than certain amounts of nutrients to limit. These amounts are specified in FDA regulations. FDA should update these criteria in accordance with changes in the NFL.

3. <u>*Trans* fat proposed GRAS revocation</u>: In 2013, FDA issued a request for comment on its tentative determination that PHOs, the major source of industrially produced dietary *trans* fats, would no longer be GRAS and thus would not be allowed in foods in the absence of premarket approval as a "food additive."

4. <u>Consumer education</u>: FDA educates consumers about understanding the implications of eating healthy and unhealthy amounts of calories and various nutrients.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Sodium: Issue draft guidance on voluntary sodium reduction in processed, packaged, and prepared foods, with both short and long term reduction targets in a wide range of food categories. Monitor industry progress toward reaching the reduction targets.

   *Estimated Additional Cost: $1,000,000 - $1,500,000 per year for data acquisition; 5 FTEs for data analysis.*

2. Databases: Use food label databases to enhance FDA's ability to monitor foods in the marketplace to determine whether and how products are being reformulated, and partnering with the United States Department of Agriculture (USDA) for access to some information.

   *Estimated Additional Cost: see the Evaluation white paper.*

3. FOP labeling: Monitor the use of FOP labeling information and issue guidance or regulations as appropriate to ensure that this labeling is truthful and not misleading.

4. *Trans* fats: Finalize FDA's preliminary determination that PHOs should no longer be GRAS.

   *Estimated Additional Cost: 1-2 FTEs for compliance/enforcement.*

5. Saturated fats: Decide whether it would be desirable for FDA to engage with industry to determine whether and how foods could be reformulated to reduce saturated fats in foods. Monitor reductions over time.

   *Estimated Additional Cost: see "database analysis" in the Evaluation white paper.*

6. Promote research into use of new substitutes: Decide how and whether FDA could work with industry to facilitate the development of healthy substitutes that can be used in reformulated foods, e.g., substitutes for salt that still impart a salty flavor.

7. Nutrition risk assessment: Use "what if" risk assessment modeling to determine the net effects of reformulation. If a food is reformulated by replacing one ingredient with another, what is the net effect of that replacement? Industry is continually experimenting with new technologies and uses for ingredients. Consider collaboration possibilities in this area.

8. Other countries' efforts: Monitor initiatives in other countries to adjust levels of various nutrients in foods.

9. "Healthy" labeling incentives: Update the criteria in accordance with changes in the NFL.

# FRONT-OF-PACK (FOP) LABELING

**What:** FOP labeling consists of symbols or numbers displayed on the front of food packages to convey information about the nutritional value and general healthfulness of the food. The purpose of FOP labeling is to facilitate the consumer's ability to make healthy food purchases. FOP labeling systems may provide information on nutrients or aspects of food to limit, such as calories, sodium, and fats, or they may provide interpretive information about the healthfulness of food products.

## Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

Providing clear, consistent, and science-based information on the front of food packages to help consumers choose healthier diets could be important in contributing to the achievement of:

- The Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease;" "Top level" result #2, "Improve rates of optimal nutritional status among adults;" and "Top level" result #3, "Ensure rates of optimal growth and development in infants and children."
- The Strategic Plan: Objective #2.1, Strategy #2.1b

## Currently:

Manufacturers are using different labeling formats with icons and symbols to inform consumers about the healthfulness of their products. FDA has not issued regulations or guidance specifically addressing FOP labeling, recognizing the need to first update the NFL, then potentially to address FOP labeling to ensure consistency with the values in the updated NFL.

The types of FOP labeling in use or described in the literature as possible approaches include the following:

1. A single symbol indicating that the product meets certain healthful criteria although these criteria are not provided in the labeling.
2. Certain numerical values from the NFL, such as the number of calories and amounts of sodium and fats per serving.
3. Quantitative information about certain ingredients, such as "low," "medium," or "high." These terms would reflect the amounts of those nutrients relative to established daily values for them, as is already the case for "nutrient content claims."
4. Symbols (e.g., stars) or a number based on an algorithm. In the algorithm, certain nutritional qualities are given numerical values and then added up. The higher the number, or the greater the number of symbols, the greater the healthfulness of the food.

There are advantages and disadvantages to each approach.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Monitoring and Consumer Studies: Continue to monitor FOP labeling in the marketplace and conduct consumer studies on how the various approaches affect decisions and purchases.

   *Estimated Additional Cost: $830,000 per year for 6 years.*

2. Involvement in FOP Labeling: Decide whether and how FDA should become involved with FOP labeling to ensure that it is truthful and not misleading, and that it is effective in enhancing consumers' ability to make healthy choices. Toward that end:
   a. Guidance: Decide whether to issue guidance that would acknowledge various approaches to FOP labeling and articulate basic principles applicable to each approach.
   b. Regulations: Alternatively, decide whether to develop regulations to mandate a standardized FOP system for all foods. The purpose would be to ensure that all FOP labeling is truthful and not misleading and that consumers are not confused by a multiplicity of FOP systems. A variation might be to issue regulations mandating a particular approach but leaving details up to the discretion of manufacturers.
   c. Considerations: Considerations to be taken into account should include:
      i. Whether FOP labeling should only refer to nutrients or food attributes to limit, such as calories, sodium, and fats, or whether it should also include nutrients or food components to increase, e.g., whole grains, milk, seafood, dietary fiber, and vitamin D;
      ii. Whether FOP labeling should appear on all foods or just on some foods, e.g., only foods meeting certain healthy criteria;
      iii. Whether algorithm-based approaches would be better than simply transferring some information from the NFL to the FOP. An algorithm-based approach could use symbols, such as stars, or a number. The greater the number of symbols or the higher the number, the healthier the food. This approach, according to the IOM, would encourage "healthful food choices through simplicity, visual clarity, and the ability to convey meaning without written information." It would also provide guidance about healthfulness, which nutrition information alone cannot do. A potential disadvantage is that the values assigned to different attributes of the food in algorithm-based scoring systems could vary from system to system. Unless there were a single, nationally-mandated system, algorithm-based systems could produce different scores for essentially the same foods.

# MEDICAL FOODS

**What:** A medical food is a food that claims on its labeling that it manages a disease or condition that has a "distinctive nutritional requirement." There is no statutory requirement that a medical food undergo premarket review and approval for safety or effectiveness as a prerequisite to making the claim, as would be required for a pharmaceutical making the same claim. To qualify as a medical food, the food must meet the definition of medical food in Section 5(b) of the Orphan Drug Act Amendments of 1988, as follows:

> "A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation."

**Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:** Ensuring that these foods are safe and effective for managing nutrition-related diseases and conditions could be important in contributing to the achievement of:

- The Strategic Framework: "Top level" result #:1, "Reduce rates of nutrition-related risk factors for chronic disease."
- The Strategic Plan: Objective #2.1, Strategy #2.1b.

## Currently:

An increasing variety of products are being labeled as medical foods and making "disease" claims without premarket review and approval by FDA. This situation places a post-market burden on FDA to determine whether the claims are truthful and not misleading. Some of these products have track records of being safe, with proven therapies that meet nutritional needs that could not otherwise be met. Examples include the management of inherited metabolic disorders such as phenylketonuria. Others, however, make claims that are not as well established, including claims relating to the dietary management of metabolic processes associated with Alzheimer's disease, or claims relating to the management of middle ear infections and the restoration of normal flora in the mouth and throat for populations that include children as young as six months of age.

FDA's regulatory options are to either disprove the claim if it is in fact false or misleading, or to determine that the food does not meet the statutory definition of medical food. (If it is not a medical food, it is not entitled to make a disease claim without first undergoing the premarket review required of new drugs.) More often than not, FDA has taken the latter approach when apparently justified and legally defensible. The statutory definition of medical food is complex, however, with many elements that lend themselves to contradictory interpretations. Manufacturers often interpret the definition broadly and in such a way that low calorie frozen dinners could apparently be identified as medical foods. FDA has interpreted the definition more

narrowly to limit foods that make unapproved disease claims to those that appear to provide proven, essential therapies.

FDA issued regulations in 1990 and draft guidance in 2013 that interpreted the statutory definition of medical foods consistent with this approach. The regulations lacked a preamble explanation or public health policy basis for the interpretation, however, and the draft guidelines are similarly lacking. Both have been criticized by industry for being too narrow in their construction and thus outside of the statutory definition. Many of the Agency's regulatory actions to date have been resisted largely on the same basis. FDA's interpretation has not been litigated, however.

## Recommendations:

FDA should strive to achieve a regulatory balance between: (1) expeditiously removing from the marketplace self-proclaimed medical foods that make questionable, false, or misleading disease claims; and (2) minimizing barriers to the development and availability of legitimate medical foods that can make a significant difference between function and dysfunction, or even life and death.

In addition to what the program is already doing, FDA should consider the following:

1. Update its interpretation of the statutory definition: FDA should update its interpretation of the statutory definition of medical foods by addressing nearly every term in that definition individually, e.g., "formulated," "distinctive," "nutritional," and "requirement." The overall interpretation should reasonably limit the types of foods that may make disease claims not subject to the premarket review system for those same claims for pharmaceuticals. At the same time, FDA's interpretation should not block the development of legitimate nutrition-related therapies. FDA should consider doing this by notice-and-comment rulemaking, with strong public health justification in the preamble. (See 4 below for other possible features of such a rulemaking.)

2. Develop a standard of evidence for disease claims: FDA should develop a standard of evidence that would be needed to support disease claims for medical foods, possibly modeled after the current FDA standard of evidence for health claims. FDA should consider doing so as part of a public, collaborative process.

3. Develop a process for reviewing claims: Develop a process for reviewing claims based on the above standard of evidence. Possibilities include the following:
    a. A requirement established by regulation for pre-market review and approval of the claim; or
    b. A requirement to submit data to FDA upon request to review a claim; or
    c. An FDA labeling statement or "mark" signifying review by FDA for those manufacturers that elect to obtain it; or
    d. A requirement for a statement on labeling signifying lack of review by FDA if such were the case, based on premise that lack of review of a disease claim would be a material fact. Consumer studies could be used to determine whether

consumers believe that claims made for medical foods have been reviewed and approved by FDA.

4. Foods for special dietary use: FDA should also consider clarifying the statutory definition of foods for special dietary use (FDSU) to distinguish such foods from medical foods. FDSU are defined in section 411(c)(3) of the FD&C Act. This clarification would potentially enable foods to qualify as FDSU that do not meet the definition of medical foods in its entirety but still have value in the nutrition-based management of diseases or conditions. This qualification may allow for certain types of labeling claims relating to an FDSU's intended use.

*Estimated Additional Cost: 1-2 FTEs.*

# DIETARY GUIDANCE STATEMENTS

**What:** "Dietary guidance statement" is a term first coined by FDA in the early 1990's in the preambles to health claim regulations to distinguish certain types of labeling claims from "health claims." Health claims were defined as those that claim that a "substance," i.e., a specific food or a component of food, may reduce the risk of a disease or health-related condition. It must include both of the above elements: (1) a "substance," and (2) a disease or health-related condition. By contrast, a "dietary guidance statement" as described in preambles to FDA regulations, is a claim that only contains one of the above elements but not both (58 FR 2478 at 2387 and 59 FR 395 at 418). An example of a dietary guidance statement would be: "Broccoli is good for general health." It contains a "substance," i.e., broccoli, but no disease or [adverse] health-related condition. Another example would be: "Vegetables reduce the risk of heart disease." "Vegetables" is a class of foods but not a specific food, i.e., "substance," but "heart disease" is a disease or [adverse] health-related condition.

**Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:** Ensuring that dietary guidance statements are truthful and not misleading, and that consumers understand and are influenced by them to make healthful dietary choices, could be important in contributing to the achievement of:

- Strategic Framework: "Top level" result # 1 "Reduce rates of nutrition-related risk factors for chronic disease;" and "Top level" result #2, "Improve rates of optimal nutritional status among adults," and
- Strategic Plan: Objective #2.1, Strategy #2.1b.

## Currently:

The preamble distinctions between health claims and "dietary guidance statements" effectively allow unsubstantiated risk reduction claims for classes of foods, e.g., vegetables, while requiring premarket substantiation for risk reduction claims for specific foods or components of foods. There is no obvious reason for this distinction.

Also, the distinction between dietary guidance statements and structure/function claims is not clear, to the point where some dietary guidance statements could also be structure/function claims and vice versa, since both can refer to health benefits. Although this apparent overlap is not currently a practical problem, since FDA does not require substantiation for either type of claim, any effort by FDA to require some form of substantiation for dietary guidance statements could be limited to those that are not arguably also structure/function claims.

There are also concerns that dietary guidance statements are appearing on products that have negative nutritional attributes, such as high levels of saturated fats, cholesterol, sodium, or added sugars. Dietary guidance statements on these foods can mislead consumers into believing that the food lacks negative attributes. A dietary guidance statement can be misleading not only because of what it states, but also because of the product on which it appears. Finally, there is concern that products are bearing dietary guidance statements without containing meaningful amounts of the foods to which the statements pertain.

## Recommendations:

FDA should consider the following:

1. Definition: Establish a clear definition of a dietary guidance statement that links a food or category of foods to a healthful diet or to general health benefits, consistent with current Federal dietary recommendations, e.g., the DGA 2010. Dietary guidance statements would no longer make unsubstantiated risk reduction claims. They would also be distinguishable from structure/function claims by their general nature, since structure/function claims are typically directed as specific structures or functions, such as bone health.

2. Accurate contents: Ensure that foods bearing a dietary guidance statement contain at least a meaningful amount of a whole food, a finished food, or a category of food that is the subject of the statement.

3. Consistency with reports: Ensure that dietary guidance statements are consistent with reports published by a reputable scientific source or authoritative scientific body.

4. Healthy contents: Ensure that dietary guidance statements do not appear on foods that contain excessive amounts of nutrients that cause the food to be potentially unhealthful.

5. Consumer research: Conduct consumer research to better understand how dietary guidance statements influence consumer behavior, and gain information regarding specific types of dietary guidance statements that may be more helpful to consumers.

> *Estimated Additional Cost: For consumer research, $166,000 per year for three years.*

# STRUCTURE/FUNCTION CLAIMS

**What:** Labeling on dietary supplements and conventional foods including infant formulas often bear "structure/function" claims that, for the most part, claim that the food helps maintain or improve a body structure (e.g., "builds strong bones") or a body function (e.g., "maintains bowel regularity") in a healthy person.

**Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:** Ensuring that consumers understand, and are influenced by, "structure/function" claims that are truthful and not misleading in order to maintain health could be important in contributing to the achievement of:

- Strategic Framework: "Top level" result #2, "Improve rates of optimal nutritional status among adults," and "Top level" result #3, "Ensure rates of adequate growth and development in infants and children;" and
- Strategic Plan: Objective #2.1, Strategy # 2.1b.

## Currently:

Dietary Supplements: The FD&C Act authorizes structure/function claims on labeling for dietary supplements. Manufacturers must have substantiation that their claims are truthful and not misleading but are not required to provide this substantiation to FDA. Dietary supplement labeling must bear a disclaimer that FDA has not evaluated the claim. Manufacturers must submit the text of the claim to FDA, however, within 30 days of its use on labeling. A structure/function claim for a dietary supplement may derive from the product's nutritive or non-nutritive effects. FDA has issued regulations on how to distinguish a structure/function claim for a dietary supplement from a "disease claim" for a drug relating to the diagnosis, cure, mitigation, treatment, or prevention of a disease and guidelines on how to substantiate a claim.

Conventional Foods: There is no statutory authorization for structure/function claims on conventional foods as there is for dietary supplements. There is no statutory requirement for substantiation, or for requiring a disclaimer that FDA has not examined the claim, or for sending the text of the claim to FDA prior to marketing. Because case law defines food as articles consumed primarily for taste, aroma, or nutritive value, FDA has stated that structure/function claims for conventional foods should be derived from nutritive value. FDA does not know the extent to which structure/function labeling claims for either dietary supplements or conventional foods are truthful and not misleading. FDA does not review these claims other than to determine that they are in fact structure/function claims and not disease claims that may only be made for drugs. FDA receives over 2,000 structure/function claim notifications for dietary supplements each year. FDA does not similarly inventory or review such claims for conventional foods. There have been some preliminary studies on how consumers respond to structure/function claims but this is a subject that could benefit from additional research.

Both the General Accounting Office (GAO) and the Department of Health and Human Services (HHS) Inspector General have issued reports that, among other things, expressed concern about the unregulated state of structure/function claims. These reports recommend that FDA issue guidance on the scientific evidence that should be needed to support structure/function claims and that legislation be obtained to grant FDA with access to manufacturers' evidence in support of their structure/function claims.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Consumer research: Conduct research to better understand how structure/function claims influence consumer choices, the extent to which consumers understand these claims, and the extent to which consumers trust them and assume that there is some regulatory oversight regarding their truthfulness.

   *Estimated Additional Cost: $166,000 per year for three years.*

2. Regulations: Develop regulations for structure/function claims to address any or all of the following ideas:
   a. Agency review: Encourage manufacturers to submit data to FDA that support the claim.
      i. Provide manufacturers with access to an FDA "mark," or statement on labeling, or letter from the Agency signifying review by FDA.
      ii. Require a disclaimer for conventional foods similar to that for dietary supplements for those claims that have not been evaluated by FDA.

   b. "Qualified" claims: Require that structure/function claims be "qualified" when the evidence in support of the claim is not clear and convincing. (An unqualified claim under such circumstances is arguably misleading.) Qualifications are now required for "health" claims, i.e., claims that a nutrient in the food reduces the risk of a disease, when the evidence in support of the claim is limited. It is not clear why the same principle should not apply to structure/function claims.

   c. Adequacy of amount: A structure/function claim for a product containing only a fraction of the amount of a nutrient that was the subject of research forming the basis of the claim is arguably false and/or misleading if it is not known whether the small amount in the food bearing the claim would have any effect. Require the amounts and significance of nutrients to be listed on labels.

3. Guidelines: Develop guidelines (or include in the above regulations) for all conventional foods for:
    a. The standard of evidence needed to substantiate structure/function claims;
    b. Criteria for distinguishing structure/function claims from "disease" claims that relate to diagnosis, cure, mitigation, treatment, or prevention of disease. Currently, FDA has issued such criteria for dietary supplements.

4. Regulatory action: Take action against claims that cannot be substantiated. For any structure/function claims that appear to have no credible evidence to support the claim, establish a reasonable literature review that FDA would conduct to look for some evidence in support of the claim. If FDA cannot substantiate the claim, then issue a warning letter to shift the burden of substantiation to the manufacturer.

5. Collaboration: Collaborate with NIH to issue grants to researchers to study the validity of structure/function claims.

*Estimated Additional Cost: as many as 4 FTEs to review underlying data and determine the accuracy of claims.*

# BIOACTIVE FOOD COMPONENTS

**What:** Bioactive components are constituents in foods or dietary supplements that can affect health but are not needed to meet basic nutritional needs. They include probiotics and prebiotics. Although FDA has not defined probiotics, they are generally regarded as live microorganisms that may confer a health benefit when consumed in adequate amounts. Prebiotics (dietary fibers) are non-digestible food components that can stimulate the growth and/or activity of bacteria in the large intestine in ways that may be beneficial to health. Dietary fiber is the indigestible portion of carbohydrates and lignin that occurs naturally in plants and is important in promoting healthy laxation. Other bioactive substances (e.g., phenolic substances, phytosterols, lutein, and the omega-3 fatty acids DHA and EPA) have been the subject of significant research and public attention.

## Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

Increasing the understanding of the physiological benefits and the safety of bioactive food components, as well as the truthfulness of claims that are made about them, could be important in contributing to the achievement of:

- Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease," "Top level" result #2, "Improve rates of optimal nutritional status among adults," and "Top level" result #3, "Ensure rates of optimal growth and development in infants and children."
- Strategic Plan: Objective #2.2, Strategy #2.2a.

## Currently:

Probiotics: The availability of probiotics in the marketplace is increasing, largely in yogurts and dietary supplements. A 2012 report by the University of Maryland identified nearly 30 strains of bacteria in probiotic products. Foods containing probiotics often bear structure/function claims on their labeling, the validity of which are not reviewed by FDA. Many of these claims relate to general health, the functioning of the immune system, or to an improvement in natural healthy gut flora. Also unknown and therefore unregulated is whether the microorganisms survive and achieve their desired effects in the intestinal ecosystem throughout the shelf life of these products. If they do not, both the labeling claim and the shelf life labeling may be false. There may also be safety issues associated with deliberately introducing live microbes into the digestive system. FDA has received 25 GRAS submissions from industry about probiotics. If the products subject to these submissions were all marketed they would likely represent only a fraction of all of the probiotic products on the market, since GRAS submissions are voluntary.

Prebiotics: The DGA 2010 identified foods that contain dietary fiber as "foods to increase." Children and adults are advised to consume foods naturally high in dietary fiber to increase nutrient density, promote healthy lipid profiles and glucose tolerance, and to ensure normal gastrointestinal function. The DGA 2010 also noted that it is unclear whether fiber added to foods provides the same health benefits as naturally occurring fiber.

The amount of dietary fiber in a food must be declared on the NFL. Dietary fiber is not regarded as "essential" but it is required by statute to be listed because it confers a health benefit. Because FDA has not defined "dietary fiber," manufacturers are declaring on NFL the amounts of fibers that have been added in addition to the fiber naturally present so long as the added fibers are GRAS or have been approved for safety through the food additive process. Because these added fibers might not confer a physiological benefit, listing them in addition to any naturally occurring dietary fiber in the food could be misleading. The proposed rule for NFL defines "dietary fiber" as including both naturally occurring fiber and added fiber that has been demonstrated to have a beneficial physiological effect. This demonstration would have to be substantiated to FDA either through the submission of a health claim petition for a specific added fiber or through a citizen's petition.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Monitoring: Continue monitoring both the emerging science and developments in the marketplace for issues that could affect the health benefits, safety, and effectiveness of bioactive substances. Marketplace monitoring could include review of food labeling databases to determine the numbers and types of products that contain certain bioactive substances such as probiotics. Consider regulatory initiatives as appropriate in response to marketplace conditions. Monitoring should also include review of regulatory activities relating to these substances in other countries.

2. Structure/Function Claims: FDA should expect a proliferation of new structure/function claims for probiotics and possibly for other bioactive components, thus adding to the inventory of unsubstantiated, nutrition-related claims in the marketplace. FDA should decide at some point whether to address the validity of structure/function claims generally, including those for probiotics. Structure/function claims are addressed in a separate white paper in this report.

   *Estimated Additional Costs: see Structure/Function white paper.*

3. Research: Consider collaborating with industry and others such as through public-private partnerships to conduct research on fiber ingredients, probiotics or other substances that industry wants to substantiate as having a beneficial physiological effect. This research

could be directed toward certain health endpoints such as effect on blood cholesterol and glucose levels, as well as blood pressure.

> *Estimated Additional Costs: see "dietary fiber" in the Laboratory and Clinical Research white paper.*

# CONSUMER STUDIES

**What:** FDA engages in surveys, interviews, focus groups, "experimental" studies to test consumers' reactions to different label formats, concepts, designs etc., and literature reviews to learn about consumers' understanding of nutrition-related matters, including their understanding of nutrition-related labeling, and whether FDA labeling and education initiatives are affecting consumer behavior.

## Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

The ability to develop and adjust FDA nutrition initiatives based on consumer feedback as obtained through studies that measure consumer knowledge and behavior could be important in contributing to the achievement of:

- Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease," "Top level" result #2, "Improve rates of optimal nutritional status among adults," and "Top level" result #3, "Ensure rates of optimal growth and development in infants and children."
- Strategic Plan: Objective #2.1, Strategy #2.1c.

## Currently:

FDA conducts consumer studies, including nutrition-related studies, with a relatively small staff and budget. Although FDA receives good value for this investment, consumer studies are limited relative to their potential to support the support the program. For example, determining the impact of FDA nutrition activities on health -- to the extent that it is possible to do so -- has barely been attempted due to resource constraints.

Studies tend to be restricted to matters germane to initiatives underway or already completed. To comply with the Paperwork Reduction Act (PRA), the public must be notified before most types of consumer studies may be conducted. Such advance notice of Agency research can sometimes raise public expectations about potential initiatives, which, in turn, can discourage conducting certain kinds of studies in the first place. Also, the ability to conduct studies that are needed relatively quickly can sometimes be affected by the extended timeframes that are often needed to obtain approval through OMB. A 2010 report from a CFSAN Research Review Committee to the FDA Science Board urged that OMB procedures be modified to allow for faster approval. It was suggested that if OMB did not respond to a written request within three months, the request would be automatically approved.

These limitations notwithstanding, consumer studies in recent years have addressed, and are addressing, a range of questions, including the following:

Nutrition Facts labeling: how different versions of the NFL affect consumer judgments about the healthfulness of foods, and how consumers interpret various declarations in that labeling, including their ability to determine the number of calories per serving and per package.

Menu labeling: (1) consumer understanding and use of calorie information on restaurant menus and collection of menu data from chain restaurants; and (2) industry practices in response to FDA menu labeling rules.

Front-of-Pack labeling: consumers' visual attention to information presented on food packages, plus analysis of commercial data to track food manufacturers' adoption of existing FOP systems.

Food labeling claims: how consumers interpret various claims, such as whole grain claims, and content claims on fortified snack foods.

Periodic health and diet surveys and special one-time surveys: Such surveys have been conducted 11 times since 1982, primarily to evaluate how FDA initiatives have affected consumers' diet-related perceptions, attitudes, knowledge, and behaviors. These surveys have also been used to identify differences in nutrition knowledge and behaviors by ethnicity and to provide information that may be used to develop targeted consumer education messages. None of these surveys measures nutrient intake, however, and they are not longitudinal, e.g., they do not track long term impact on individuals.

## Recommendations:

In addition to what the program is already doing, FDA should consider the following:

1. Impact of FDA's initiatives on health: Conduct a multi-year, longitudinal cohort study to monitor and assess the relationships between health and: nutrition label use over time, diet-related knowledge and attitudes, and food choices. This could be a major step forward in being able to relate FDA nutrition initiatives and activities to actual health impacts.

   *Estimated Additional Costs: $500,000 for year one, $1 million for year two, and $300,000 for years four-eight; 1 additional FTE.*

2. Food label use among subpopulations: Conduct a study on food label usage, comprehension, and engagement among people of color and people from low-income backgrounds. This area constitutes a major knowledge gap that, if filled, could support more effective nutrition labeling policies and education programs.

   *Estimated Additional Costs: $200,000 per year for four years.*

3. Pilot project on mobile technologies: Launch one or more pilot projects to explore how mobile technologies can be used to inform and improve the healthfulness of consumer food choices, particularly during grocery store and restaurant visits. Free applications could be developed for consumers to use to scan food labels to find out more information about products, i.e., "digital labeling." Universal Product Codes (UPCs) could be scanned to find out information customized to consumers' individual nutritional needs. Quick Response Codes (QRs) could be scanned to reveal more nutritional information about products.

   *Estimated Additional Cost: $500,000 per year for four years; 1 FTE.*

4. Focus group testing and economic analyses: (1) Conduct focus group studies in advance of economic analyses to test the validity of assumptions that are to be used in modeling the economic impact of nutrition-related regulations. Current economic models that predict the market impact of nutrition labeling revisions are based on market changes that were observed following the creation of the original NFL in the 1990's. Determining whether those assumptions are valid must usually await the completion of "before" and "after" market research. (2) Conduct focus group studies to test the validity of assumptions that were used in the modeling of recent previous economic impact analyses.

   *Estimated Additional Cost: $120,000 per focus group study.*

5. Expedited OMB clearance: Request the expedited clearance of initiatives through the OMB, since the Administration is supportive of improving nutrition. The document clearance process is so lengthy that it can jeopardize advances in research.

# CONSUMER EDUCATION

**What:** FDA engages in consumer education to inform and influence consumers about how to make healthier food choices. FDA consumer education is designed to help consumers read and understand nutrition-related labeling and understand why this information is important to them in maintaining good health.

## Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:

Using education to increase consumers' understanding of nutrition labeling and the importance of nutrition in their own lives and motivating them to use this knowledge when making food choices could be important in achieving:

- Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease," "Top level" result #2, "Improve rates of optimal nutritional status among adults," and "Top level" result #3, "Ensure rates of optimal growth and development in infants and children."

- Strategic Plan: Objective #2.1, Strategy #2.1a.

## Currently:

Current activities and initiatives include:

1. READ THE LABEL Campaign: This campaign has education and programming components for use by "tweens," parents, organizations with after-school programs, and community educators who run health education programs in libraries, community centers, etc.

2. Multimedia/Social Marketing Outreach: Many nutrition-related materials have been developed and are on-line (Facebook, Twitter, YouTube, and Pinterest). An on-line game and interactive food label are being developed for FDA's web page. Articles, infographics, and video materials are used by radio, television, newspapers, magazines, online, and social media outlets and reach millions of people.

3. Continuing Medical Education (CME) Nutrition Program: FDA is producing a CME program with AMA that includes video training materials and handouts that train medical professionals on the most effective way to educate patients about using the NFL to make healthier food choices.

4. SCIENCE AND OUR FOOD SUPPLY: FDA partnered with the National Science Teachers Association (NSTA) to create an interactive food safety program that contains

web-based teacher tutorials, lesson plans for use in secondary school classrooms, and a professional development program for teachers.

## Recommendations:

There is evidence indicating that well-designed nutrition education can be effective in improving consumers' dietary practices (Contento 2007). FDA needs to decide how much and what types of education strategies contribute significantly to the Agency's strategic goals for nutrition. Long-term programs and media-related campaigns are needed to achieve changes in consumer behavior.

In addition to current activities, FDA should consider the following:

1. Layered consumer education goals: Decide what successful consumer education programs would achieve, either with current funding or with greater resources. Explore whether success could be achieved through collaboration with private and public entities, and through enhanced use of "multipliers," e.g., groups with direct access to consumers, such as local health departments and the medical community, "unconventional" influencers such as chefs, and the industry. Examples of possible enhanced activities with multipliers include:

a. Nutrition Outreach Team: Broaden the reach of the READ THE LABEL campaign by creating a Nutrition Outreach Team of educators and providing grants at the local level to conduct nutrition labeling education.

*Estimated Additional Costs: $500,000 annually; can be accomplished within one to three years.*

b. CME Nutrition Program: Expand the current FDA and AMA CME program to include additional medical specialties.

*Estimated Additional Costs: $350,000 per organization; can be accomplished within one to three years.*

c.Multimedia/social marketing outreach: Expand outreach by creating new initiatives for different platforms (Face Book, Twitter, Pinterest, YouTube, etc.) and developing new and innovative ways of social media engagement. Create a new initiative with a media partner (e.g., Nickelodeon or Disney) that reaches youth via multiple channels.

*Estimated Additional Costs: $500,000 to $1.5 million annually; can be initiated in one to three years.*

d. SCIENCE AND OUR FOOD SUPPLY: Expand the school-based food safety program to include nutrition and extend the program's reach to "underserved" students. The current food safety program has reached over 7,000 teachers and 2.8 million students. Develop a specialized "train the trainer" program for selected teachers to teach underserved populations about overcoming barriers to good nutrition.

*Estimated Additional Costs: $155,000 for three states in five sites annually, can be initiated in one to three years; one FTE.*

e. Expansion of other nutrition education activities: Expand nutrition education to further assist consumers in understanding nutrition materials and labeling such as promoting an understanding of information on menus and menu boards and in vending machines.

2. Consumer studies: Develop consumer studies to evaluate the effectiveness of current activities and to help generate new ideas. For example, educating children about how to read the NFL through the use of messaging on the Cartoon Network was perceived to be highly successful in conveying information, but was never evaluated to determine how it was affecting eating behavior at the time, or whether the learning carried over to behavior later in life.

*Estimated Additional Costs: $75,000; can be initiated in one to three years.*

3. New strategies to reach specific audiences: Develop strategies to reach audiences such as children, elderly, under-served and at-risk sub-populations. Create new and better ways to obtain education continuity from one stage of life to another. Consider how best to ensure that education begins in childhood to adopt healthy eating patterns, then as people age, educate them about how their nutrient requirements change through life and how they need to adjust their diets to maintain their health. Low income consumers are especially vulnerable to poor nutrition because their food choices as well as their understanding of nutrition can be relatively limited. New strategies could include educating at-risk subpopulations about how to prepare nutritious meals that are economical and appealing. Consider how best to partner with public health and local organizations to convey this information in a culturally sensitive and relevant ways.

*Estimated Additional Costs: ½ FTE; can be completed in one to three years.*

4. New public-private partnerships: Develop new partnerships to enhance nutrition education. Working with industry partners and other stakeholders on topics such as

sodium, the nutrition label, menu labeling, etc., could positively affect overall nutritional quality of packaged and restaurant foods.

> *Estimated Additional Costs: $50,000 annually; ½ FTE; can be initiated in one to three years.*

5. Enhance evaluation of nutrition education efforts: Develop and implement plans to evaluate future nutrition education efforts.

# LABORATORY RESEARCH

**What:** CFSAN conducts nutrition-related research in support of program needs. The majority of laboratory research is directed toward methods development and method validation, the latter reflecting the need to develop targeted methods that can be transferred to FDA field laboratories.

**Relevance to FDA Strategic Framework for Nutrition and New 10 Year Strategic Plan for Food and Veterinary Medicine:**

Improved methods for the analysis of nutrients and other bioactive ingredients in foods and dietary supplements and monitoring of changes in food composition are important in contributing to the achievement of:

- Strategic Framework: "Top level" result #1, "Reduce rates of nutrition-related risk factors for chronic disease," "Top level" result #2, "Improve rates of optimal nutritional status among adults", and "Top level" result #3, "Ensure rates of optimal growth and development in infants and children."
  - Strategic Plan**:** Objective # 2.2. Strategy #2.2c

    Objective # 2.3. Strategy # 2.3b

**Currently:**

Intramural laboratory research supports critical regulatory and public health goals. Examples of current laboratory activities include the following:

Bioactive food components (structure/function claims and health claims): Bioactive food components are constituents other than nutrients that can affect health (e.g., omega-3-fatty acids and plant phytosterols). An improved method to detect levels of omega-3-fatty acids in marine oil dietary supplements has been developed as has a method for the analysis of phytosterols.

Product reformulation: Laboratory research has been conducted to optimize gas chromatograph and other methods for the analysis of low levels of *trans* fat in edible oils. Methods are now available for quantitation of saturated fatty acids, monounsaturated fatty acids, and polyunsaturated fatty acids, as well.

**Recommendations:**

In addition to laboratory research that is currently underway, FDA should consider the following:

Collaborative activities: CFSAN should participate in professional societies and consider collaborating with industry and others (e.g., through public-private partnerships) to conduct methods development and validation work as needed on new components (e.g., sugar substitutes and salt substitutes).

Structure/function claims and health claims: Foods and dietary supplements carry an increasing variety of structure/function claims for nutrients and bioactive food components. As FDA decides how to address the validity of such claims in general, laboratory research activities could focus on ensuring that adequate methods are developed for bioactive food components that are or may become the subject of such claims.

Dietary fiber: FDA's definition for dietary fiber in its proposed rule for NFL includes both naturally occurring fiber and added fiber that has been demonstrated to have beneficial physiological effects. The nutrition program should consider collaborating with IFSH to conduct human studies, specifically on studies about the functionality of new dietary fiber sources. Laboratory activities can support such initiatives through the development of methods for new fiber sources. Collaborative efforts with producers of such ingredients should also be considered.

> *Estimated Additional Cost: Cost of clinical trials will vary from between $500,000 and $1,000,000 per trial depending on design and number of subjects. Trials on functionality of new dietary fiber sources should be short, i.e., months.*

Medical foods: Analysis of essential nutrients and bioactive components in such products, which vary widely in content of fat, amino acids, proteins, and carbohydrates is often a difficult task. Contributions of laboratory research in this area could include the development of methods for essential nutrients and other constituents (e.g., oil-soluble vitamins and phytochemicals).

## Appendix B. Cost and Benefits of Existing and Contemplated Food Initiative Proposals*

This table indicates that the potential annualized net benefits for FDA's recent and contemplated nutrition-related initiatives could be considerably greater than those for its food safety initiatives directed toward contaminants in the food supply.

| | Annualized Costs | Annualized Benefits | Annualized Net Benefits |
|---|---|---|---|
| **Nutrition** | | | |
| Sodium<br>(1,264 mg/day reduction in sodium intake) | $2.48 billion | $120 billion | $118 billion |
| Trans Fat | $0.8 billion | $10.1 billion | $9.2 billion |
| Nutrition Facts/Serving Size | $0.2 billion | $2.0 billion | $1.8 billion |
| Menu Labeling/Vending Machine Labeling Combined | $0.12 billion | $0.60 billion | $0.48 billion |
| Menu Labeling | $0.08 billion | $0.60 billion | $0.52 billion |
| Vending Machine Labeling | $0.04 billion | Small, but not quantified | Likely negative |
| | | | |

| | | | |
|---|---|---|---|
| | **Annualized Costs** | **Annualized Benefits** | **Annualized Net Benefits** |
| **FSMA** | | | |
| **Produce** | $0.53 billion | $0.93 billion | $0.40 billion |
| **Preventive Controls** | $0.48 billion | not quantified | break even analysis performed |
| **Intentional Adulteration** | $0.36 billion | not quantified | break even analysis performed |
| **FSVP/3P** | $0.46 – 0.47 billion | not quantified | not quantified |
| | **Annualized Costs** | **Annualized Benefits** | **Annualized Net Benefits** |
| | | | |
| **Other** | | | |
| **Gluten-Free Labels** | < $0.01 billion | $0.14 billion | $0.13 billion |
| **Infant Formula GMP** | < $0.01 billion | $0.01 billion | < 0.01 billion |

*All costs/benefits/net benefits used 3% discount rate, and are presented in 2012 equivalent dollars.

# Appendix C. External and Internal Interview Summaries

The first step in the NRP process involved conducting interviews with 56 FDA employees and 32 individuals outside of FDA. The external individuals included leaders in nutrition in academia, other government agencies, former government employees, consumer advocacy organizations, the food industry, and food consultants. The purpose of those interviews was to obtain views on what the FDA nutrition mission should be and how it should be carried out. Here are the interview summaries developed by the contractor that conducted the interviews.

## FDA Nutrition Program Review:

## Results of External Interviews

**FINAL**

**February 24, 2014**

Contract No. HHSF223201210011B

BPA No. 3

**Prepared by:**

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## ES. EXECUTIVE SUMMARY

To support the increasing emphasis of FDA's role as a public health agency and the importance of nutrition in preventing the pressing problems of chronic disease and obesity in the United States, CFSAN is undertaking a major review of its nutrition activities. This review is intended to ensure that FDA's nutrition program efficiently and effectively supports healthy eating and a nutritionally healthy food supply.

Under Phase 1 of the nutrition program review, FDA organized interviews of personnel working within the nutrition program in CFSAN and OFVM. Under Phase 2 of the nutrition program review, FDA has organized interviews of 34 leaders in nutrition working in academia, other government agencies (including CDC, USDA, NIH, and former government employees), nonprofit organizations (NPOs), the food industry, and food consulting to help assess FDA's current goals, responsibilities and priorities in addressing nutrition-related issues.

The following report summarizes the responses of external interviewees who shared their thoughts and opinions on FDA's role in nutrition, as well as their recommendations for improvements and changes.

### ES.1. Salient Points

A number of the salient points identified in the internal interviewee report were reinforced during the external interview process, which may have been due in part to both internal and external interviewees being asked similar questions. However, the external interviews also yielded valuable additional recommendations which appeared to be attributable to the differences in perspectives of the external interviewees, many of whose work is affected by FDA actions.

#### ES.1.a. Salient points resulting from the internal interview process that were reinforced during the external interviews

**Garner Support for Goals and Initiatives: Strategic Plan Goal 5**

- Nutrition leadership should address the mixed responses from external interviewees for Goal 5 of the FVMP Strategic Plan regarding reformulation. The following issues were raised:
    - Whether FDA should undertake reformulation as a full-scale regulatory approach to controlling levels of sodium and *trans* fats in the diets of Americans (endorsed by public health proponents) or a partnership approach to encouraging reformulation (endorsed by industry proponents).
    - The need to evaluate the impact of reformulation in terms of its effectiveness in changing consumer behavior and in improving health.
    - The need to resolve whether this is an appropriate goal in terms of FDA's role or mandate.

**Re-evaluate Statutory Mandate for Nutrition**

- FDA should carefully re-examine its statutory mandate with respect to nutrition and confirm that the current parameters, and particularly those pertaining to education and outreach, are in fact sufficient to support an expanded public health role in nutrition.

**Set Measurable Goals**

- FDA should set measurable goals for nutrition-related activities.
    - Because of the long-term nature of most nutrition impacts, measuring the effectiveness of nutrition activities may not be possible as part of the daily job, aside from assessing increases in consumer knowledge of nutrition via consumer research or conducting laboratory research to assess the impact of nutrition on health.
    - The need to assess and evaluate the effectiveness of nutrition-related activities was seen for all agencies involved in nutrition.
    - Interviewees specifically felt there was a need for FDA to assess the impact of its regulatory actions on influencing consumer behavior and improving nutrition.

**Clarify FDA's Role in Nutrition: Inter-agency**

- FDA should clarify and define its role in supporting Federal policies on the prevention of chronic disease and obesity in conjunction with and vs. other HHS components and Federal agencies so as not to duplicate efforts.

**Increase FDA's Visibility in Nutrition**

- FDA should increase its visibility to the public when it comes to nutrition-related matters.
    - Much of the public is largely unaware of FDA's role in nutrition.
    - FDA's nutrition-related activities, particularly those related to research and education and outreach, are not visible, even to professionals working in the nutrition field.
        - FDA should publicize agency research efforts to increase awareness of these activities.

**ES.1.b. Additional salient points identified during the external interview process**

**Finish Activities In-House**

- Rather than starting new programs and initiatives, FDA should finish initiatives already underway at the Agency, including:
    - Updating the Nutrition Facts Label;
    - Finalizing menu and vending machine labeling regulations;
    - Moving forward on front-of-pack labeling; and
    - Establishing definitions for terms like "natural," and "whole grains."

- Addressing front-of-pack labeling may have far-reaching nutritional impacts, including as a means of facilitating healthy food choices for consumers and as a means of encouraging industry to reformulate.

**Partner, Partner, Partner**

- FDA should increase partnering as a means of maximizing resources and access to consumers and to avoid conflicting messages and duplication of efforts.
    - Interest and willingness to partner were expressed by interviewees from all groups.
    - Partnerships with USDA were specifically recommended in setting and aligning standards for nutrition recommendations and measurements, expanding education efforts, exploring options for premarket reviews, and addressing chronic disease and obesity.
    - The importance of finding ways to partner with industry was addressed by interviewees from all groups.
- FDA should expand collaborations to allow consultation and input throughout the process, from conception and development through execution and follow-up.

**Use the DGA 2010 as a Starting Point for Messaging and Activities**

- The DGA 2010 should guide all government-oriented nutrition-related messaging.
    - Relying on the Guidelines would maintain consistent messaging across all groups
    - Starting from the Guidelines would maximize resources by eliminating the need to develop new or different recommendations.
    - Because the Guidelines are updated every 5 years, nutrition-related recommendations and activities would be up-to-date.

**Prioritize Nutrition-Related Activities and Outcomes**

- FDA should prioritize its nutrition-related activities to be more effective, including:
    - Identifying and prioritizing those issues with the most significant impact for consumers;
    - Prioritizing regulatory efforts over education;
    - Re-assessing the prioritization of activities related to food safety, nutrition, and dietary supplements;
    - Prioritizing a public health focus;
    - Exercising discretion in the application and enforcement of regulations for actions with positive public health outcomes; and
    - Re-exploring authorities pertaining to: premarket review of food additives; freedom of speech objections for claims; and regulation of dietary supplements.

**Continue to Expand Outreach and Communication with Stakeholders**

- FDA has improved its communication with stakeholders and should continue to expand these efforts, via:
    - Establishing regular meetings to share and solicit information;
    - Providing more information concerning agency activities, especially in the earlier stages; and
    - Inviting feedback for proposed activities.

**Accentuate the positive and be more proactive in approach**

- FDA should focus efforts on communicating the positive aspects of good nutrition, rather than focusing most of its efforts on the negative impacts of poor nutrition, including:
    - Communicating the positive effects of specific nutrients;
    - Issuing authoritative statements that are positive about foods rather than negative; and
    - Focusing more efforts on monitoring positive enhancements in the food supply.

# FDA Nutrition Program Review:

## Results of Nutrition Assessment Personnel Interviews




**REVISED**

**July 22, 2013**

Contract No. HHSF223201210011B

BPA No. 3

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## ES. EXECUTIVE SUMMARY

To support the increasing emphasis of FDA's role as a public health agency and the importance of nutrition in preventing the pressing problems of chronic disease and obesity in the United States, CFSAN is undertaking a major review of its nutrition activities. This review is intended to ensure that FDA's nutrition program efficiently and effectively supports healthy eating and a nutritionally healthy food supply.

As part of this review, FDA organized interviews of personnel working within the nutrition program in CFSAN and OF to help assess and update as needed FDA's current goals, responsibilities and priorities to support healthy eating and a nutritionally healthy food supply. The major objectives of the interview process were to seek input on staff perceptions about the goals and purposes of the nutrition activities at FDA and to document the range and emphasis of the various nutrition-related activities currently addressed at FDA. Interviewees were asked a series of 17 open-ended questions that can be broken down roughly into three groups: 4 opinion questions concerning what are the most important nutrition issues facing the United States; 7 questions intended to establish a baseline of understanding and awareness of FDA's nutrition mission and current FDA nutrition-related activities and to solicit recommendations for changes; and 6 questions intended to solicit suggestions and recommendations for changes to current FDA nutrition-related activities and potential new activities that could be undertaken to improve the diet and health of the U.S. population and contribute to the reduction in the prevalence of nutrition-related chronic disease and obesity in the United States. The review questions are presented in Appendix A. The desired outcome of the interview process is a true picture from within the program itself of where improvements might be made from the inside and where outside help may be needed to address issues.

The following report summarizes the responses of 56 FDA employees who shared their thoughts and opinions on working within the nutrition program, as well as their recommendations for improvements and changes.

### ES.1. Salient Points

#### Formalize In-house Nutrition Group

- There is a need for a formal multi-disciplinary nutrition group within FDA to oversee the further development of nutrition-related goals and activities to support the current path towards an increased public health role.
- Members of the group should be drawn from all of the offices included in the interview process, and should include a cross-section of personnel involved in the various research programs, education and outreach, and regulatory and enforcement programs.
- A number of advantages should accrue from the establishment of a formal group, including the potential to develop a more robust set of goals and activities that have been vetted from more angles, as well as increased communication of and support for goals and activities within the various offices.

**Clarify Nutrition-related Activities In-house**

- FDA should focus efforts on educating personnel working within the nutrition program concerning the various program activities: what is done by each group or office, who is involved in doing the work, what the work products/objectives are, and what the supporting mandates are.
    - There is broad understanding among interviewees of how various nutrition-related activities contribute to FDA's nutrition mission, but there are also misconceptions at the individual staff level concerning activities in other offices, particularly regarding the areas of nutrition-related research, education and outreach, and regulation of dietary supplements.
    - There does not currently appear to be an easy way to access this information within the Agency.
- The simplest and most efficient way to distribute this type of information may be to have each office or group prepare a fact sheet delineating their roles and activities within nutrition to be disseminated to all personnel involved in the nutrition program.

**Garner Support for Goals and Initiatives In-house: Expanded Initiatives**

- Nutrition program leadership should expend additional efforts to gain the full support of program staff for FDA's current goals, responsibilities, and priorities to address concerns that could be significant impediments to moving the nutrition program successfully in the desired direction:
    - Many interviewees were not confident that FDA's mandate and authorities extend to education directed at improving nutrition or promoting health in general.
    - Many also felt that efforts to change consumer behavior or to regulate food content with respect to specific nutrients were beyond the purview of the Agency.
- These concerns should be thoughtfully addressed, possibly through small group meetings or discussions to address staff questions and issues.
- Achieving more widespread support from the staff is likely to encourage more creative thinking on ways to establish, set, and achieve goals, and may help nutrition leadership to get a clearer picture of the resources that are available or needed to achieve these goals.

**Garner Support for Goals and Initiatives In-house: Strategic Plan**

- Nutrition leadership should address the less than enthusiastic support for Goal 5 of the FVMP Strategic Plan.
- Interviewees' perception that reformulation is an industry responsibility rather than an Agency responsibility should be recognized, and the reasoning and support behind selection of this goal as one of only two nutrition goals in the Strategic Plan should be explained.

**Re-evaluate Statutory Mandate for Nutrition**

- There is a need for FDA to carefully re-examine its statutory mandate with respect to nutrition and confirm that the current parameters, and particularly those pertaining to education and outreach, are in fact sufficient to support an expanded public health role in nutrition.
- This process may require an external review or review at a higher level within the Agency.
- When this review has been completed, its results should be conveyed to nutrition program personnel as support for the proposed goals and objectives under the nutrition program.

**Set Measurable Goals**

- There is a need to set measurable goals for nutrition-related activities.
    - The long-term nature of most nutrition impacts means that measuring the effectiveness of nutrition activities may not be possible as part of the daily job, aside from assessing increases in consumer knowledge of nutrition via consumer research or conducting laboratory research to assess the impact of nutrition on health.
- It should be possible for the nutrition program itself to identify and set measurable goals within the parameters of each office's regular activities in support of the nutrition program, with long-term assessment and evaluation of the nutrition impact left to appropriate resources, possibly outside the Agency.
- Setting measurable goals could offer two benefits: (1) providing the nutrition program with metrics for evaluating and demonstrating the success of nutrition initiatives; and (2) improving staff motivation by establishing achievable objectives.

**Expand Education and Outreach**

- There is a need to expand the education and outreach group to support an expanded public health aspect of the proposed nutrition-related goals and activities.
    - Interviewees generally acknowledged that the small existing staff has done an excellent job with the available resources and identified education and outreach as an area that does not get enough priority within the nutrition program.
- Education and outreach are key components of any public health initiative, and additional personnel and funding would be needed to expand FDA's activities in this area.
- Provided the Agency mandate allows, resources for additional nutrition activities might be redirected from the following areas identified by interviewees as less important: qualified heath claims, certificates of free sale, and temporary marketing permits.

**Clarify FDA's Role in Nutrition: Inter-agency**

- There is a need to clarify and define FDA's role in supporting federal policies on the prevention of chronic disease and obesity in conjunction with and vs. other HHS components and Federal agencies so as not to duplicate efforts.
    - Interviewees noted that USDA does more consumer education and has better community access, that CDC tends to make more dietary recommendations, and that NIH does more nutrition-related research.
    - Given the limitations in government-wide resources at this time, leveraging resources across agencies is crucial.
- FDA should set meetings with the other key players in nutrition to discuss the best distribution of activities across the entities.

**Increase FDA's Visibility in Nutrition**

- There is a need for FDA to increase its visibility to the public when it comes to nutrition-related matters.
    - Much of the public is largely unaware of FDA's role in nutrition.
    - Interviewees felt that the Agency tended to rely on passive messaging via the website.
- FDA should make more efforts to respond to current nutrition issues in a timely manner and take its nutrition efforts public via popular press and the media.

**Encourage More Input**

- To identify new activities in addressing chronic disease, nutrition needs of certain population groups, and other nutrition issues, the Agency should pursue more small-group discussions with inter- and intra-office groups to encourage brainstorming.
    - Interviewees were able to identify specific shortcomings of current programs; however, there were few specific ideas for new nutrition-related activities that FDA could undertake.
    - The shortage of specific suggestions may have been due in part to the one-on-one format of the interview process.

**ES.2. Nutrition Issues (Questions 2.1.1-2.1.4)**

The majority of interviewees identified obesity and chronic diseases as the most important nutrition-related health concerns in the United States. Additional areas of concern included food choices, malnutrition (both over- and under-nutrition), food supply/availability, specific nutrients (imbalance of intakes and fortification), use and regulation of dietary supplements, and the needs of sensitive populations. Interviewees felt that obesity and chronic diseases would continue to be significant issues over the next decade due to limited resources and lack of progress in addressing these problems, insufficient understanding of all the factors influencing these problems, and the need to increase emphasis on the importance of good nutrition and dietary recommendations. The issue of consumer food choices was expected to gain in importance as an

area of concern over the next decade, as were the importance of specific nutrients and the food supply, and new topics, including functional and medical foods and personalized nutrition.

When asked specifically about trends in consumer behavior or industry that were likely to affect food, nutrition, and health, interviewees felt that some trends, such as demand for locally produced, less processed, and organic foods, and availability of new additives, although likely to affect consumer behavior, were unlikely to have a significant impact because they were limited to specific demographics and/or would have limited impact on nutrition *per se*. The increasing use of dietary supplements was expected to have a significant impact due to high consumer demand, potential health effects, and the limitations on FDA's authority to assess efficacy. Fortification was another trend that was expected to have a more significant impact due to potential benefits for target population groups and potential negative impacts due to increases in unnecessary fortification, effects on non-target groups, and limited FDA regulatory authority. Interviewees noted that many of these trends are not under the purview of FDA.

Interviewees saw the key challenges for FDA in addressing nutrition issues and trends as including how to address external factors beyond FDA's control (e.g., factors influenced by education and socioeconomic factors, food supply, and consumer behavior), as well as a number of factors that needed to be addressed within the Agency, including clarifying FDA's role in nutrition, refining FDA's nutrition message, addressing existing statutory authority and limitations, improving communication, and evaluating specific programs (e.g., education and research), resources, and activities. Regarding FDA's role in nutrition, some interviewees stressed the importance of determining whether certain aspects of nutrition should be part of FDA's nutrition mission, given FDA's role as a regulatory agency.

Interviewees felt there were opportunities for FDA to address nutrition issues and trends in the areas of communication and education and outreach, increasing consumer awareness and motivation, and exploring new approaches, including developing tools to assess the chronic effects of poor nutrition as well as the effectiveness of Agency activities, and expanding the use of technology and partnerships to addressing nutrition issues.

### ES.3. Nutrition Mission and Current Nutrition-Related Activities (Questions 2.2.1-2.2.7)

Nutrition Mission

Regarding FDA's mission and responsibility with respect to nutrition-related matters, the majority of interviewees felt that regulatory activities were an important part of FDA's nutrition mission, followed by education, consumer research, protecting the food supply and safety, laboratory and other research, and protecting the public health. Within OFAS, ONLDS, and ORPSS, the offices most responsible for regulatory activities, the area of regulatory activities received the most responses. Within OAO, where the bulk of the education component of the nutrition program resides, the distribution of responses between regulatory activities, education, and consumer studies was more evenly distributed. There was also disagreement among interviewees concerning the relevance of certain areas to the mission, and the relative importance of different areas. Interviewees generally felt confident about the importance of regulatory activities, activities tied to statutory mandates (e.g., education on the Nutrition Facts Label as mandated by the NLEA), and activities intended to support regulatory activities (e.g., consumer research). However, there tended to be less confidence in areas that were not specifically

mandated (e.g., education directed at improving nutrition or promoting health in general, or laboratory research into the factors and effects of nutrition). The majority of responses indicated that interviewees knew about FDA's nutrition mission primarily through their job and that they discussed FDA's nutrition mission primarily with their staff or team.

In conjunction with assessing FDA's nutrition mission, interviewees were asked to indicate whether or not they agreed with Goals 4 and 5 of the FVMP Strategic Plan (2012-2016) as major objectives for nutrition-related activities at FDA. The majority of interviewees fully agreed with Goal 4 (Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity) and its objectives, including updating the Nutrition Facts Label, implementing menu and vending machine regulations, and improving consumer access to and use of nutrition information; however, only about 50% of interviewees fully agreed with Goal 5 (Encourage food product reformulation and safe production of dietary supplements) and its objectives, including reducing sodium content in the food supply, reducing industrially produced *trans* fat in the food supply, and improving the safety of dietary supplements and the supply chain. For those who disagreed with Goal 4 objectives, the primary objections were that information-based initiatives have not been demonstrated to affect consumer choices and have not thus far been demonstrated to reduce the risks of chronic disease and obesity. The primary objection to Goal 5 was that reformulation is an industry responsibility and is not or should not be under the control of FDA.

Current Nutrition-Related Activities

The two areas of nutrition-related research that were most often recognized by interviewees were consumer studies and laboratory research. In response to this question and others, many interviewees noted that nutrition-related laboratory research has been greatly reduced within the program. There appeared to be a great deal of overlap in interviewee responses regarding what comprised surveillance, evaluation, and epidemiologic research (some felt that FDA conducted little or no epidemiologic research, while others felt that investigation into nutrient consumption constituted epidemiologic research). The majority of responses concerning changes to the scope, scale, and prioritization of nutrition-related research had to do with increasing and/or expanding laboratory research and consumer studies. A number of interviewees also felt that efforts should be made to evaluate and/or improve the effectiveness of current research approaches.

The partnerships identified most often by interviewees were those with USDA, CDC, and NIH, followed by partnerships with universities, other Federal agencies, industry, and health organizations, other FDA entities (e.g., CDER, NCTR), states, research institutes, professional organizations, and consumer groups. The majority of suggestions for improving the effectiveness of FDA partnerships had to do with improving coordination and sharing between partners, followed by increasing partnerships in general, increasing partnerships with industry, and increasing informal partnerships. When taken as a whole, the suggestions for improving coordination and sharing yielded what appears to be a readily implementable road-map for facilitating interactions between partners. The issue of insufficient funding for partnerships came up several times in comments concerning what partnerships interviewees were aware of. This was addressed specifically in connection with working with NIH on investigating behavioral nutrition, and generally in terms of the inability to obtain grant money for work with USDA, NIH, or academia.

When asked to identify additional partnerships, the majority of suggestions were to increase partnerships with other Federal agencies, primarily partnerships with USDA, CDC, and NIH. There were additional recommendations to increase partnerships with academia, and with a variety of professional associations and societies. In response to the question of how to partner more effectively with other HHS components, relevant responses and comments generally fell under three categories: improving coordination and sharing, increasing communication between components, and increasing support to programs of the other components that are used by FDA.

In terms of international nutrition-related activities, interviewees most often identified those involving: Codex Alimentarius, WHO, and WTO; Canada; and the Quadrilateral Group (QUADs) of Canada, Australia, and New Zealand, an off-shoot of Codex involving English-speaking countries with similar labeling standards. Activities with the EU and with China and Japan were also identified, along with numerous minor activities involving other countries. FDA's participation in Codex was felt to be particularly valuable. Many interviewees commented on FDA's acknowledged leadership status in international nutrition-related activities. The main suggestions for improving the effectiveness of these activities were distributed among increasing communication, increasing opportunities and training, improving coordination and sharing, and increasing inspections of imported foods.

The education and consumer information activities most often identified by interviewees were media efforts (e.g., Label Man and Spot the Block) and the Agency's website, as well as school-based and community programs. Additional identified activities included education on the Nutrition Facts Label and other topics; presentations/conferences, and webinars; print materials; and the call center. Although media campaigns were cited most often by interviewees, many interviewees felt these activities were not successful. The Agency's website also received a mix of positive and negative comments: interviewees mainly felt that it contained valuable information but was difficult to navigate and unlikely to be accessed by consumers looking for nutrition information. In this area in particular, there seemed to be many interviewees who were not aware of many of the activities that are currently being undertaken by FDA.

The majority of interviewees felt that education or consumer information activities were important or very important to achieving FDA's mission and priorities. When asked how well FDA communicates its nutrition-related messages, only 10 interviewees felt the Agency's efforts were adequate or very good, while 19 interviewees felt results were variable, and 17 interviewees felt the Agency did not do well. The variable success in communicating nutrition-related messages was attributed to lack of sufficient or successful means of communication, resource issues, and lack of observable impact on consumer understanding of the label and key nutrition issues. In terms of the means of communication FDA should be using, interviewees most often identified the website, social media, and mass media. Other suggestions included: phone apps; printed materials; communication through multipliers including schools, professional associations, and healthcare providers; and talks and presentations.

Interviewees were also asked what information they thought consumers want FDA to provide and what they thought FDA's primary messages on nutrition issues should be. Interviewees felt that consumers wanted additional information concerning reading, understanding, and using the label, and more, simpler, more specific nutrition information. Additional areas in which consumers might want additional information included food safety information, information on dietary supplements, responses to what is in the media, and information concerning FDA's

current efforts. In terms of FDA's primary messages on nutrition-related issues, information concerning reading, understanding, and using the Nutrition Facts Label was considered to be important; however, two additional issues were considered to be more important here: emphasis on a whole diet/lifestyle approach to nutrition, and focus on serving size and portion control. Additional areas for FDA messaging included identification of key nutrients (per interviewees: calcium, vitamins and minerals, fats, sugars, fiber, etc.), safety of food and ingredients, what FDA is working on, and individualized nutrition.

Additional suggestions for improving the effectiveness of FDA nutrition-related education or consumer information activities included: increasing the allocation of funding and staff to education efforts; improving communication; increasing partnerships; simplifying the message; being more strategic; evaluating FDA's role in education; and contracting with outside entities to improve effectiveness. In terms of being more strategic, interviewees felt the Agency should: investigate the effectiveness of subpopulation-based communication; develop a means of evaluating the effect of FDA messaging on the population in general; and assess the areas where FDA could be most effective in education and increase efforts in those areas. In terms of evaluating FDA's role in education interviewees recommended that FDA rethink its strategy in terms of meeting the nutrition challenges of the country, and determine whether FDA is "in" or "out" and allocate resources accordingly.

In terms of nutrition-related regulatory activities at FDA, most interviewees identified activities related to the Nutrition Facts Label and label claims. Additional identified activities included regulatory activities involving dietary supplements, vending/menu/front of pack labeling, the sodium initiative, regulation of fortification, the *trans* fat initiative, and regulation of infant formula. The majority of interviewees felt that FDA's regulatory activities supported its mission and priorities well or very well; however, in terms of how well FDA's regulatory authority allows it to address nutrition-related issues, the majority of interviewees felt effectiveness was variable or worse. Responses concerning how well regulatory activities support the mission tended to vary, depending on interviewees' perception of what the mission should be. As evidenced in other sections of this report, there appeared to be the most disagreement over the adequacy of regulatory activities and authorities for dietary supplements. In addition, the rule-making process itself was cited by many as an obstacle to supporting FDA's mission and priorities and addressing nutrition-related issues.

When asked what additional regulatory authority was needed to address FDA's nutrition-related priorities, responses fell into two general categories: additional authorities pertaining to specific regulatory activities and the need to assess the effectiveness of FDA's regulatory authority. For specific regulatory activities, increased authority over labeling (and related activities) and regulation of dietary supplements were most often identified. Better authorities pertaining to medical foods and better ability to obtain industry records were also cited. The need to re-evaluate FDA's regulatory authorities with respect to nutrition issues received ~13% of responses. Several interviewees indicated that no additional regulatory authorities were needed.

## ES.4. Changes to Current FDA Nutrition-Related Activities and Potential New ActivitieS

### (Questions 2.2.8-2.2.13)

In identifying nutrition-related activities that FDA is doing well, the top four identified activities were work on the Nutrition Facts Label, regulation of health claims and qualified health claims, and work on the sodium and *trans* fat initiatives. Other areas in which FDA was felt to be doing well included regulation of infant formula and dietary supplements, enforcement and compliance efforts, education and outreach, and consumer studies. The Agency's emphasis on integrating science and policy and the caliber and scientific qualifications of Agency personnel were also identified by interviewees, either in conjunction with other activities or alone.

The key area in which interviewees felt nutrition-related activities needed improvement were communication and collaboration, both inside and outside the Agency. Other areas identified as being in need of improvement were: regulatory work, including specific programs and enforcement and compliance; education and outreach; the rulemaking process; research, including both laboratory and consumer research; and label claims. The need to clarify and define the Agency's nutrition mission and the need to address personnel issues were also identified.

The majority of interviewees felt that nutrition should be a higher priority at FDA; however, regarding the priority given to nutrition-related activities within their team or office, the majority of interviewees felt that the priority was appropriate. In terms of specific activities that do not get enough priority, interviewees identified education and outreach first, followed by regulatory work including dietary supplements, research, and communication and collaboration.

Efforts to address nutrition-related chronic diseases through labeling and through various initiatives targeted at these issues, including primarily the sodium and *trans* fat initiatives, were cited by most interviewees as evidence of FDA's focus on this issue. About 20% of interviewees felt that the Agency's efforts in this area were not evident. The majority of interviewees felt this focus was appropriate or partly to mostly appropriate. Many interviewees commented on the problem of how to assess FDA's impact on any of these diseases. When asked to identify FDA activities that had been successful or those that had been less than successful or largely unsuccessful in reducing chronic disease risk, the distribution of responses to the two questions was similar. Agency initiatives including the sodium and *trans* fat initiatives and labeling activities were counted as both successful and unsuccessful activities by majorities of interviewees. The *trans* fat initiative, for example, was felt to be successful because it resulted in a reduction of *trans* fat in foods, and, according to some interviewees, resulted in measurable health improvements. However, other interviewees argued that, despite a reduction in *trans* fats in foods, there were no measurable health improvements. The Nutrition Facts Label and regulation of label claims were also listed as both successful and unsuccessful activities.

When interviewees were asked to identify new activities or strategies that FDA should undertake in the short or long term to address chronic disease risk, other nutrition-related issues, and nutrition needs of certain population groups, responses varied widely, mainly because of the scope of the question and the degree of overlap between the categories. As a result, many responses did not necessarily reflect new or additional nutritional-related activities or strategies. There were many suggestions related to increasing and/or expanding laboratory and consumer

research and education efforts, as well as suggestions for expanding FDA's regulatory authority in certain areas. For addressing population groups, the majority of suggestions fell under the category of targeted messaging.

When interviewees were asked what nutrition-related or non-nutrition-related activities could be given up in order to have resources for a new activity, the majority of responses fell under the categories of No idea or NA (not answered). This was generally the result of interviewees either being reluctant to target a specific program or feeling they did not know enough about all of the nutrition-related activities undertaken by FDA to make a conclusion. Many interviewees also felt that no activities should be given up. Among remaining responses, there were suggestions for halting or reducing nutrition-related efforts on health claims (qualified health claims in particular), other labeling activities, certificates of free sale, temporary marketing permits, the Total Diet Study, maintaining Standards of Identity, consumer studies, and efforts in dietary supplement regulation and education, as well as other suggestions. For non-nutrition-related activities, interviewees felt that efforts in food safety and defense relative to nutrition could be reduced as well as some laboratory research.

Additional resources, in terms of level of expertise, manpower, and funding were identified in response to the question of what assistance FDA needs in setting nutrition-related priorities and policies. In terms of expertise, additional expertise was seen to be needed in nutrition epidemiology, nutrition science perspective and public health perspective, nutrition policy, data analysis and technology, and medical expertise for dietary supplements. Responses concerning the authorities needed were similar to those seen in response to the current activities question above: more authorities for labeling and related activities and for regulation of dietary supplements and better access to data and industry records. Again, interviewees mentioned the need for authorities to assess the effectiveness of FDA's nutrition-related activities, as well as the need to re-evaluate FDA's regulatory authorities with respect to nutrition. In evaluating FDA's tools and information in terms of staff expertise, statutory authority, data sets, and funding, more interviewees felt the level of expertise (and manpower) and the current statutory authorities were adequate or better than adequate than felt these areas were inadequate. Of interviewees who addressed the adequacy of data sets, the majority of interviewees felt that, despite some shortcomings, FDA had sufficient access to data sets, while fewer felt access to data sets was insufficient. Many interviewees felt that funding was insufficient.

The external resources identified by interviewees that FDA relies on for prioritizing its activities and achieving its mission included primarily data and databases from USDA and CDC. Other identified sources included IOM, EPA, industry, academia, and consumer groups. Concerning how FDA can obtain the additional tools and information it needs for nutrition-related activities, interviewees identified partnerships, lobbying Congress, and improving the hiring process. The majority of interviewees felt that FDA should be conducting additional research and exploring the use of risk assessment-type tools for use in nutrition. Identified nutrition-related resources that have been developed or are maintained by FDA and used by others included: the Nutrition Facts Label; regulations and authorities to regulate the food supply and labeling; health claims and supporting information; actions, injunctions, GMP warning letters; postings about recalls; the Total Diet Study; contaminant detection methods; FLAPS; consumer studies research including the Food Intake Survey, Food Safety Survey, and Health and Diet Survey; infant

formula regulator activities; certain data sets; consumer education and school-based materials; health advisories; and guidance and documents for industry.

# Appendix D. Industry Listening Session Notes

FDA was invited to contribute questions and listen in on what was essentially a round table discussion by industry representatives of how FDA could strengthen its nutrition activities. These are the notes taken by FDA staff.

Industry Listening Session

Institute for Food Safety and Health (IFSH) Listening Session

September 16, 2014

Burr Ridge, Illinois

FDA is conducting a review of its nutrition program to determine whether it should do things differently, e.g., whether it should be modified, enhanced or re-envisioned, and if so, in what ways. The core assumption behind the "Nutrition Review Project" is that improving the diet of the U.S. population can have a significant impact on public health. The core question that the "Nutrition Review Project" is addressing is whether the FDA program is getting the most public health "bang for the buck" that it reasonably can and if not, what it should or could do differently, and how industry may participate in, or facilitate, these efforts. Toward those ends, FDA sought and received industry's views related to the categories below.

Nutrition-Related Labeling Claims

The participants were asked what they thought FDA's role should be pertaining to the use of claims. They responded that they want to ensure honest practices and to prevent competitors from making untruthful claims. Industry should be self-policing and if they see others behaving inappropriately, they should challenge them and ask for substantiation. FDA should do likewise and request from firms the basis for their claims even when there is no statutory requirement that the firms provide it. Claims should be based purely on science and not emotion.

The participants mentioned the Federal Trade Commission's (FTC) practices as an example to follow. The FTC requires manufacturers to conduct controlled placebo trials and FDA should do the same. There needs to be more coordination between FDA and FTC.

Industry needs FDA to give guidance about what competent and reliable science is expected. Guidance has been muddled since the enactment of the Dietary Supplement Health and Education Act (DSHEA). Regulations are inconsistent. Well-meaning companies find it difficult to try to follow the rules.

FDA issued guidance about how to establish cause and effect pertaining to drug claims. Something similar should be done for foods. Guidance is needed about significant scientific agreement standards. Companies use information that they interpret to be reliable, but they find that the government often does not agree. For that reason, companies often find it difficult and

are hesitant to convey what they want to state on labels. FDA needs to help companies do the right thing. Regulations may be needed, primarily to protect companies against litigation. Congressional intervention could be helpful.

The use of disclaimers to explain the qualified nature of certain health claims can be confusing to consumers. The language needs to be clearer and understandable. Consumers find that 'legalese' makes these disclaimers sound deceiving.

Different groups of consumers interpret claims differently. We all need to understand how consumers interpret claims. E.g., the term 'natural' is perceived by younger consumers as an important health-related claim, while older consumers would consider the term meaningless. FDA needs to partner with industry about claims and terms like "natural", etc. Guidance is needed about its accurate use on labels. Countries outside of the U.S. have defined "natural".

There should be a focus on providing positive vs. negative information on labels.

Clarification is needed about nutrient content claims. Consideration should be given to whether nutrient content claims (e.g., 'this food is a good source of nutrient "x"') should still be allowable in the absence of an established daily value for the nutrient in question against which the claim can be compared. This may be a matter that should be referred to the Institute of Medicine (IOM).

FDA "Mark"

The participants were asked what they thought about the idea of an FDA "mark". The "mark" could be a symbol or text that would be placed on packages to convey FDA's review of nutrition-related claims. It could be an incentive for companies to seek FDA review of their claims. They responded that they were concerned about the length of a preapproval process that they would have to go through in order to obtain such a "mark", and that they already contend with many levels of clearance. They would need to race to beat their competition for approval to market their products with the "mark." It might be useful if it could be obtained relatively quickly, although the participants were unsure of whether consumers would think that a "mark" would lend more credibility to their products. They said it would be useful to conduct consumer studies on a case-by-case basis.

Front-of-Pack (FOP) Labeling

When asked about FOP labeling, attendees questioned what types of labeling helps consumers the most. The Nutrition Facts Label (NFL) is already on the backs of packages. One attendee suggested that FDA should shy away from influencing or modifying consumer behavior. Rather, FDA's actions should be limited to educating consumers on how to use nutrition-related labeling. There would be inherent risks in any effort by FDA to influence certain behaviors by mandating a system, like red and green lights (using red to signify foods that are 'bad' vs. using green to signify that foods are 'good'). Such a system would have a subjective quality to it that could inadvertently cause consumers to make poor decisions. For example, the UK's use of traffic lights confuses consumers (e.g., mangoes are marked red due to high levels of natural sugar, while soda pop receives a better mark due to lower levels of sugar). Given its judgmental nature, algorithm-based labeling that provides a single number or symbol should be regarded as a form

of health claim that should be subject to substantiation. FDA should focus on educating about the total diet and not about individual foods. The Nutrition Labeling and Education Act (NLEA) focused on education instead of behavior.

Other participants felt that FDA could still provide guidance on FOP labeling and called for collaboration in that area.

Emerging Areas

Bioactive components in food were discussed. Even though they are not nutrients, they do add benefits. They are limited to quantitative claims and it is difficult to convey information in consumer-friendly language. FDA should work with an organization like IOM to establish appropriate levels for bioactive food components.

Reformulation

When asked about reformulation, the participants mentioned changing the levels of *trans* fat and sodium as examples. Companies need incentives to reformulate. FDA should have forums to discuss concerns and share data. Companies do want to make healthy products, e.g., they are mindful of what they should substitute in place of *trans* fat. They also have concerns about what to substitute in place of sugar. It could be replaced with a starch that is metabolized just like sugar, which may not be any healthier than sugar. "Shaming" the industry to take things out of food without good science to support it can have unexpected consequences. FDA needs to be mindful of basing decisions on science, including the unanticipated health consequences that could occur as a consequence of reformation and not just on the component of the food to be limited or removed. Some dialogue is needed about sodium reduction. When considering reformulation, FDA needs to consider other factors that have an effect on health, like overall diet and exercise.

Collaboration

The group was very supportive of collaboration and mentioned it numerous times. FDA should follow USDA's example. They collaborated with the National Forest Foundation and the industry to successfully set priorities and common goals. Incentives are needed to promote healthy diets. FDA should move away from fear mongering and work closely with industry, non-governmental organizations (NGOs), consumer groups, and academia.

Education

When asked about the need for more education, there was wide agreement that FDA should focus more on, and use simple messages supported by the DGA 2010. Consumers do not understand complicated messages and often lack a basic understanding of nutrition, including an understanding of calories. The positive vs. negative aspects of nutrition should be promoted rather than demonizing groups of foods or focusing on foods to avoid. Messaging should be balanced and focus on a healthy diet overall. Children should be educated so they can carry that information with them, share it at home, and improve their lives long-term. FDA needs to communicate messages customized for different subgroups and work with health educators on local levels. For example, malnutrition can be a problem for the elderly even though they might not realize it since their nutritional needs have changed over time. Perhaps basic and simple

messages should be created about chemicals in processed foods. Be realistic and teach consumers how to improve the good things that they are already doing (e.g., they are already eating fiber, tell them to eat more). The participants were receptive to collaborating with FDA on nutrition education and also suggested that FDA partner with PR agencies to get consumers excited about improving their diets.

Regulation

FDA should decide how to advise people about changing science (new discoveries about the changing risks and benefits of foods). Any regulations about claims should be issued at the same time. Consumers get confused each time something about the label changes.

Barriers to Healthier Diets

There are many barriers that prevent consumers from making better choices. They may be too busy to shop for and prepare healthy foods. Snacking is more convenient. FDA should keep moderation in mind and beware of extremes. A school district banned chocolate milk because they wanted children to drink unsweetened milk. The effort backfired and there was a drastic reduction in overall milk consumption. Unhealthy food is readily available everywhere. This society doesn't exercise as much due to technology (e.g., people don't have to get up to change TV channels anymore). People with lower income don't have as much knowledge of or access to healthier foods.

Risk Assessments

FDA should conduct quantitative risk assessments. Assessments of food safety are easier to do than nutrition. FDA could use risk assessments to study benefits over a range of exposures, e.g., modeling the risk of not eating vs. eating healthy foods. FDA could study swapping sugars for carbohydrates and see if the risk would increase or decrease. Unintended consequences should be kept in mind.

Medical Foods

A clearer definition is needed. It is a dilemma the way that the law is written: if a product meets the definition, drug claims could be made without premarket approval. There's a loophole, but it could be a boon. FDA should oversee the marketplace to separate the good from the bad actors. The FDA guidance on medical foods should be updated. FDA should figure out how to fit this into its regulatory scheme. FDA should partner with industry to create a regulatory framework for substantiating claims made for medical foods. Data could be used to make labeling truthful and easy to understand.

Research/Consumer Studies

When asked about research needs, participants said that it should increase. An orphan model should be used to look at smaller issues around metabolic disorders and celiac disease. The gap should be filled by serving the underserved. A small amount of methods development is being done now. FDA should partner with industry to find out what's missing. Research should be conducted with the National institutes of Health (NIH) to do long-term studies. FDA should partner with IOM to learn about what motivates consumers and how to change their behavior.

Some companies that are doing research on motivation should collaborate with FDA. When choosing foods, research reveals that taste is the main driver in decision-making. If sodium is reduced in products, consumers will think that the products will not taste good. It may be possible for sodium levels in products to be lowered and replaced with potassium without compromising taste.

# Appendix E. Steering Committee and Nutrition Implementation Team Members

Steering Committee Members:
*OFVM:* Jessica Leighton, Claudine Kavanaugh
*CFSAN Deputy Director for Regulatory Affairs:* Roberta Wagner
*Office of Nutrition, Labeling, and Dietary Supplements:* Phil Spiller
*Office of Analytics and Outreach:* Andrew Stivers, Sharmi Das, Steve Bradbard
*Office of Food Additive Safety:* Judy Kidwell
*Office of Regulatory Science:* Greg Diachenko
*Office of Regulatory Policy and Social Science:* Susan Bernard, Bradley Brown
*Special Assistant to the CFSAN Deputy Director for Regulatory Affairs:* Carrie Ainsworth

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*Office of Analytics and Outreach:* Steve Bradbard, Sharmi Das, Marjorie Davidson, Serena Lo
*Office of Food Additive Safety:* Jason Deitz, Kasey Heintz
*Office of Regulatory Science:* Jeanne Rader
*Office of Regulatory Policy and Social Science:* Travis Minor
*Special Assistant to the CFSAN Deputy Director for Regulatory Affairs:* Carrie Ainsworth

# Appendix F. Offices Responsible for Nutrition and Nutrition-Related Activities

- The Office of Food and Veterinary Medicine (OFVM) is responsible for overseeing significant FDA nutrition-related initiatives, supporting FDA's development of nutrition materials, and facilitating communications with other FDA offices, Federal agencies, industry, public health organizations and State and local jurisdictions on nutrition issues.

- The Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) is responsible for developing labeling rules and guidelines relating to nutrition-related information and claims, reviewing the evidence in support of proposed health claims, reviewing submissions from industry relating to the nutritional sufficiency of new and modified infant formulas, establishing policy for medical foods, and reviewing or initiating enforcement actions against labeling violations in consultation with the CFSAN Office of Compliance and the Office of the Chief Counsel.

- The Office of Analytics and Outreach (OAO) is responsible for conducting consumer behavioral studies and consumer education.

  The Office of Food Additive Safety (OFAS) is responsible for developing policy relating to the reformulation of foods to reduce *trans* fats and sodium in the food supply. (Note: as a related matter, OFAS is responsible for evaluating whether submitted notices or food additive petitions for nutrients or bioactive components of food adequately address the safety of these food components.)

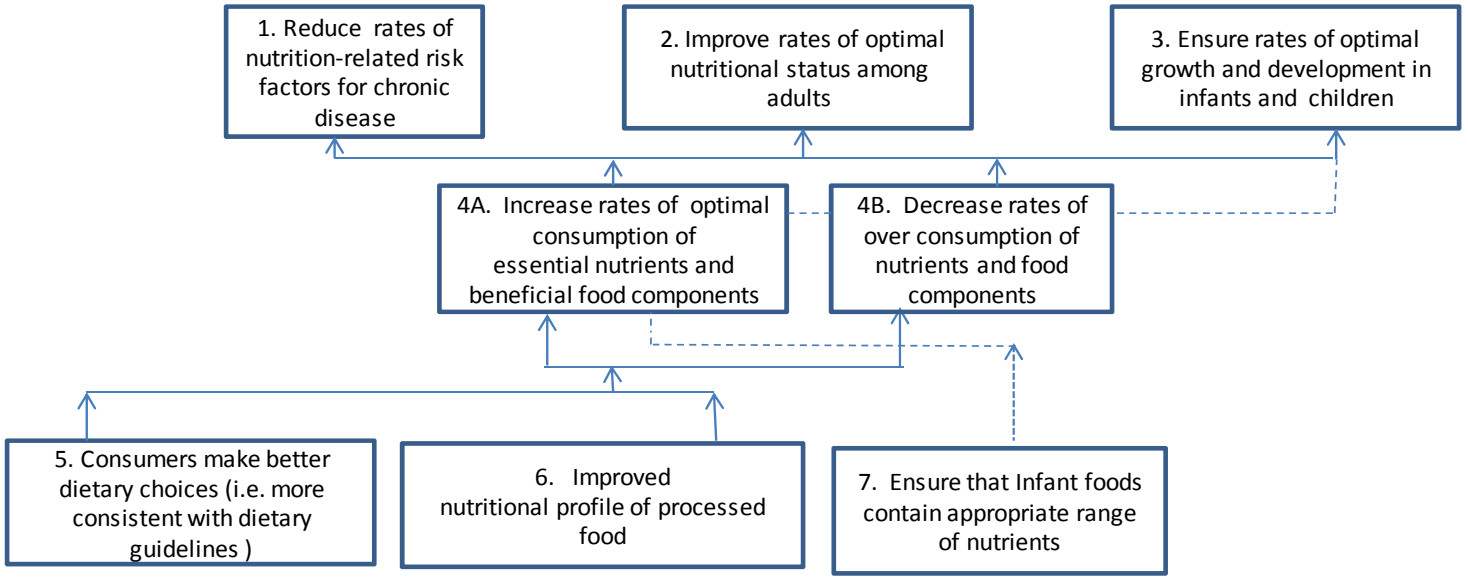
- The Office of Regulatory Science (ORS) is responsible for developing laboratory methods for detecting the presence of various nutrients in food.

- The Office of Regulations Policy and Social Sciences (ORPSS) is responsible for review and, on a case-by-case basis, drafting nutrition-related regulations and guidelines. Until recently, it was responsible for conducting economic analyses in support of these documents. That function has been transferred to the Office of the Commissioner.

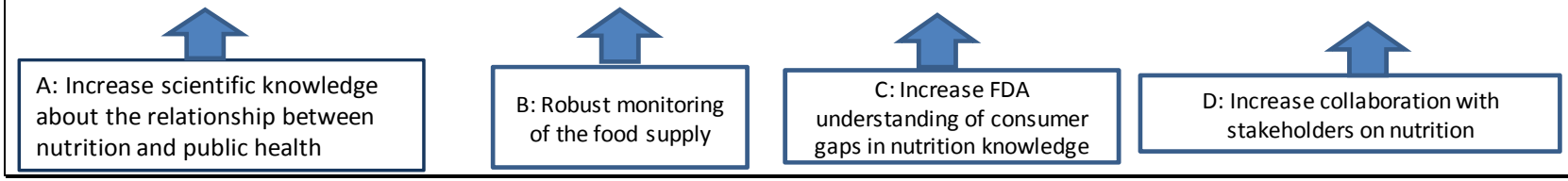
# Appendix G. Strategic Framework

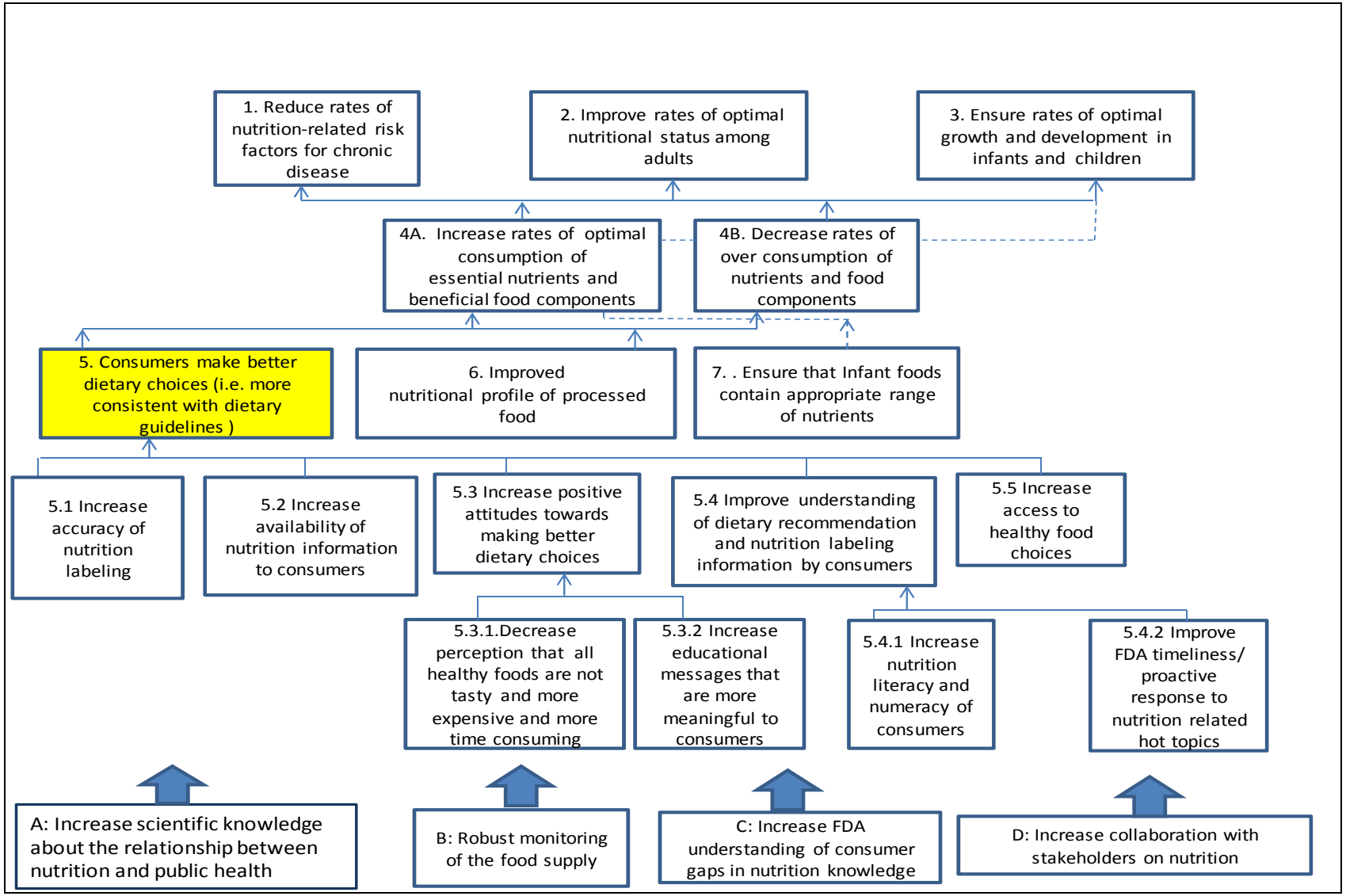
This is the strategic framework that the NRP is proposing for the nutrition portion of the FDA food program. Each box represents a result that FDA's activities should achieve. The lower level results, i.e., the boxes on the lower levels, must be achieved in order for the higher level results to be achieved. In this appendix the framework is followed by a narrative explanation that explains each result and the relationship between the lower and upper level results.

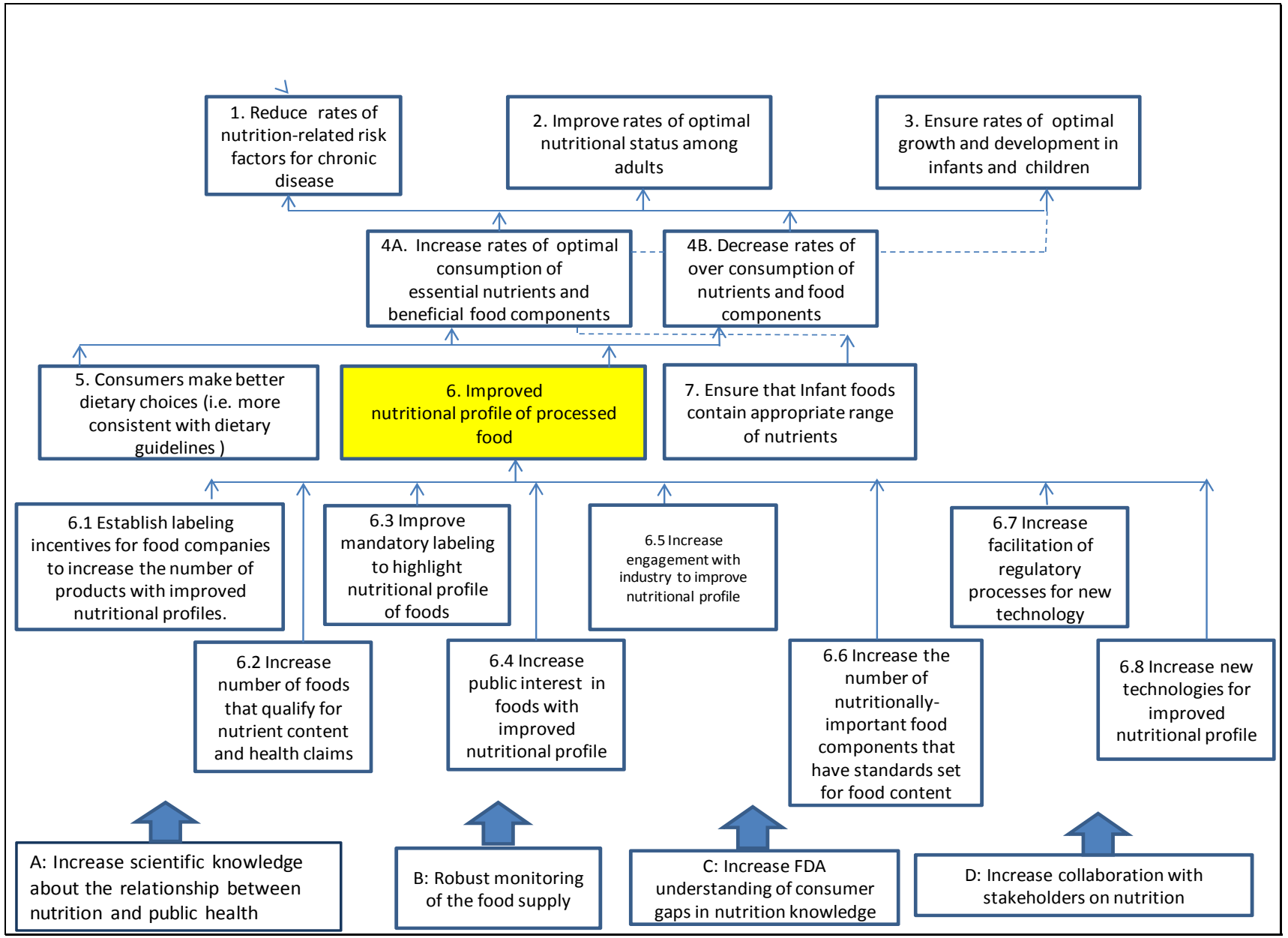
## Top level results for the Nutrition Strategic Framework




## Foundational results for the Nutrition Strategic Framework




1. Reduce rates of nutrition-related risk factors for chronic disease
2. Improve rates of optimal nutritional status among adults
3. Ensure rates of optimal growth and development in infants and children
4A. Increase rates of optimal consumption of essential nutrients and beneficial food components
4B. Decrease rates of over consumption of nutrients and food components
5. Consumers make better dietary choices (i.e. more consistent with dietary guidelines )
6. Improved nutritional profile of processed food
7. . Ensure that Infant foods contain appropriate range of nutrients
5.1 Increase accuracy of nutrition labeling
5.2 Increase availability of nutrition information to consumers
5.3 Increase positive attitudes towards making better dietary choices
5.4 Improve understanding of dietary recommendation and nutrition labeling information by consumers
5.5 Increase access to healthy food choices
5.3.1.Decrease perception that all healthy foods are not tasty and more expensive and more time consuming
5.3.2 Increase educational messages that are more meaningful to consumers
5.4.1 Increase nutrition literacy and numeracy of consumers
5.4.2 Improve FDA timeliness/ proactive response to nutrition related hot topics
A: Increase scientific knowledge about the relationship between nutrition and public health
B: Robust monitoring of the food supply
C: Increase FDA understanding of consumer gaps in nutrition knowledge
D: Increase collaboration with stakeholders on nutrition


1. Reduce rates of nutrition-related risk factors for chronic disease
2. Improve rates of optimal nutritional status among adults
3. Ensure rates of optimal growth and development in infants and children
4A. Increase rates of optimal consumption of essential nutrients and beneficial food components
4B. Decrease rates of over consumption of nutrients and food components
5. Consumers make better dietary choices (i.e. more consistent with dietary guidelines )
6. Improved nutritional profile of processed food
7. Ensure that Infant foods contain appropriate range of nutrients
6.1 Establish labeling incentives for food companies to increase the number of products with improved nutritional profiles.
6.3 Improve mandatory labeling to highlight nutritional profile of foods
6.5 Increase engagement with industry to improve nutritional profile
6.7 Increase facilitation of regulatory processes for new technology
6.2 Increase number of foods that qualify for nutrient content and health claims
6.4 Increase public interest in foods with improved nutritional profile
6.6 Increase the number of nutritionally-important food components that have standards set for food content
6.8 Increase new technologies for improved nutritional profile
A: Increase scientific knowledge about the relationship between nutrition and public health
B: Robust monitoring of the food supply
C: Increase FDA understanding of consumer gaps in nutrition knowledge
D: Increase collaboration with stakeholders on nutrition

# The FDA Nutrition Strategic Framework Narrative

## Introduction

FDA recognizes that improving the American diet is a critical factor in preventing the pressing and complex problems of chronic disease, and more generally, improving health, in the U.S. To ensure long-term strategic planning and management of the nutrition program, the FDA Office of Planning (OP) is supporting the development of Strategic Program Management (SPM) approach for Nutrition.

The first step in a SPM approach is the development of a Strategic Framework (SF). Initially, a "straw-man" Nutrition SF was developed. The mini-workshop included a brief review of SPM to ensure the participants had a common understanding of the purpose and benefits of SPM as well as the key steps, components and tools of an SPM approach. Special emphasis was given to the SF component of the work, since that is the first phase. After the brief discussion, participants reviewed and provided input on the draft straw-man SF that was developed from the existing materials. The small group spent the remainder of the time building the details out and refining a straw-man SF that would help guide FDA's work on nutrition.

The straw-man SF was shared with the larger "team" that was identified to bring all the needed expertise to bear. The team met and expanded the ideas in the straw-man to a full SF. This document describes the result of the work by the larger team. This framework articulates a theory of change for how to successfully implement various programs and initiatives in ways that will achieve the highest level Strategic Goals (SGs). The SF is composed of a set of results that need to be achieved in order to attain the SGs. The results are organized in "if…then" relationships that together constitute the program hypothesis – or strategy - that will link day-to-day activities supporting the nutrition mission with the achievement of key results, and ultimately, supporting the SGs of the nutrition program.

## Strategic Framework

There are three distinct but related strategic goals that are being proposed by the Nutrition Review Project for the nutrition component of the FDA food program. The first goal would be to reduce rates of chronic disease through reducing nutrition-related risk factors. The second goal would be to improve the rates of optimal nutritional status among adults and maintaining that level once achieved, and the third goal would be related to ensuring rates of optimal growth and development among infants and children. They are included separately in the framework because they have different measures associated with them and, more importantly, because there may be different strategies that FDA takes to reach them.

**Reduce rates of nutrition-related chronic disease including obesity**

The goal to reduce rates of nutrition-related chronic disease would be one of the highest level strategic goals for nutrition at FDA. There is recognition that the ability to calculate the portion of chronic disease rates due to nutrition would be limited, but it is still important to specify that this is the portion of the chronic disease rate that the framework is meant to reduce. In other words, some portions of chronic disease rates are due to other factors such as genetics, environment, life style, and that portion of the chronic disease rates will not be affected by this work – only the nutrition-related portion. For this framework, obesity is included in the language of the result as an example of chronic disease – this is not meant to indicate that obesity is more important than other chronic diseases – rather, it is called out separately because many people are unaware that obesity is now considered chronic disease. *What is the theory of change for reducing the rates of nutrition-related chronic disease?* Answer: Nutrition-related chronic disease rates are reduced by reducing nutrition-related risk factors for chronic disease (described under Result 4).

**Result 1. Reduce rates of nutrition-related risk factors for chronic disease**

A risk factor is any attribute, characteristic, or exposure of an individual that increases the likelihood of developing a disease or injury. Risk factors for chronic diseases related to nutrition include hypertension, high cholesterol, and raised blood glucose levels. Nutrition-related habits related to these risk factors include diets rich in saturated fats, diets rich in sugars and salts, and diets without a sufficient amount of fruits and vegetables. What is the theory of change for reducing the rates of nutrition-related risk factors for chronic disease? Answer: The rates of nutrition-related risk factors for chronic disease can be reduced by (1) an increase in the population rate of optimal consumption of essential nutrients and beneficial food components, and (2) a decrease in the population rate of overconsumption of nutrients and food components such as *trans* fats and sodium. Note: "Rate" is meant to include both dimensions of prevalence and incidence. These results are described further under Results 4A and 4B below.

**Result 2. Improve rates of optimal nutritional status among adults**

This result specifically identifies the health of the adult population. This result is based on the idea that there is more to health than the absence of disease, so it should to be tracked separately from Result 1. A possible measure for this result is rates of "healthy" Body Mass Indexes (BMIs) in the adult population. There was acknowledgment that BMI is only one dimension of "optimal nutrition status" and that additional work will be needed to define exactly what is meant by "optimal nutrition status." How can rates of optimal nutrition status among adults be improved? Answer: (1) an increase in the population rate of optimal consumption of essential nutrients and beneficial food components, and (2) a decrease in the population rate of overconsumption of nutrients and food components.

**Result 3. Ensure rates of optimal growth and development in infants and children**

This result focuses on ensuring rates of optimal growth and development among infants and children. How can rates of optimal growth and development in infants and children be ensured? Answer: (1) an increase in the population rate of optimal consumption of essential nutrients and beneficial food components, and (2) a decrease in the population rate of overconsumption of nutrients and food components.

**4A. Increase rates of optimal consumption of essential nutrients and beneficial food components**

As shown in the accompanying figure, Results 4A and 4B all contribute directly to the three SGs for the nutrition program. This result involves nutrients including components (could include things like bioactives). "Optimal consumption" could be different for adults and children, and may be different for subpopulations such as pregnant and nursing women. This result would include the wide range of essential nutrients and beneficial food components including calories, healthy fats, calcium, potassium, and many others. What leads to increased rates of optimal consumption of essential nutrients and beneficial food components? Answer: (1) Consumers making better dietary choices, AND (2) Improved nutritional profile of processed food. For goal 3 – ensure rates of optimal growth and development in infants and children ensuring optimal consumption of essential nutrients and beneficial food components is also accomplished by (4) ensuring that infant foods that contain an appropriate range of nutrients.

**4B. Decrease rates of overconsumption of nutrients and food components**

This result recognizes the negative impact on health that overconsumption of some food components can have. The "overconsumption" threshold would likely be different for adults and children, and may be different for subpopulations such as pregnant and nursing women. Areas of particular interest in terms of overconsumption include calories, sugars and fats. What leads to decreased rates of overconsumption of nutrients and food components? Answer: (1) Consumers making better dietary choices, AND (2) Improved nutritional profile of processed food. For goal 3 – ensuring rates of optimal growth and development in infants and children, the improvement in optimal consumption of essential nutrients and beneficial food components is also accomplished by (4) ensuring that infant foods that contain an appropriate range of nutrients.

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**Result 5. Consumers make better dietary choices (i.e., more consistent with DGA 2010)**

This result is meant to capture consumer behavior related to nutrition that contributes to risk factors, and to optimal health and optimal growth and development. Some examples of these types of behaviors are illustrated by Healthy People 2020 Nutrition objectives, namely, a reduction in the average consumption of sodium, saturated fats and sugars, and increased population rate of a daily consumption of five servings of fruits and vegetables. What is the theory of change for changing consumer behavior? Answer: by (1) Increasing the accuracy of nutrition labeling, AND (2) Increasing the availability of nutrition information to consumers AND (3) Increasing positive attitudes towards making better dietary choices, AND (4)

Improving the understanding of dietary recommendations and nutrition labeling information by consumers AND (5) Increasing access to healthy food choices.

### 5.1 Increase accuracy of nutrition labeling

This result captures the idea that if the information on the label is inaccurate, then consumers are not able to make better dietary choices. For example, if the number of calories listed on the label is wrong, then the consumer does not have the information needed to make a better dietary choice. Also, if there is information on the packaging that leads consumers to think that the food is a good dietary choice, when actually it is not (e.g., a "whole grains" label on cereals with high sugar levels), that could be considered an inaccurate labeling issue.

### 5.2 Increase availability of nutrition information to consumers

This result acknowledges the need to make information available to consumers. This availability could include physical availability such as a requirement for restaurants and vending machines to display nutrition information, and could also include issues such as language, disabilities that limit some consumers' access to written documentation, lack of access to internet resources, etc.

### 5.3 Increase positive attitudes towards making better dietary choices

This result acknowledges the role that attitude plays in decision-making. Having the needed information is important, but if consumers understand the information, but do not care about making good dietary choices, then their behavior is not likely to be affected by the information.

#### 5.3.1 Decrease perception that all healthy foods are not tasty and more expensive and more time consuming

This result recognizes that perceptions about the taste, cost, and convenience of healthy food will affect the attitudes people have towards making good dietary choices. If the negative perceptions are decreased, then the overall positive attitudes about healthy eating will increase, which would contribute to better dietary choices.

#### 5.3.2 Increase educational messages that are more meaningful to consumers

This result acknowledges that meaningful messages that resonate with consumers can not only provide information, but also affect attitudes. FDA's anti-smoking campaign was used as an example of crafting messages that are meaningful to consumers.

### 5.4 Improve understanding of dietary recommendation and nutrition labeling information by consumers

This result recognizes that in order to behave in a way that is consistent with the DGA 2010, consumers need to understand the Guidelines, and how labels relate to them. Examples were given of situations in which people had partial information about a

healthy diet which lead to decisions that were not consistent with the Guidelines – for example, thinking a salad is healthy even when it is full of cheese and dressing with a high fat content, or thinking that fish is a healthy choice even when it is fried.

#### 5.4.1 Increase nutrition literacy and numeracy of consumers

This result recognizes that if consumers cannot read or do not know how to understand numbers, the labeling will be of limited use to them. If literacy and numeracy was increased, then the understanding of the labels would increase.

#### 5.4.2 Improve FDA timeliness/pro-activeness of response to nutrition-related hot topics

This result recognizes that there are many sources of information that people use to inform their decisions about what to eat. The theory of change is that if FDA engaged in a more timely way with these sources of information, then people's understanding of the issues related to healthy dietary choices would increase. The theory of change recognizes the significant impact that these types of sources can have on people, and therefore acknowledges a role that FDA can play in amplifying the valuable information that these sources convey. If FDA's involvement in these types of "hot topics," was timelier, consumers' understanding of the information would increase.

### 5.5 Increase access to healthy food choices.

This result captures the fact that healthy food choices need to be available to consumers in order for them to access such choices. This result includes the idea of both the cost of healthy foods and the availability of these foods to consumers (e.g., food deserts). Programs that USDA has in this area will likely contribute to this result – the FDA role in supporting this type of result is to be determined. However, it was decided that this was a significant factor in consumers making healthy choices, so it was included in the framework even if FDA may not be actively working in this area.

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## Result 6. Improved nutritional profile of processed food

This result focuses on the aspect of reformulation of the product – how to make the food itself more nutritious so that the consumer behavior and consumer choice are not critical factors. *Trans* fat is the classic example here – after the amount of trans fat was displayed on the label, manufacturers reformulated their products to remove a good portion of the *trans* fat, so that even though consumers were making the same choices, their diet was more consistent with the DGA 2010 (in that one area of trans fat consumption). The definition of "improved" has to do with consistency with DGA 2010 as well as consistency with dietary recommendations from IOM reports and those based on public health science findings.

The question is, what role can FDA play in creating an improved nutritional profile of processed food? The theory of change discussed at the workshop included several possible areas in which

FDA could work that may lead to an improved nutritional profile of processed food. They are described in the results below.

### 6.1 Establish labeling incentives for food companies to increase the number of products with improved nutritional profiles

The idea around 6.1 is that labeling incentives would benefit both companies and consumers. Informed consumers view labels to seek out healthier products. Products with labels that identify healthier products attract consumers' attention. These products would be in higher demand, and companies could sell more. For example, FDA could develop a system in which products with healthier nutritional profiles would earn the privilege of using an "FDA gold star", similar to Good Housekeeping's seal of approval. Having gold stars on packages could influence companies to reformulate and make healthier products, thereby increasing sales.

An "FDA gold star" would be something appealing to consumers, and therefore provide an incentive to industry to reformulate.

### 6.2 Increase number of foods that qualify for nutrient content and health claims

The idea under this result is that there are foods that are on the market now that do not qualify for nutrient content or health claims, but they are close, and a little reformulation would give these products the ability to use the nutrition content or health claim. If the companies saw a benefit into including those claims, and understood how close they are to being able to use those claims, that might provide a sufficient incentive to reformulate. The current estimate is that 2% of foods on the market are approved for health claims.

### 6.3 Improve mandatory labeling to highlight nutritional profile of foods

The idea under this result is the use of the approach that was used in *trans* fat labeling. There was no requirement to reduce the amount of *trans* fat – there was simply the requirement to label the product with the amount of *trans* fat. The manufacturers decided that it was in their best interest to reformulate the foods in order to reduce the amount of *trans* fat that is shown on the label. This result would involve similar label requirements. Note that some of the team expressed concern that the purpose of labeling would be identified as providing an incentive for manufacturers to reformulate. These team members stated that the purpose of labeling should be to provide useful information to the consumer. Generally, it would be reasonable to expect that the types of nutrition information labeling requirements that would lead to food with an improve nutrition profile would be the same as the types of nutrition information that would be helpful to consumers; however team members expressed the view that the consumer's need for information should drive any mandatory labeling, not an FDA interest in product reformulation.

### 6.4 Increase public interest in foods with improved nutritional profile

This result is strongly related to result 5 and to some of the sub-results under result 5. An increased interest in consumers wanting to make dietary choices consistent with the DGA 2010 will lead to an increased consumer demand for products with an improved nutritional profile. One specific type of activity that was discussed as related to this result would be a public sharing of information about companies that have not responded to dietary recommendations, for example, by reducing sodium according to guidance (that may be issued in the future). If that information were collected, analyzed, and shared publically, there could be increased public interest that would provide companies with incentives to improve their products. This type of monitoring and analysis would be informed by work done under foundational element B, "Robust monitoring of the food supply."

### 6.5 Increase engagement with industry to improve nutritional profile

This result is about FDA making direct appeals to companies to improve the nutritional profile of their foods or, in the case of retailers, of foods sold in their stores..

### 6.6 Increase the number of nutritionally-important food components that have standards set for food content

This result is related to the idea of setting regulatory standards for food components. For example, a standard might be that one ounce of cheese could have no more than X mg of sodium. There may be some food components for which regulation is determined to be the best option, and then that work of setting the standards and ensuring the standards are met would contribute to this result. The foundational result A, "Increase scientific knowledge about the relationship between nutrition and public health" will make an important contribution to this result.

### 6.7 Increase facilitation of regulatory processes for new technology

This result relates to the ability of firms to innovate in order to improve the nutritional profile of food. For example, more nutritious foods may be developed by small companies or academics that do not have experience with regulatory requirements. An increase in facilitation of the regulatory process may overcome those barriers. "Facilitation" may include pre-submission meetings, and the development of product-specific policy.

### 6.8 Increase new technologies for improved nutritional profile

This result is related to the creation of technologies that would help manufacturers improve the nutritional profile of their foods. An example may be a technology that reduces sodium in food without changing the taste. Standards of identity may also fit here – for example, the standard of identity for cheese does not permit manufacturers to add potassium, which could otherwise be a healthier substitute for sodium. This result will be informed by foundational result A, "Increase scientific knowledge about the relationship between nutrition and public health," which could include technology-related research to achieve nutritional improvements in food.

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**Result 7. Increase rates of infant foods that contain an appropriate range of nutrients**

This result acknowledges that an appropriate range of nutrients in infant foods contributes to the rates of optimal growth and development in infants. Any work FDA does in the area of breast milk donations would also come under this result. Finally, work to ensure infant food is nutritious would contribute to this result. Infant food is not currently regulated as closely as infant formula. Note that the dashed line in the figure is meant to indicate that this result contributes only to SG 3, focused on infants and children and not on SGs 1 and 2, which are focused on adults.

**Foundational Results**

There can be a set of foundational results that sit beneath the framework. The foundational results would be results that support the achievement of many, if not all results in the framework. If there are foundational results identified, making progress on these foundational results will be essential to achieving the SGs.

**A. Increase scientific knowledge about the relationship between nutrition and public health**

This result captures the fact that as research increases, the definition of "improved nutritional profiles" will be updated accordingly, as will the DGs.

1. **B. Robust monitoring of the food supply**

This result is related to FDA's monitoring of information about the nutritional quality of foods on the market.

2. **C. Increase FDA understanding of consumer gaps in nutrition knowledge**

   This result relates to the importance of FDA's awareness of areas in which consumers lack knowledge. Gaps need to be identified in order for FDA to take action and educate consumers in those areas.

3. **D. Increase collaboration with stakeholders on nutrition**

   This result suggests that FDA work with stakeholders and leverage resources to improve many aspects of nutrition issues.

## Critical Assumptions

Critical assumptions are recognized external conditions that would be necessary for the success of the results. No critical assumptions have been identified for this framework.

# Appendix H. Nutrition Portion of the Current OFVM Strategic Plan 2012 – 2016

The nutrition portion of the current strategic plan is included here to enable a comparison against the strategic plan that the NRP is proposing as a successor for the next 10 years.

## Program Goal 4 – Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity

Food products sold in the United States have to be labeled so consumers can understand the products' nutritional qualities and use that information to improve their diets. The FVM Program will continue to work with industry and consumer groups to determine the best methods for conveying nutrition information on food items, menus and vending machines. Similar efforts will be pursued in pet food labels to protect and enhance animal health. By improving the way nutrition information is communicated to the public and by promoting awareness and education around these initiatives, the FVM Program can help improve the way consumers make dietary choices for themselves and their pets to ultimately enhance public health and animal health.

***Objectives:***

***4.1 –Update the Nutrition Facts label.***

The nutrition facts label will be updated in light of the most current information about nutrition and health, including potentially giving greater prominence to calorie declarations. The manner in which serving size information, daily values and key nutrients are communicated will also be updated.

| Key Initiatives |
|---|
| **4.1.1:** Publish proposed rules updating the nutrition facts label and serving sizes. |
| **4.1.2:** Publish final rules updating the nutrition facts label and serving sizes. |

***4.2 – Implement menu and vending machine labeling regulations.***

Appropriate nutrition information needs to be available for all foods sold in retail settings. By making calorie and other nutrition information readily available at the point of purchase such as in restaurants, similar retail food establishments and on vending machines, consumers can be equipped with the right information to make better choices regarding what they eat.

| Key Initiatives |
| --- |
| **4.2.1:** Publish final menu and vending machine labeling regulations.<br><br>**4.2.2:** Collaborate with states, localities and other partners to ensure high rates of compliance. |

***4.3 – Improve consumer access to and use of nutrition information.***

The FVM Program will contribute its expertise to educate consumers and improve the way they interpret and use nutrition information. As evidence-based approaches for informative labeling in food and feed products are developed, consumers will be able to make healthier choices about the food they eat or the pet food products they select that can support improved health and well-being in people and animals.

| Key Initiatives |
| --- |
| **4.3.1:** Explore front-of-pack nutrition labeling opportunities.<br><br>**4.3.2:** Collaborate with public/private sector parties on nutrition education.<br><br>**4.3.3:** Implement updated standards for the labeling of pet food including nutrition and ingredient information.<br><br>**4.3.4:** Implement standards for animal feed ingredients.<br><br>**4.3.5:** Publish final rule defining and permitting use of the term “gluten free” in the labeling of foods. |

## Program Goal 5 – Encourage food product reformulation and safe production of dietary supplements

In addition to undertaking initiatives that empower consumers to make better health choices, the FVM Program is committed to using its scientific leadership and influence and, when appropriate, regulatory tools to promote a healthier food supply for American consumers. This includes fostering the development of healthier food products and improving safety oversight of dietary supplements.

***Objectives:***

***5.1 – Reduce sodium content in the food supply.***

The FVM Program is committed to encouraging the food industry to reduce the amount of sodium included in packaged foods and served in restaurants. In order to inform decisions about how best to reduce sodium content, the FVM Program will research and analyze all relevant considerations, including the role of sodium in taste, safety and other important attributes of food products, as well as consumer behavior.

| Key Initiatives |
| --- |
| **5.1.1:** Conduct modeling to assess sodium intake resulting from varying levels of salt added to foods.<br><br>**5.1.2:** Consider options to identify and implement sodium reduction targets.<br><br>**5.1.3**: Collaborate with CDC and USDA to monitor sodium intake. |

***5.2 – Reduce industrially produced trans fat in the food supply.***

The FVM Program will continue its efforts to reduce artificial *trans* fat in the food supply.

| Key Initiatives |
| --- |
| **5.2.1:** Complete and publish updated *trans* fat intake assessment.<br><br>**5.2.2:** Implement options for further reduction of *trans* fat in the food supply.<br><br>**5.2.2**: Collaborate with CDC and USDA to monitor *trans* fat intake. |

***5.3 – Improve the safety of dietary supplement products and the supply chain.***

The program will continue executing a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, and other relevant statutes and regulations.

| Key Initiatives |
| --- |
| **5.3.1:** Develop and implement strategic, risk-based, and innovative compliance and regulatory strategies to address dietary supplement safety issues.<br><br>**5.3.2**: Advance post-market surveillance systems in the regulation of dietary supplements.<br>**5.3.3**: Advance pre-market oversight of dietary supplements by finalizing and implementing new dietary ingredient (NDI) guidance. |

# Appendix I. References


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