

Merging Quality Science With Supplement Research

*A Strategic Plan for the
Office of Dietary Supplements*





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Office of Dietary Supplements
Office of the Director
National Institutes of Health

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PREFACE

As the Director of the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH), I am pleased to present the first strategic plan for this new office. The plan outlines the ODS research goals and objectives and serves as a guide for activities and resource needs for the office for the next three to five years.

The strategic plan was developed through collective input from over 120 scientists and professionals from academia, government, industry, public interest, and professional groups. The final plan reflects more than 700 comments, suggestions, and concerns, from these strategic plan participants which have been carefully analyzed and incorporated through reviews of earlier drafts. I would like to acknowledge these individuals who volunteered their time and participated in this planning process (see Appendix A). It is their shared vision with ODS that is reflected in this document. I am also grateful to the ODS team for their diligence and commitment to creating an exceptional plan for the office. The ODS is mandated to foster the broadening of the science base in dietary supplement research. Another important ODS responsibility is collecting these results and disseminating them in a meaningful manner. These dual roles of promoting research and disseminating research results are reflected in this strategic plan.

This plan is not meant to be a static document, but one that will evolve and grow. Please do not hesitate to contact the ODS with comments and suggestions regarding the plan or office activities, through the contact addresses below. Also be sure to visit the ODS Internet web page, <http://dietary-supplements.info.nih.gov>.

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BACKGROUND

Introduction

In the United States, dietary supplements have been defined by the Dietary Supplement Health and Education Act (DSHEA) [Public Law 103-417, Section 3.(a), October 1994] to include

a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

Scientific inquiry linking dietary supplements to a healthier life can be viewed as a relatively new area of research. In the early part of the twentieth century, nutrition sciences and dietary recommendations focused on the identification and treatment of nutritional deficiency diseases. Although Americans have long been consuming vitamin and mineral supplements, it is only within the last two decades that a direct relationship between diet and health (and, therefore, the potential beneficial role for nutrient supplements beyond the minimum amounts required to avoid deficiency) has become apparent. The possible roles for food ingredients, dietary supplements and other natural product derivatives to promote health and reduce the risk of disease have also become recognized. The publication of *The Surgeon General's Report on Nutrition and Health* (DHHS, 1988) and the *Diet and Health* report (NRC, 1989a) highlighted the

the diet-health relationship and led to a paradigm shift: nutrition professionals began to recognize the potential value of supplements to reduce disease risk. Since the publication of these reports, scientific research that characterizes the potential roles of individual nutrients and food ingredients as dietary supplements has grown dramatically.

Important government studies, such as the National Health and Nutrition Examination Survey (NHANES), the Baltimore Longitudinal Study on Aging, and other large-scale studies have included information on the use of dietary supplements. These studies provide important scientific information on the links between disease and dietary parameters and also serve as key monitors of change in healthful behaviors and health trends.

In contrast to the large scientific literature on individual nutrients as supplements, there is a much smaller database of scientific information on botanical ingredients. Considerable research on the effects of botanical ingredients has been conducted in Europe and Asia where plant products have a long tradition of use. However, the overwhelming majority of nonnutrient dietary supplements has not received in-depth scientific scrutiny. It is important, therefore, to conduct scientific research to determine the benefits and risks of promising botanical ingredients and to interpret available scientific information for the public.

As with any scientific research involving human health, a series of research steps will lead to a solid scientific base from which public health policy advice can be generated. New hypotheses are often generated from epidemiological studies of supplement exposures and specific health out-

comes, or basic research, such as the characterization of an active compound from a plant. Testing for biological activity, or experimental intervention studies with laboratory animals, is often a second step. Results from these types of studies, when coupled with clinical observations, often lead to health-related hypotheses and indicate research areas worth pursuing with clinical trials. Structured observational studies and small, direct intervention studies also may provide additional evidence. Large-scale clinical trials of safety and efficacy are characterized by diverse study populations and highly monitored protocols. This latter type of study or combinations of the various study types can form the basis for recommending health policy changes.

Careful research is costly. While the cost of basic biological research, animal studies, and small-scale epidemiological studies may range from less than one hundred to several hundred thousand dollars, the cost of large-scale, randomized clinical trials of efficacy and safety of a compound tested

against disease endpoints may typically range into millions of dollars for a single study. The ensuring value to the health of the public can be great.

Dietary supplements do not have the advantages of potential market exclusivity that stimulates corporate research investment with prescription drugs. As a result, the dietary supplement industry has not yet invested heavily in research. The federal government alone cannot move dietary supplement research forward. A combined effort of good scientific research supported by government and industry is needed to clearly identify how and when supplements can be beneficial. *The Report of the Commission on Dietary Supplement Labels* (CDSL, 1997) highlighted the need for government-academic-industry partnership in dietary supplement research. Professionals from these three groups participated in the development of the ODS Strategic Plan. It is hoped that this plan will lay the groundwork for a three to five year government-academic-industry partnership in research.

Brief History

Public Law 103-417, the DSHEA, amended the Federal Food, Drug, and Cosmetic Act “to establish standards with respect to dietary supplements.” This law authorized the establishment of the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH). The DSHEA designated tasks for the office and its director that were deemed necessary by Congress to improve knowledge about dietary supplements. The ODS was established within the Office of the Director, NIH, under the supervision of the Associate Director for Disease Prevention, William R. Harlan, M.D. (Figure 1).

In November 1995, Harold E. Varbus, M.D., Director of NIH, appointed

Bernadette M. Marriott, Ph.D. as the Director of ODS. She came to NIH from the Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, Washington, D.C., where she was Deputy Director, responsible for planning and managing the research evaluation of national and international food and nutrition activities.

Since assuming the position of director, Dr. Marriott has promoted dialogue among scientists and academicians, government, and industry regarding dietary supplements and encouraged these groups to participate in the strategic planning process

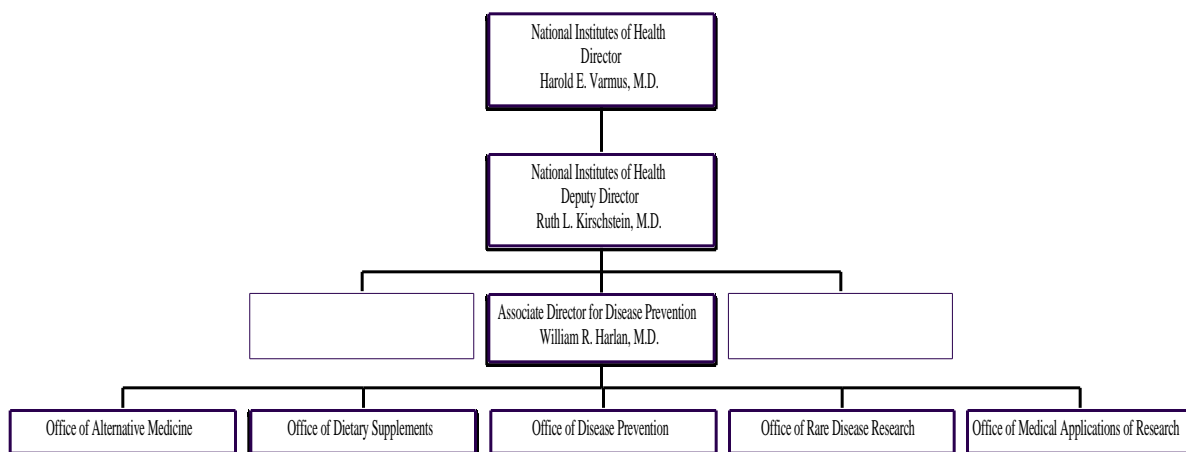


FIGURE 1 Organization of the Office of the Director, NIH, showing the location of the Office of Dietary Supplements, summer 1998.

for the ODS. In addition, Dr. Marriott has been meeting with each NIH Institute and Center (IC) Director to introduce the purpose and activities of the ODS as well as identify common areas of scientific interest. The initial costs of the ODS for 1995 were funded through the NIH Director's Discretionary Fund. Since fiscal year (FY) 1996, the operating and program funds for the

ODS have been a line item in the budget of the NIH Office of the Director.

In its first two years, the ODS has addressed its congressional mandates and begun to fulfill the purposes and duties defined in the DSHEA. A separate status report, *Report of the First Years of the Office of Dietary Supplements, 1995–1998*, will be published that provides an overview of these activities and accomplishments.

Why a Strategic Plan?

Establishing a new government office can be both exciting and overwhelming. From the inception, numerous decisions regarding both the operation and the activities of the office must be made. Many decisions will affect the future direction and success of the office. In order for the office to move forward systematically, it is necessary to have a coherent plan with well-defined short- and long-term goals that can be evaluated, reviewed, and improved. One of

the first activities undertaken by the ODS was the development of a strategic plan. This plan will serve as the framework for decision making for the next three to five years.

The ODS Strategic Plan will not be static. It will be evaluated regularly in order to assess the effectiveness of the strategies and methods used to achieve the office purpose and goals. This process will also allow for adjustments in response to unforeseen

changes in scientific or public health needs and opportunities.

DSHEA also authorized the establishment of a Presidential Commission on Dietary Supplement Labels (Public Law 103-417, Section 12). This commission was given the task to

...conduct a study on, and provide recommendations for, the regulation of label claims, and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims.

The resulting commission report (CDSL, 1997) included the findings and specific guidance and recommendations to federal

agencies and industry. As part of its fact-finding, the Commission reviewed the activities of the ODS and made the following recommendations:

- ODS should strive to be an effective focal point for research on and understanding of the health effects of dietary supplements.
- ODS should place greater emphasis on its assigned role of advising other government agencies on a broad range of issues relating to dietary supplements.

By developing this strategic plan the ODS has laid out a blueprint for its future that directly addresses these recommendations.

Development of the Strategic Plan

In its first year, a principal goal of the ODS was to inform the biomedical and professional communities about the new office. To accomplish this goal, the ODS Director attended numerous national meetings and gave more than 35 presentations describing the new office. Each presentation included a request that individuals from academia, industry, government, and the public participate in the development of a strategic plan for the ODS.

Through this process, professional groups were identified that represented the major scientific and public interests in the field of dietary supplements. These groups were then formally contacted and asked to recommend individuals who were knowledgeable about the scientific and public issues related to dietary supplements. The recommended individuals were formally invited to participate as *ad hoc* advisers to the ODS. Over 98 per cent of those contacted accepted the invitation.

Seven strategic planning meetings were held from September 1996 through February 1997. The meetings involved over 120 scientists and professionals from academia, industry, government, and public interest groups (see Appendix A for a list of participants). The first three meetings, each attended by a different set of specialists, focused on the definition and scope of dietary supplements, and the setting of scientific priorities. The next three meetings involved different *ad hoc* advisers and built on the first phase to develop a mission statement, further define scientific priorities, and identify specific activities for the ODS.

The collective input from these groups was used to develop a preliminary draft of the ODS Strategic Plan. At the seventh meeting, the ODS convened representatives from the NIH ICs and other interested federal agencies to review and critique the preliminary draft. Comments on the preliminary draft, coupled with comments and suggestions from the earlier sessions led

to a final draft of the ODS Strategic Plan. This draft was sent to all 129 participants for their review and comments. Over 700 comments, concerns, and suggestions were re-

ceived, carefully reviewed by the ODS staff, and incorporated into the final ODS Strategic Plan.

OVERVIEW

The ODS Strategic Plan comprises three major components: Foundation, Scientific Goals and Objectives, and Methods. Each component is summarized below and developed more fully in subsequent pages.

Foundation

Three areas lay the groundwork for the ODS Strategic Plan:

1. *The Congressional Mandates* were set forth by the 103d Congress. This section presents the congressional mandates within the context of the ODS in general, the Department of Health and Human Services (DHHS), and the NIH.
2. The term *Dietary Supplements* was defined by the DSHEA, and the activities of the ODS will be guided by this definition. An *Operating Definition of Dietary Supplements* has been developed by ODS to provide further clarification, categories, and examples that scientists and administrators can readily interpret. This operating definition was proposed and refined through the strategic planning process.
3. The *ODS Mission Statement* succinctly states the purpose and mandates of the ODS.

Scientific Goals and Objectives

The ODS has identified five equally weighted scientific goals and specific objectives:

Goal 1: Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.

Goal 2: Evaluate the role of dietary supplements in physical and mental health and in performance.

Goal 3: Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.

Goal 4: Improve scientific methodology as related to the study of dietary supplements.

Goal 5: Inform and educate scientists, health care providers, and the public about the benefits and risks of dietary supplements.

Collectively, these goals will guide the ODS toward fulfillment of its mission.

Methods

The ODS has identified five general methods that it will use to move its objectives forward.

1. *Operating Principles* describes the underlying approaches of all the ODS activities.

2. *Criteria* defines what the ODS will use to evaluate competing scientific priorities.

3. *Types of Activities* outlines the approaches ODS will use to accomplish its goals, for example, through research support, research dissemination, and education.

4. *Emerging Science* describes how the ODS will identify and promote new or developing scientific topics of merit.

5. *Plan Evaluation Process* outlines ways in which the ODS will continually review its progress toward meeting its goals and objectives.

FOUNDATION

Congressional Mandates

The DSHEA created the ODS and specifies the general scientific functions and duties for the office and also a number of distinct tasks for the office and its director. The complete provisions from the DSHEA that are applicable to the ODS are included in Appendix B. These mandates are interpreted here in terms of their applicability to ODS in general, within the DHHS, and within NIH.

ODS GENERAL MANDATES

The DSHEA [Public Law 103-417, Section 13.(a)] included two overarching mandates for the ODS that govern its general activities:

- “...explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care;...”
- “...promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.”

ODS MANDATES WITHIN THE DHHS

The Department of Health and Human Services (DHHS) is the principal unit with the federal government responsible for protecting and promoting health. As such, the DHHS has a leadership role in helping

all Americans develop and maintain healthy, productive, and independent lives. The ODS also has a dual mandate to provide science support related to dietary supplements within the DHHS:

- “...compile a database of scientific research on dietary supplements and individual nutrients;...”
- “...serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements... .”

ODS MANDATES AT NIH

In addition to these general mandates, ODS has specific mandates within NIH. As the major funding agency of biomedical research in the United States, NIH has a leadership role in setting the agenda for scientific research and establishing policy on how and by whom research is conducted (NIH, 1997). The DSHEA gave the ODS a threefold mandate within NIH:

- “...conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary sup-

plements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism; ...”

- “...collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine; ...”

- “...coordinate funding relating to dietary supplements for the National Institutes of Health.”

Operating Definition of Dietary Supplements

The term dietary supplements is defined in the DSHEA as:

“ a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)...is not represented for use as a conventional food or as a sole item of a meal or the diet; and is labeled as a dietary supplement.” [Public Law 103-417, Section 3.(a)]

Meetings with NIH Institute Directors and individuals from other agencies indicated that the definition stated in DSHEA required clarification so that scientists and administrators could readily interpret whether compounds of interest to them would fall within the ODS mandate.

Further, the DSHEA definition encompassed such a wide array of compounds that some type of categorization was required to promote science in a systematic fashion. The ODS therefore enlisted the assistance of participants in the strategic planning meetings to develop an operating definition and broad categories within which to

group dietary supplements to help focus ODS activities.

ODS Approach to Dietary Supplements

The ODS accordingly has determined that its research focus will be on the types and quantities of ingredients that may be contained in commercially marketed dietary supplements and their role in maintenance and promotion of health. Thus there are two basic assumptions that govern ODS activities: compounds that are under consideration 1) currently have an intended use as dietary supplements or ingredients in dietary

supplements; and 2) compounds or ingredients therefore must meet the method of delivery and other statutory definitions for dietary supplements described in DSHEA. Ingredients or chemical constituents derived from items that may be termed “functional foods”¹, or some compounds that may be termed “nutraceuticals”², may also be dietary supplements if they fall within the statutory definitions of DSHEA. The ODS considers solutions that are used to provide total parenteral or full enteral nutrition (by tube feeding) to be outside the scope of the office. However, research on the health effects of specific supplement ingredients that may be added experimentally to these solutions may be considered within the scientific scope of the ODS depending upon the ingredient and study design.

Therefore, the ODS will identify and foster research on the health benefits and risks of substances based on the merit of the underlying scientific evidence regardless of how they might be currently incorporated into the different categories of commercial products or their regulatory status in the commercial marketplace. This approach allows the ODS flexibility to address the scientific questions relevant to the role of specific substances in promoting health without being unnecessarily constrained by the nuances that bear on whether a substance may be lawfully used in a dietary supplement, or whether specific information on the label/labeling causes a product to be marketed under regulatory frameworks other than as a dietary supplement.

¹ Functional Food - any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains (Thomas and Earl, 1994).

² Nutraceutical - any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease (DeFelice, 1993).

Operating Definition

Following DSHEA, a *Dietary Supplement* is viewed by the ODS as any substance that is consumed in addition to the regular diet - that is, in addition to meals, snacks, and beverages - and follows the methods of delivery clauses outlined in the Act. Food items, in any physical form (such as a liquid or a powder intended to be added to a liquid, etc.) that are intended to be a sole source of nutrition, meal replacements, or conventional foods are not dietary supplements as defined in DSHEA, and thus are outside of the scope of ODS.

Categories of Dietary Supplement Ingredients

Dietary supplements may contain one or more ingredients whose health benefits and risks are of interest singly and in combination. To simplify the ODS management of information and activities pertaining to the broad and heterogeneous spectrum of ingredients that are included in dietary supplements, it will group dietary supplement ingredients into three categories: **Botanicals**, **Nutrients**, and **Other Dietary Substances**. The reference sources used by the ODS for definitions and terminology for each category are described in Appendix C.

Botanical Ingredients include all plant-derived materials whether fresh, preserved, or dried full plants, plant parts, plant species mixtures, plant extracts, and compounds found in such materials. Thus, items that are commonly termed “herbs” or “herbal products”, regardless of whether they meet the dictionary definition of herb³ or that are comprised of parts, extracts, or preparations of woody plants will be included as botanical ingredients.

³ Herb- a flowering plant whose stem above ground does not become woody.

Nutrient Ingredients include all essential and non-essential nutrients and other food constituents, that are typically described in standard nutrition reference texts or that fall within the review parameters of the Food and Nutrition Board, National Academy of Sciences in consideration of Dietary Reference Intakes (DRIs). Thus, this category would include substances recognized as essential nutrients (i.e., iron, vitamin C, essential amino acids, etc.) and substances not generally recognized as being essential but that have or may have a dietary or nutrient role in humans.

Other Dietary Substances comprises a broad and diverse group of substances that are neither of plant origin nor alone could be viewed as “nutrients” within the common-sense meaning of the term. For example, such substances could include animal or plant metabolites or constituents, microorganisms and certain of their constituents, etc. The substances subject to inclusion in this category are limited by the statutory definition of “dietary supplement” in the DSHEA (i.e., not an approved or investigational drug, not a conventional food or meal replacement, and intended to be used to supplement the diet, etc.).

Mission Statement

The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.

SCIENTIFIC GOALS AND OBJECTIVES

A major purpose set forth for the ODS by Congress is to increase scientific research on dietary supplements. However, the broad array of dietary supplements makes it impossible to promote research in all available areas simultaneously. It is necessary, therefore, to focus on specific goals and on objectives that will support and accomplish these goals. As a unit within NIH, ODS will promote and support clinically relevant, basic research, including animal studies, as well as clinical studies of efficacy and safety (NIH, 1997). Therefore, basic research that is likely to advance particular areas of science related to dietary supple-

ment use and health will be an important aspect of ODS activities.

A DHHS wide mandate for the ODS is to “serve as the principal advisor ...relating to dietary supplements” [Public Law 103-417, Section 13. (a)]. Through addressing the following goals and objectives the ODS will further develop a scientific base from which to provide information and advice.

During the strategic planning process, numerous approaches to goal setting were developed, revised, discarded, reinvented, and recommended. As a result, the ODS has identified **five equally weighted**

scientific goals that form the cornerstone of its programs. Each goal addresses a pivotal role for the ODS. The objectives listed with each goal represent specific scientific areas that were identified by the OSD staff and *ad hoc* advisers as scientific priorities for the next three to five years. In the objectives, basic and clinical research related to the same field of study may be addressed in one or more goals, or not at all depending on the

research gaps identified in the strategic planning process. These goals and objectives were selected for their relevance to dietary supplements and the likelihood that they would produce successful outcomes.

These goals and objectives will guide the ODS when preparing future budgets and determining ODS activities on an annual basis.

Goal 1: Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.

Over 100 million Americans regularly use dietary supplements (Aartes, 1997). Many supplement users report that they take dietary supplements to reduce the risk of disease or generally to promote health (Brevoort, 1998). Disease prevention research includes the identification of risk factors and interventions that prevent the occurrence of disease (or its progression, if detectable but asymptomatic). In a broader sense, it also includes analysis of the etiology and mechanisms of disease that may contribute basic knowledge applicable to future preventive interventions (Harlan, 1998). As a unit within the NIH, the ODS must promote and support basic research that is likely to advance particular areas of science that may be relevant to clinical studies of efficacy and safety and specific health problems. To address Goal 1, the ODS sets the following objectives:

- Advance the understanding of the specific impact of nutrient and botanical supplements or their ingredients on immunocompetence particularly related to HIV/AIDS and infectious agents.

- Stimulate research on the potential roles of dietary supplements in reducing the risk and control of cancer*, particularly cancer of the breast, ovary, and prostate*.
- Evaluate the role of specific supplements in reducing the symptoms or pathology of coronary heart disease* and diabetes.
- Identify those dietary supplements that reduce the symptoms of, and possibly retard the progression of arthritis, including osteoarthritis.
- Introduce a cross-disciplinary initiative to study the interactions among diet, supplements, and physical activity in bone health and reducing the risk and progression of osteoporosis*.
- Develop strategies to evaluate the role of individual and multiple supplements to reduce the risk and progression of ocular disease, particularly cataracts* and macular degeneration.
- Foster the inclusion of research on the role of dietary supplements in federal initiatives to address the etiology, reduction, and health outcomes of obesity in the U.S. population.

*Specific areas of scientific priority included in the DSHEA legislation.

- Examine whether dietary supplement use may influence the progression of oral diseases.

Goal 2: Evaluate the role of dietary supplements in physical and mental health and in performance.

In 1996, the U.S. Surgeon General issued a report recommending that Americans increase their physical activity (DHHS, 1996). In response to the Senate Appropriations Committee of the U.S. Congress, the Institute of Medicine, National Academy of Sciences prepared a report that detailed recommendations for mental health research (IOM, 1994). In keeping with these reports and the congressional mandate, ODS seeks to promote research on the scientific benefits and risks of dietary supplements in maintaining health and performance. The following are objectives to address Goal 2:

- Encourage research efforts to evaluate the relationships among dietary supplements and physical health and performance that includes the full range of age and population groups, hydration status, temperature regulation, environmental stress, and physical activity.

- Advance research on the role of dietary supplements in altering body composition and weight control.
- Advance research on the role of dietary supplements for increasing muscle strength, endurance, conditioning, and anaerobic power.
- Initiate research to identify and characterize the unique nutrient and caloric needs of persons with disabilities and elucidate potential roles for dietary supplements.
- Encourage research to determine the beneficial and detrimental effects of dietary supplements on mood, fatigue, stress, and psychological well-being.
- Promote further study of dietary supplements that have been demonstrated scientifically to enhance cognitive performance.

Goal 3: Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.

The use of dietary supplements may influence biological systems or the physiological challenges to these systems during human development. One function of the ODS is to define areas of research focus and foster exploration of the biologic variables related to acute and chronic use of dietary supplements. The following objectives have been identified to carry out this goal:

- Investigate how dietary supplements may moderate specific processes of aging.
- Explore how the assimilation of dietary supplements varies with age-related physiologic changes.

- Advance the understanding of how dietary supplements may influence reproductive systems, birth defects*, and fetal development.
- Characterize the relationships among dietary supplements and basic cognitive processes, including attention, learning, and memory.

- Evaluate the role of individual supplements and supplement ingredients in the underlying pathophysiology of metabolic, endocrine, and gastrointestinal disorders, particularly those associated with drug abuse.
- Identify the changes in basic metabolic and physiologic processes that may occur with physical disabilities and potential roles for dietary supplements.

Goal 4: Improve scientific methodology as related to the study of dietary supplements.

Dietary supplement research is conducted across many scientific disciplines and supported by a wide array of methods. Key to enhancing progress in the field is the integration of research that accommodates the variety of supplements, supplement delivery systems, sites and mechanisms of action, and groups of individuals who take supplements. Scientific advancement with a particular supplement may hinge, therefore, on the development or refinement of appropriate and/or novel instrumentation or methods. To meet this goal, the ODS proposes the following objectives:

- Promote the identification and characterization of bioactive compounds in dietary supplements by delineating their mode of absorption, distribution, metabolism, mechanism of action, and excretion.

*Specific areas of scientific priority included in the DSHEA legislation.

- Evaluate and develop animal and clinical methods for determining the efficacy and safety of dietary supplements.

- Develop new and validate existing epidemiological/survey methods for assessing dietary supplement usage.
- Promote the collection of reliable and valid data on dietary supplement usage.
- Promote academic-government-industry partnerships to advance dietary supplement research and technology transfer.
- Develop model systems to predict and characterize the potential for adverse effects resulting from interactions among dietary supplements and nutrients, other supplements, and drugs.
- Identify and facilitate the development of new methods for characterizing supplements and their active components.
- Establish guidelines to delineate the combination of experimental methods necessary to demonstrate high confidence levels for efficacy and safety of dietary supplement use.

Goal 5: Inform and educate scientists, health care providers, and the public about the benefits and risks of dietary supplements.

The ODS Director was mandated by Congress [Public Law 103-417, Section 13.(a)] to serve in an advisory capacity to the DHHS regarding “(A) dietary intake regulations; (B) the safety of dietary supplements, (C) claims characterizing the relationship between (i) dietary supplements; and (ii) (I) prevention of disease or other health-related conditions; and (II) maintenance of health; and (D) scientific issues arising in connection with the labeling and composition of dietary supplements”. The Report of the Commission on Dietary Supplement Labels, (CDSL, 1997) recommends that the ODS place greater emphasis on this advisory role. The ODS has included this mandate as a specific objective for achieving goal 5.

Since the ODS began in November 1995, the office has received over 1,200 calls or requests from the public for personal health care information about dietary supplements. An almost equal number of calls have been logged in the ODS from scientists and health care professionals. To assist these groups, the ODS will promote and support the development of scientifically valid information and educational materials on dietary supplements and individual nutrients through the objectives that follow:

- Serve as a key resource and adviser for policy makers about dietary supplements.*

- Develop and maintain a publicly accessible database of federally funded scientific research on dietary supplements.*
- Stimulate dialogue about dietary supplements among government agencies, academia, public advocacy groups, and industry.
- Facilitate the integration of scientific information on dietary supplements within standard and continuing education programs for health care providers.
- Promote training of scientific investigators in dietary supplements research, as well as effective communication of research results.
- Encourage the regular inclusion of dietary supplement intake information as part of a patient’s medical history.
- Conduct a survey to assess the need for a public information system on dietary supplements.
- Evaluate and effectively communicate to the public the results of recent scientific research.

*Specific areas of scientific priority included in the DSHEA legislation.

- Develop and maintain a publicly accessible database of published, peer-reviewed, scientific literature on dietary supplements.*

METHODS

Operating Principles

The ODS has identified a number of operating principles that will guide its activities. The fundamental theme behind these principles is sound scientific methodology. ODS supports the highest quality science with regard to conducting research and communicating research findings to the public. A focus on efficacy and safety in any intervention study must be considered to ensure this high-quality science. While some goals and objectives may specifically mention safety, the ODS will approach all research from the perspective that benefits and risks must be addressed where possible. The ODS will interpret the scientific research on dietary supplements and present a balanced view of scientific evidence to the public. To maximize public access and keep costs as low as possible, the ODS will use its Internet World Wide Web site to disseminate information. As directed by Executive

Order 12862 (see Appendix D), the ODS will be open to new concepts of customer service orientation in order to provide quality service to the public. In addition, the ODS will visibly and actively communicate and receive commentary on its research plans, accomplishments, and activities through a variety of forums. The ODS will also strive to coordinate with other agencies, institutes, or the private sector in all areas of dietary supplement research in order to avoid duplication of efforts and potential waste of government resources. (NIH, 1997) Within NIH, ODS will work with its Dietary Supplements Liaison Panel (see Types of Activities section) to promote and coordinate activities. Finally, the ODS will focus its activities on the mission and goals set forth in this strategic plan.

Criteria

The ODS will not have the resources to financially support all of the dietary supplements research submitted for consideration. The ODS therefore has established the following evaluation criteria to facilitate decision making among competing scientific priorities:

- *Relevance to the Mission of the ODS*

The ODS is committed to implementing its goals and objectives. ODS-supported research must delineate a clear link between dietary supplements

and health. Similar to the ICs, the ODS is responsive to the areas of research emphasis that are identified by the NIH Director (NIH, 1997).

- *Expand experimental possibilities, or develop emerging or innovative research strategies and methods.*

As experimental possibilities expand, the ODS will strive to develop innovative research strategies and methods. Priority research strategies will: prevent disease where other treatment

modalities fail, complement existing preventive strategies, present and/or develop a needed novel methodology or approach, provide a biomarker for disease, have a high biological plausibility, and/or have the possibility of multiple positive health impacts. Innovative research methods will open new directions in basic research, allow specific key research questions to be addressed, and move research forward toward clinical applications.

- *Fund research of the highest quality.*

The ODS will adhere to the values of the NIH, which are based on the highest quality science. High-quality science must provide enough methodological detail to be validated or refuted, have an appropriate experimental design, and consider the quantity and quality of prior studies. The ODS will promote and fund research that is based on these premises.

- *Demonstrate a relationship to important public health need(s).*

The ODS recognizes its responsibility in supporting dietary supplements research that addresses an important public health need. As a funding source, the ODS must consider the relevance of research to important problems in health and the potential for reducing health care costs.

- *Offer potential for partnership or collaborative efforts with other institutions and organizations.*

The ODS acknowledges the importance of maximizing the use of funds by avoiding duplication of ongoing research strategies. As a member of the NIH community, the ODS strives for potential partnerships and/or collaborative efforts with the ICs, other agencies, and members of the private sector that may reduce duplication. The ODS also recognizes the importance of DHHS-targeted subpopulations (DHHS, 1997) that are underrepresented in research efforts. The ODS will emphasize these populations in all of its activities.

Types of Activities

The ODS has identified five scientific goals and the strategic objectives needed to accomplish them. The activities ODS will initiate to move this agenda forward are described below. These activities focus on research promotion, support, dissemination, and coordination, as well as advisory activities, education, and partnering programs. The complete description of ODS' accomplishments to date will be published separately in the forthcoming status re-

port, *Report of the First Years of the Office of Dietary Supplements, 1995–1998*.

Research Promotion and Support

Grants, Contracts, and Awards

As an office within the Office of the Director at NIH, the ODS does not have the authority to directly fund investigator-initiated research grant appli-

cations. Instead, the ODS may support research by partnering with ICs at the NIH or with another federal agency to co-fund research grants or initiate Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs). Those last mechanisms stimulate research in specific key areas. NIH uses groups of outside experts through workshops, conferences and symposia to gather opinions on the gaps in science that may be identified for research support through PAs, RFAs, and RFPs.

A specific example of an intra-agency agreement that is being used by the ODS is the **Research Enhancement Awards Program (REAP)**. Through REAP, grant applications are received and reviewed by the ICs following the standard NIH extramural research grant process. Highly meritorious applications that fall outside an IC's funding resources and are within the research interests of the ODS can be nominated by NIH ICs to receive partial or full funding from ODS. This innovative and successful program was originally designed by the NIH Office of Research on Women's Health. The ODS has recently co-funded a total of 13 research studies with the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Cancer Institute, the National Institute of Child Health and Human Development, the National Institute of Deafness and Other Communication Disorders, the National Institute of Dental Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Eye Institute, and the National Institute of Neurological Disorders and Stroke.

Contracts are a mechanism that the ODS may use to conduct research, such as the *Public Information Center Needs Assessment Survey* that was initiated by the ODS and is being conducted in collaboration with the Food and Nutrition Information Center (FNIC), U.S. Department of Agriculture (USDA). This study is evaluating the need for a Dietary Supplements Information Center for the public, and it capitalizes on the extensive experience of the FNIC staff in responding to public questions and developing information centers for other issues.

The ODS also supports projects jointly with other government agencies such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Department of Defense (DoD). An example is the joint federal contract with the National Academy of Sciences for the Food and Nutrition Board study on the *Dietary Reference Intakes (DRIs) for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin, and Choline* (IOM, 1998).

Periodically, funds are also provided for individual **awards** of merit to new or promising investigators, scientists, or staff who further the mission of the office. Travel awards are also provided to defray the cost of scientist's attendance at conferences co-sponsored by the ODS. Various mechanisms including intra/interagency agreements, are used to implement these awards.

Centers for Dietary Supplement Research

The ODS believes that there is a need to identify/create Centers for Dietary Supplement Research to effectively promote dietary supplement research.

By a “research center” the ODS is following the standard NIH definition of a “center” which means a group of collaborating scientists who have demonstrated/can demonstrate their expertise and capabilities in conducting research on a specific topic. The ODS therefore seeks to collaborate with the NIH ICs, other government agencies, and industry to jointly develop and fund eight research centers that will focus on the efficacy and safety of dietary supplements. Four of these centers will each focus on one of the ODS’ major goal areas. Four other centers will each focus on botanical supplements research, including basic scientific issues of botanical supplement characterization and quality. These centers will be developed following standard NIH competitive centers mechanisms and, where possible, build on the infrastructure of existing government-funded research centers to reduce overhead costs and maximize money directed toward research. It is expected that some or all of these centers will be linked as consortia in order to share resources and avoid duplication. The ODS will actively facilitate this consortium concept.

Conferences, Workshops, and Symposia

To stimulate research, the ODS plans, organizes, and supports small conferences, workshops, and symposia on scientific topics related to dietary supplements. The ODS can initiate such activities alone, but more often will work in conjunction with NIH ICs, other government agencies, and professional organizations. The specific goals and outcomes of these convening activities vary with the scientific topic.

Occasionally, the ODS will sponsor **large conferences** or **workshops** to provide an overview of a scientific area and bring together scientists and professionals from different disciplines to identify gaps in research and directions for future joint endeavors. For example, the ODS held a major two-day workshop, “The Role of Dietary Supplements for Physically Active People” in conjunction with the American Society for Nutritional Sciences and the American Society for Clinical Nutrition. Co-sponsored by 11 NIH ICs, this workshop presented a state-of-the-art scientific review of dietary supplements that may enhance the health of people who actively engage in regular exercise.

More typically, the ODS sponsors or co-sponsors **small workshops** to assist in defining research gaps in a specific scientific area of dietary supplement research. In 1996–1997, for example, the ODS co-sponsored two workshops that were initiated by the National Institute on Aging: “Melatonin and Sleep” and “Melatonin and Aging”. The ODS is co-sponsoring 15 conferences or workshops in 1998 that were initiated by various NIH ICs in response to a request from the ODS.

Research Dissemination

Databases

To fulfill the congressional directives to collect and compile **databases** of federally funded research and peer-reviewed scientific literature on dietary supplements, the ODS is developing two databases that will be accessible to the public through the ODS Internet home page. **CARDS** (Computer Access to Research on Dietary Supplements) will be a database of existing and

ongoing dietary supplement research currently supported by federal agencies. The database will start with FY95-funded extramural and intramural research activities of the NIH. CARDS will include the funded research activities of other federal agencies when the data are available. **IBIDS** (International Bibliographic Information on Dietary Supplements) is a database of published international scientific literature on dietary supplements. IBIDS is being developed and maintained by the FNIC under contract with the ODS. The IBIDS database is a compilation of dietary supplement bibliographic citations from 11 medical and scientific databases. The search engine is user-friendly to encourage both researchers and the general public to identify scientific literature on dietary supplements quickly and easily.

Internet Home Page

The ODS has completed an **Internet home page** to disseminate information to scientists and the public. This web site provides information about the ODS, including its origins, mandates, databases, publications, current Program Announcements and Requests for Proposals sponsored by various ICs at the NIH, as well as other activities, programs, and scientific resources.

Publications

The ODS publishes **scholarly reviews** about dietary supplements in peer-reviewed scientific journals. In addition, **information pages** that are derived from the reviews will be prepared for the public that interpret the literature findings in a more applied sense.

The ODS also plans to publish **proceedings** from some of the major workshops it sponsors, such as the recent “The Role of Dietary Supplements for Physically Active People,” which will be published as a supplement to the *American Journal of Clinical Nutrition*. A formal **bibliography** was prepared for that workshop in conjunction with the National Library of Medicine. This bibliography, like all other ODS publications, is available through the ODS Internet web site.

Advisory Activities

The ODS is mandated to serve as principal adviser to the Secretary and Assistant Secretary for Health, as well as advise the NIH Director, the CDC Director, and the Commissioner of Food and Drugs about issues related to dietary supplements. The ODS also advises Congress on these matters by answering **inquiries**, writing **reports**, delivering **presentations**, and participating in **interagency committee** activities on a regular basis.

Research Coordination

To coordinate research and funding on dietary supplements at the NIH, the ODS has established a **Dietary Supplements Liaison Panel**, which consists of members appointed by the directors of the ICs at the NIH. This group meets periodically to identify fruitful areas for joint research and to coordinate those research efforts. The liaison group is currently developing a mechanism for trans-NIH research coordination on dietary supplements.

The ODS also serves as a member of the **NIH Nutrition Research Coordinating Committee** (NCC),

which is managed through the NIH Division of Nutrition Research Coordination, National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK). The NCC coordinates all nutrition research at NIH and provides a regular forum for dialogue between ICs about scientific issues related to nutrition, diet, and health. In addition, the NCC staff provides a link to the DHHS inter-agency Nutrition Policy Board, which coordinates nutrition research among the public health agencies and the Inter-agency Committee on Human Nutrition Research (a subcommittee of the Committee on Health, Safety and Food of the National Science and Technology Council in the Office of the President).

Education

Historically, exposure to nutrition research and training has been limited in medical schools, as documented by several National Academy of Science reports (NRC, 1983, 1994, 1995). Therefore, to improve medical student education about the benefits and risks of dietary supplements in health care, the ODS is collaborating with the developers of a **CD-ROM educational program** that has been successfully introduced into medical school curricula. The ODS intends to support a dietary supplement module for this series.

The ODS is also initiating a series of small-scale, focused sessions for scientists and professionals to promote the submission of high-caliber proposals for botanical supplements research. These training sessions will be held regionally as part of national professional meetings.

Partnering Programs

As part of the NIH, the ODS can accept donations and bequests to support the mission of the office. Donations are handled in a **gift fund** account that is separate from the appropriation that NIH receives from Congress. These funds support research, in general and therefore cannot be earmarked for specific projects or investigations. Gift funds may be specified for use in particular broad categories of dietary supplement research, such as vitamin, mineral, or botanical supplement research.

The **Small Business Innovation Research (SBIR)** program is a three-phase research and development federal government set-aside program that supports innovative research that has potential for commercialization and that is conducted by a small business. The SBIR is therefore oriented toward developing a research-based "product" that moves toward commercialization through the grant process. NIH has a substantial set-aside for the SBIR program.

The **Small Business Technology Transfer Research (STTR)** program encourages technology transfer through cooperative research between small business concerns and nonprofit research institutions. The ODS encourages corporate groups and academic institutions to form partnerships and apply for STTR grants related to dietary supplements and the technology needed to understand the mechanism of action of dietary supplement components.

The role of the ODS in the SBIR and STTR programs, in general, will be to facilitate and coordinate such partnerships with the NIH ICs. ODS envisions that the SBIR and STTR programs may have an important role in advancing a number of the objectives listed under Goal 4.

Emerging Science

The ODS has outlined an ambitious scientific agenda. However, despite carefully laid plans, unpredictable advances in science can create opportunities that were not anticipated. The ODS will therefore, reserve funds that will be used annually to conduct one activity that responds to an emerging science issue, or “hot topic,” in dietary supple-

ments research or education that may lie outside the objectives in the strategic plan. The ODS will avail itself of the opinions of outside experts, as needed, to identify emerging science topics and recommend appropriate activities. This approach will help the ODS identify unanticipated links between supplements and health.

Plan Evaluation Process

Preparing a strategic plan that covers a three to five year span is an important step. However, if there are no interim evaluations it is unlikely that the plan will be successful. Therefore, if the plan’s goals and objectives need to be adjusted because of a shift in scientific priorities, the strategic plan will be re-evaluated. In addition, progress toward the goals and objectives of the strategic plan will be reviewed annually by the ODS staff, ODS *ad hoc* advisers and the

NIH Dietary Supplements Liaison Panel. The ODS also will prepare periodic status reports of its activities.

The ODS will maintain dialogue with other interested federal agencies and offices and dietary supplement interest groups. Through this dialogue, ODS will continue to welcome comments and suggestions regarding the strategic plan.

CONCLUSION

The ODS Strategic Plan sets the future course of scientific activities for the ODS during the next three to five years. It will guide the office toward the systematic fulfillment of its Congressionally mandated purpose to advance the scientific study of dietary supplements for disease prevention and health maintenance.

Five key scientific goals and specific objectives to realize these goals have been established with the partici-

pation of more than 120 scientists, professionals, and government representatives. Every effort was made to focus on the scientific and public health issues that are most relevant to the field of dietary supplements and which have a high probability of success. Specific areas in which it was felt that the ODS is able to make unique contributions were also identified and these will be a priority.

Through the systematic execution and dynamic evaluation of this plan,

the ODS will merge the highest quality science into the field of dietary supplements by evaluating the scientific information, as well as providing the stimulus, training and support for research. The ODS is also committed to the dissemination of research results for the education of the public and scientific communities in order to foster an enhanced quality of life and health for the U.S. population.

In FY 1998, the ODS has initiated and is proceeding with its goals and objectives. The office will continue to work with advisers from many disciplines to develop its programs. In addition, the office is committed to enhancing cross-institute coordination within the NIH and providing a customer service approach in all its endeavors. The ODS welcomes comments and suggestions on all aspects of this strategic plan.

ACKNOWLEDGMENTS

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The ODS appreciates the positive interactions, assistance, and suggestions in all aspects of its work from the members and staff of the Nutrition Coordinating Committee, (NCC), Division of Nutrition Research Coordination (DNRC), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and NCC's director, Van S. Hubbard. The ODS works closely in all its endeavors with the Office of Alternative Medicine (OAM) and appreciates the helpful insight and collaborative approach of the OAM staff, particularly its Director, Wayne B. Jonas, and Deputy Director, Geoffrey P. Cheung. The ODS could not have worked so rapidly with its databases without the contributions of Jim Krebs-Smith, Carole I. Hudgings (NINR), Eric Manheimer (ODS student intern, 1996–1997), Rebecca I. Erickson (ODS 1996–1997), and staff of the Office of Extramural Research (OER).

The ODS also appreciates the support of colleagues from other offices that work under the Associate Director for Disease Prevention in the difficult steps involved in starting a new office. William H. Hall (Office of the Medical Applications of Research; OMAR) was instrumental in the success of the first ODS workshop, "Dietary Supplement for Physically Active People", as well as helping with all aspects of ODS communications. Susanne Strickland (Health Promotion Program Manager) initially provided much useful background information and has continued to keep the ODS staff informed about any and all dietary supplement issues that come to her attention. The other ODP office directors, John H. Ferguson (OMAR) and Stephen C. Groft (Office of Rare Disease, ORD) have provided invaluable assistance to ODS.

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REFERENCES

- Aartes, T. (ed.) 1997. Nutrition Industry Momentum Builds, *Nutrition Business Journal* 2:9, 1–5.
- Brevoort, P. 1998. Is America Hungry for Herbal Supplements? *Nutraceutical News* 1:5, 1.
- Brody, T. 1994. *Nutritional Biochemistry*. San Diego, California: Academic Press, Inc.
- CDSL (Commission on Dietary Supplement Labels). 1997. Report of the Commission on Dietary Supplement Labels. Washington, D.C.: U.S. Government Printing Office.
- DeFelice, S.L. 1993. A Comparison of the U.S., European and Japanese Nutraceutical Health and Medical Claim Rules, *Regulatory Affairs* 5:163-8.
- Duke, J.A. 1992. *Database of Biologically Active Phytochemicals and Their Activities*, Boca Raton, Florida: CRC Press, Inc.
- Ensminger, A.H., Ensminger, M.E., Konlande, J.E., and J.R.K. Robson. 1995. *The Concise Encyclopedia of Foods and Nutrition*. Boca Raton, Florida: CRC Press.
- Flora of North America Editorial Committee 1993. *Flora of North America, North of Mexico*, New York, New York: Oxford University Press.
- Foster, S. (ed.) 1992. *Herbs of Commerce*. Austin, Texas: American Herbal Products Association.
- Glasby, J.S. 1991. *Dictionary of Plants Containing Secondary Metabolites*. Bristol, Pennsylvania: Taylor & Francis Inc.
- Harlan, W.R. 1998. Prevention Research at the National Institutes of Health, *American Journal of Preventive Medicine* 14:4, 302–307.
- Hedrick, U.P. (ed.) 1972. *Sturtevant's Edible Plants of the World*. New York: Dover Publications, Inc.
- DHHS (U.S. Department of Health and Human Services). 1988. *The Surgeon General's Report on Nutrition and Health*. Washington, D.C.: Government Printing Office pp. 727.
- DHHS (U.S. Department of Health and Human Services). 1996. *Physical Activity and Health: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control Prevention, National Center for Chronic Disease Prevention and Health Promotion.
- DHHS (U.S. Department of Health and Human Services). 1997. *Strategic Plan*.
- Hocking, G.M. 1997. *A Dictionary of Natural Products: Terms in the Field of Pharmacognosy Relating to Natural Medicinal and Pharmaceutical Materials, and the Plants, Animals, and Minerals from Which They Are Derived*. Medford, New Jersey: Plexus Publishers.

IOM (Institute of Medicine). 1994. Reducing Risks for Mental Disorders, Frontiers for Preventive Intervention Research. Committee on Prevention of Mental Disorders. Washington, D.C.: National Academy Press.

IOM (Institute of Medicine). 1996. Food Chemicals Codex, Fourth Edition, Committee on Food Chemicals Codex. National Academy Press. Washington, D.C.: National Academy Press.

IOM (Institute of Medicine). 1997. Food Chemicals Codex, First Supplement to the Fourth Edition, Committee on Food Chemicals Codex. Washington, D.C.: National Academy Press.

IOM (Institute of Medicine). 1998. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin, and Choline. A Report of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients, Food and Nutrition Board. Washington, D.C.: National Academy Press.

Leung, A.Y. and S. Foster. 1996. Encyclopedia of Common Natural Ingredients Used in Food, Drugs, and Cosmetics, Second Edition. New York: John Wiley & Sons, Inc. pp. 750.

Mabberley, D.J. 1997. The Plant-Book. A Portable Dictionary of the Vascular Plants. Second Edition. Cambridge, United Kingdom: Cambridge University Press.

NIH (National Institutes of Health). 1997. Setting Research Priorities at the National Institutes of Health, NIH Working Group on Priority Setting. NIH Publication No. 97-4265. Bethesda, Maryland.

NRC (National Research Council) 1983. Medical Education and Societal Needs: A Planning Report for Health Professions, Committee to Plan a Comprehensive Review of Medical Education in the United States, Division of Health Sciences Policy, National Research Council. Washington, D.C.: National Academy Press pp. 397.

NRC (National Research Council) 1989a. Diet and Health: Implications for Reducing Chronic Disease Risk, Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, Washington, D.C.: National Academy Press pp. 750.

NRC (National Research Council) 1989b. Recommended Dietary Allowances, Tenth Edition. Report of the Subcommittee on the Tenth Edition of the RDA. Food and Nutrition Board, Commission on Life Sciences, National Research Council, Washington, D.C.: National Academy Press pp. 284.

NRC (National Research Council) 1994. Careers in Clinical Research: Obstacles and Opportunities, Committee on Addressing Career Paths for Clinical Research, Institute of Medicine, National Research Council, Washington, D.C. National Academy Press pp. 344.

NRC (National Research Council). 1995. Environmental Medicine: Integrating a Missing Element into Medical Education. Committee on Curriculum Development in Environmental Medicine, Institute of Medicine, Washington, D.C.: National Academy Press,

Public Law 103-417, 103d Congress, 2nd session. (25 October 1994), Dietary Supplement Health and Education Act of 1994.

Thomas, P.R. and R.O. Earl. 1994. Opportunities in the Nutrition and Food Sciences: Research Challenges and the Next Generation of Investigators. Institute of Medicine, Committee on Opportunities in the Nutrition and Food Sciences. Washington, D.C.: National Academy Press.

Zeigler, E.E. and L.J. Filer, Jr. (eds.) 1996. Present Knowledge in Nutrition, Seventh Edition, Washington, D.C.: International Life Sciences Institute.

APPENDIXES

APPENDIX A

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APPENDIX B

Excerpt from the Dietary Supplement Health and Education Act of 1994

The Dietary Supplement Health and Education Act (DSHEA) [Public Law 103-417, Section 13.(a)] set out the following functions and duties for the Office of Dietary Supplements (ODS) as authorized at the National Institutes of Health:

“SEC. 485C. DIETARY SUPPLEMENTS.

“(a) ESTABLISHMENT.-The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

“(b) PURPOSE.-The purposes of the Office are--

“(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

“(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

“(c) DUTIES.-The Director of the Office of Dietary Supplements shall—

“(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

“(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

“(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including--

“(A) dietary intake regulations;

“(B) the safety of dietary supplements;

“(C) claims characterizing the relationship between--

“(i) dietary supplements; and

“(ii) (I) prevention of disease or other health-related conditions;

and

“(II) maintenance of health; and

“(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

“(4) compile a database of scientific research on dietary supplements and individual nutrients; and

“(5) coordinate funding relating to dietary supplements for the National Institutes of Health.”

APPENDIX C

Reference Sources for Definitions and Terminology

Through its advisory groups, the ODS obtained recommendations for other scientific publications that could serve as the basic reference materials for the three categories of dietary supplement ingredients: **botanicals**, **nutrients**, and **other dietary substances**.

For botanical ingredients, the ODS will follow the International Rules of Botanical Nomenclature and include proper botanical authorities after taxa names. *The Plant Book* (Mabberley, 1997) and *Flora of North America* (Flora of North America Committee, 1993) will be standard references used by the ODS to assist with taxonomic clarification. An additional reference source will be *Herbs of Commerce* (Foster, 1992). This report, undertaken by the American Herbal Products Association, is a compilation of common plant names representing botanical ingredients that are available commercially for ingestion in one form or another in the United States. The common names were keyed to one Latin binomial by a consensus panel. In areas where taxonomy is unclear, the ODS will contact botanical experts for their opinion. Additional reference sources that will be used by the ODS for botanical supplements are: *Sturtevant's Edible Plants of the World* (Hedrick, 1972), *Dictionary of Plants Containing Secondary Metabolites* (Glasby, 1991), *The Database of Biologically Active Phytochemicals and Their Activities* (Duke, 1992), *Encyclopedia of Common Natural Ingredients Used in Food, Drugs and Cosmetics* (Leung and Foster, 1996), and *A Dictionary of Natural Products: Terms in the Field of Pharmacognosy Relating to Natural Medicinal and Pharmaceutical Materials, and the Plants, Animals, and Minerals From Which They Are Derived* (Hocking, 1997).

A single reference could not be identified as compendium for the nutrient supplements category. The ODS thus will use the *Recommended Dietary Allowances, tenth edition* (NRC, 1989b) as its primary reference for traditional nutrients and incorporate the new Dietary Reference Intake volumes as they become available. The ODS is creating a selected library of nutrition reference books to use for this category. Additional primary references for nutrient supplements are: *Diet and Health* (NRC, 1989a), *Nutritional Biochemistry* (Brody, 1994), *The Concise Encyclopedia of Foods and Nutrition* (Ensminger et al., 1995), *Present Knowledge in Nutrition, seventh edition* (Zeigler

and Filer, 1996), the *Food Chemicals Codex, fourth edition* (IOM, 1996), and the *Food Chemicals Codex First Supplement to the fourth edition* (IOM, 1997).

Reference resources are limited for the third supplement category, other dietary substances. Many of the books listed above will provide basic information on these other supplements, and the ODS will also use relevant government reports and compendiums. The ODS welcomes recommendations for additional acquisitions that can serve as basic references for supplement nomenclature, structure, and properties.

APPENDIX D

INCORPORATION OF CUSTOMER SERVICE PLAN

Executive Order 12862

Just prior to establishment of the Office of Dietary Supplements (ODS), and as part of the administration's reinventing government initiative, President Clinton issued Executive Order 12862, "Setting Customer Service Standards." In it, the President called for a revolution within the federal government to change the way it does business and to become customer driven. The goal was to achieve standards of quality within government and customer service for the American people equal to the best in the business environment. Each agency was to develop, publish, and make readily available to the public its own customer service plan with specific standards of performance.

DHHS Customer Service Plan

In response to the Executive Order, Donna E. Shalala, Secretary of the Department of Health and Human Services (DHHS), established a plan that integrated new customer service goals into the agency's mission. The DHHS goal was "to protect and promote the health, social, and economic well-being of all Americans in a way that proves the highest quality service."

Two of the DHHS goals are particularly relevant to the ODS:

1. to promote the public health through knowledge and education, and
2. to invite partners to collaborate in program and policy development.

ODS Customer Service Plan

The ODS has embraced the DHHS customer service philosophy and incorporated it into its own operating plan. As a new office, the ODS does not have to change to a customer-oriented approach, it can simply develop customer service standards as it builds and expands the office.

Throughout DHHS, advisory panels and focus groups are working to enhance information exchange and strengthen partnerships. Similarly, the ODS has demonstrated its commitment to the DHHS customer service philosophy by convening the series of seven *ad hoc advisory* meetings that led to this strategic plan. The ODS plans to develop and maintain such partnerships and continue the dialogue; these activities are critical to the success of the office and to ODS meeting its mandates, goals and objectives.



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