

Office of Dietary Supplements Update

National Institutes of Health
U.S. Department of Health and Human Services

ODS Celebrates Its 10th Birthday

The National Institutes of Health (NIH) Office of Dietary Supplements (ODS) was formally established on November 27, 1995 as part of a Congressional law that developed a regulatory structure for dietary supplements and increased the availability of these products to consumers. "Congress was responding to the growing public interest in the potential value of supplements in maintaining optimal health and reducing the risk of disease," notes ODS Director Paul M. Coates, PhD. "Over the years, our office has become the focal point for supporting research and providing information about those relationships." This special issue of the ODS newsletter provides an overview of ODS's first ten years, highlighting significant programs and activities.

In the Beginning...

In late 1994, the Dietary Supplement Health and Education Act (DSHEA) became Public Law 103-417, which set policies relating to the definition, regulation, and labeling of dietary supplements. DSHEA also authorized the creation of ODS, with numerous mandates (see the sidebar on page 2).

ODS began its operations in November 1995 with the appointment of Dr. Bernadette M. Marriott, PhD as its first director, several temporary staff, and a budget of approximately \$1 million for fiscal year (FY) 1996. Housed within the Office of Disease Prevention in the Office of the Director of NIH, Dr. Marriott met with NIH institute and center directors



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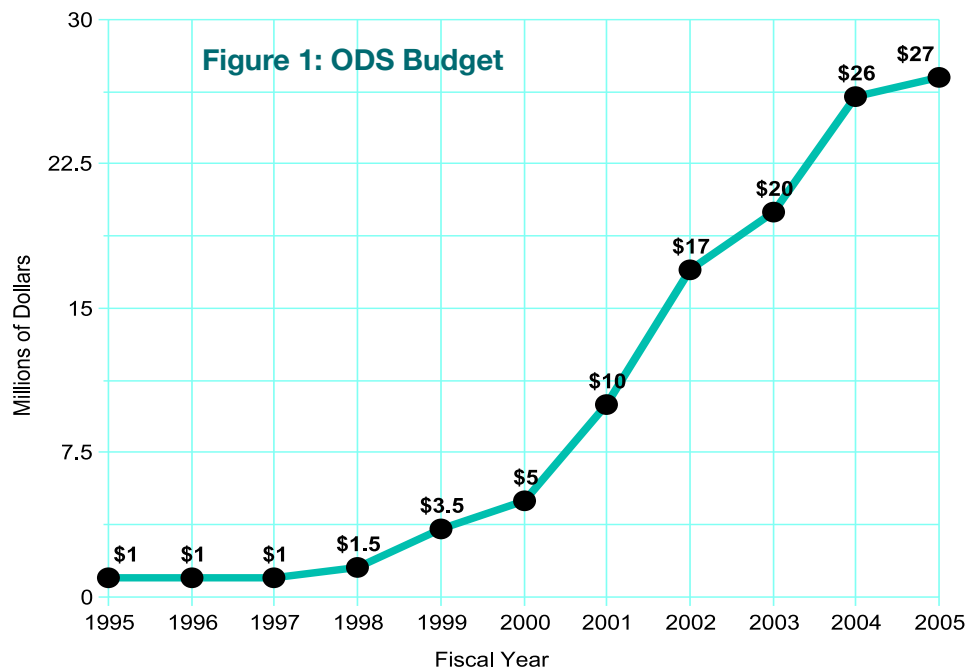
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DSHEA Mandates to ODS

- **Explore** the role of dietary supplements to improve health care;
- **Promote** scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease;
- **Conduct and coordinate** research within NIH relating to dietary supplements and the extent to which their use can limit or reduce the risk of diseases;
- **Collect and compile** databases of federally funded research and scientific papers on dietary supplements;
- **Coordinate** funding related to dietary supplements for NIH; and
- **Provide** advice to other Department of Health and Human Services [DHHS] agencies (including the Food and Drug Administration [FDA]) related to dietary supplements.

to identify areas of common interest on dietary supplements. She also met with representatives of the scientific community, industry, federal government, and public in an effort to enlist their cooperation in the future development of ODS.

As a result of these efforts, a mission statement was developed: ***"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."

In addition, a Five Year Strategic Plan (1998-2003) was developed to implement that mission. The plan's five goals emphasized the important role of ODS in research, education, and communication about dietary supplements (see the sidebar on this page). It is a tribute to the sound framework provided by ODS's original mission statement and strategic-plan goals that they were essentially retained as the mission and goals to guide ODS programs for a second five-year period, 2004-2009. (The 2004-2009 strategic plan document and supporting materials are available at http://dietary-supplements.info.nih.gov/Strategic_Planning_2004-2009/Planning.aspx). "The plan guides and challenges ODS and provides a solid basis for further program development and support of current activities," notes Senior Scientific Consultant Kenneth D. Fisher, PhD, who coordinates implementation of the strategic plan.

Dr. Coates became Director of ODS on October 25, 1999. The budget of the office has continued to grow, to approximately \$27 million in FY 2005 (see Figure 1 on page 1). Today, ODS has 10 full-time senior scientific and two full-time support staff federal-government employees as well as three scientific and six staff consultants.

ODS Activities and Programs

ODS staff work on a broad variety of initiatives and projects related directly or indirectly to dietary supplements. They are organized here along the lines of providing support for research and the training of investigators, developing

information resources and tools, and others.

Research Support

The majority of ODS funding supports research on dietary supplements, most of it investigator initiated. ODS does not have direct grant-making authority, so it works closely with the NIH institutes and centers to co-fund relevant research through NIH mechanisms that include funding awards, interagency agreements, and contracts and grants.

ODS Goals

1. **Expand** the evaluation of the role of dietary supplements in disease prevention and in reduction of risk factors associated with disease.
2. **Foster** research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance.
3. **Stimulate and support** research to further understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
4. **Promote and support** the development and improvement of methodologies appropriate to the scientific study of dietary supplement ingredients.
5. **Expand and conduct** outreach activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.

As the ODS budget has grown, so have the opportunities for research support. ODS first began to fund research in FY 1996 for six grants. Ten years later, in FY 2005, \$17.5 million of ODS's \$27 million budget went to fund 103 grants (see Figure 2 on this page). Much of the funding for these awards have been focused on botanicals; the primary co-funders were the National Center for Complementary and Alternative Medicine (NCCAM), National Cancer Institute (NCI), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

According to Deputy Director Rebecca B. Costello, PhD, who coordinates the ODS grant-funding process, "we've established a tradition of working across the spectrum from in vitro laboratory and animal experiments to human studies and clinical trials as well as using innovative research approaches and techniques." A complete listing of all ODS co-funded grants from 1996 through 2005 can be found at http://dietary-supplements.info.nih.gov/Funding/Grants_Contracts.aspx.

Botanical Research Center Program

Beginning in 1999, ODS collaborated with other NIH entities to fund six Dietary Supplement Research Centers focused on botanicals at academic research institutions across the United States. These Centers are a direct result of a Congressional mandate for the ODS to establish a botanical research initiative, reflecting the recognition that botanicals are widely used as dietary supplements, though the research base is inadequate to determine the roles they may play in health care.

Collectively, the Centers identify and characterize botanicals, assess their bioavailability and bioactivity, explore mechanisms of action, conduct preclinical and clinical evaluations, help select botanicals to be tested in clinical trials, and provide a rich environment for training

and career development. Six centers are currently being funded, each one with a different focus (see the sidebar on page 4).

ODS nutritionist and epidemiologist Christine Swanson, PhD, RD is the Program Director for the Botanical Research Centers. "There's no doubt that the centers are advancing the scientific base of knowledge of botanicals, including issues of their safety, efficacy, and biological action," she notes. More information about the NIH Botanical Research Center Program is available at http://dietary-supplements.info.nih.gov/Research/Dietary_Supplement_Research_Centers.aspx.

Analytical Methods and Reference Materials

An estimated 40,000 to 50,000 dietary supplements are available to consumers. The growth of this market, however, has outstripped the ability of scientists to develop reliable analytical methods that can verify the identity of ingredients and measure the amounts of various constituents present in raw materials and finished products. In 2002, Congress called on the NIH to speed up efforts to develop and disseminate validated analytical

methods and reference materials for the most commonly used botanical and other dietary supplements.

In response, ODS convened two meetings in 2002 with representatives of the supplement industry, the contract analytical laboratories industry, government, and other interested organizations and consumers to develop and support innovative and coordinated responses to the task. The early stages of this initiative involved locating and collating sources of existing information, identifying potential collaborators, and building the infrastructure for developing and validating analytical methods and reference materials for dietary supplements (see the sidebar on page 4). ODS has established contracts or co-funding arrangements with AOAC International, the National Institute of Standards and Technology (NIST), the U.S. Department of Agriculture (USDA), and NIH's National Heart, Lung, and Blood Institute (NHLBI).

ODS pharmacognosist Joseph M. Betz, PhD directs the Analytical Methods and Reference Materials Program. "Our efforts in this area, which we are now

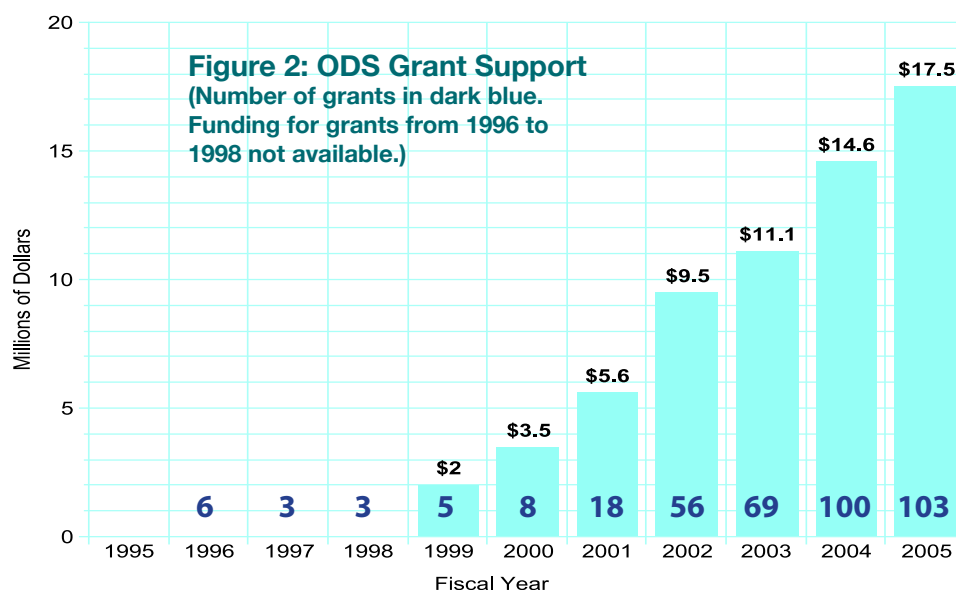


Figure 2: ODS Grant Support
(Number of grants in dark blue.
Funding for grants from 1996 to
1998 not available.)

Interests of the Botanical Centers

University of Illinois at Chicago

Botanicals with potential benefits for women's health, particularly therapies for the symptoms of menopause.

Purdue University and the University of Alabama at Birmingham

Polyphenol-rich botanicals and their implications for diseases of aging such as heart disease, osteoporosis, cognitive decline, and cataracts.

Iowa State University and the University of Iowa

Plant compounds that have activity in modulating immunity and preventing viral infection as well as preventing inflammation and cellular proliferation.

Pennington Biomedical Research Center, Louisiana State University

Botanicals that may influence molecular, cellular, and physiological mechanisms to prevent or reverse the development of insulin resistance and metabolic syndrome.

Wake Forest University and Harvard University

Investigation of the biological mechanisms and clinical applications of botanical sources of polyunsaturated fatty acids that may have benefits in the prevention and treatment of inflammatory diseases such as atherosclerosis and asthma.

Memorial Sloan Kettering Cancer Center

Botanicals with immunomodulatory activities (such as echinacea, astragalus, turmeric, and several herbs used in Traditional Chinese Medicine) relevant to the treatment of cancer and infectious diseases.

formally evaluating, should help restore confidence in label claims," he notes. More information about the program is available at http://dietary-supplements.info.nih.gov/Research/Analytical_Methods_and_Reference_Materials_Program.aspx.

Evidence-Based Reviews

In FY 2001, Congress encouraged ODS to review the current scientific evidence on the efficacy and safety of dietary supplements and identify research needs. ODS responded by developing an evidence-based review program using the Evidence-Based Practice Centers established by the Agency for Healthcare Research and Quality (AHRQ) to conduct

systematic reviews of the scientific literature and prepare reports of their findings.

A number of these reviews have been conducted. A review of the safety and efficacy of ephedra-containing dietary supplements for weight loss and performance enhancement was used by FDA in its decision in 2004 to ban these products from the marketplace. A series of reviews on the health benefits of omega-3 fatty acids was published in 2004 and 2005, addressing their effects on various body systems and conditions such as eye health, child and maternal health, cardiovascular disease, stroke, asthma,

Analyze and Verify

Methods and/or reference materials are being developed and validated for

- Ephedra
- Aristolochic acid
- Ginkgo
- St. John's wort
- Saw palmetto
- A standard multivitamin-mineral supplement

and type 2 diabetes. Other reviews are in progress (see the sidebar on this page).

Anne L. Thurn, PhD, who directs the Evidence-Based Review Program, notes that "the goal of the program is to produce evidence-based reviews that will assist the NIH institutes to develop research agendas." More information about

Evidence Reviews in Progress

- Vitamin D and bone health
- B-vitamins and antioxidant phytochemicals from berries in relation to neurodegenerative conditions such as Alzheimer's and Parkinson's diseases
- Role of multivitamin/multimineral supplements in the prevention of chronic disease (to be released in conjunction with a state-of-the-science conference on this topic to be held at the NIH on May 15-17)

the program, including the published reports, are available at http://dietary-supplements.info.nih.gov/Research/Evidence-Based_Review_Program.aspx#reportsinprogress.

Conferences

Over the past 10 years, ODS has planned, organized, and/or supported more than 100 conferences, workshops, and symposia on dietary supplements, usually with the collaboration of other units within NIH, other governmental agencies, and professional organizations. These programs typically bring together scientists from various disciplines to provide an overview of a topic, assess new and emerging research areas, and identify gaps in research and/or directions for future research. In many cases, proceedings are published in the peer-reviewed literature.

ODS's first sponsored workshop, held March 18-20, 1996, evaluated determinants of copper needs across the lifespan, with proceedings published as a supplement to the May 1998 *American Journal of Clinical Nutrition*. As for conferences to come, ODS is co-sponsoring a State-of-the-Science Conference on multivitamin/mineral supplements and chronic disease prevention, which will be convened by the Office of Medical Applications of Research (OMAR) on May 15-17, 2006. A complete listing of ODS conferences from 1996-2006 is available at <http://dietary-supplements.info.nih.gov/News/News.aspx>.

Training and Career Development

ODS has consistently worked to create opportunities for dietary-supplement and nutrition-research training and career development by utilizing the existing systems within the NIH intramural and extramural programs. See the sidebar on this page for several examples.

Examples of Career Training

- Support of 5 young scientists at NIH conducting dietary supplement research at the predoctoral and postdoctoral levels
- Support of 3 postdoctoral fellows at NIST and 3 postdoctoral candidates at USDA
- 14 trainees supported at 6 Botanical Research Centers
- Institutional training grants support individuals at:
 - Baylor College of Medicine
 - Cornell University
 - Harvard University
 - Tulane University
 - University of Alabama at Birmingham
 - University of Missouri
- Young Investigator Travel Awards enable students to attend and participate in major conferences and symposia convened by ODS

Mary Frances Picciano, PhD, a Senior Nutrition Research Scientist at ODS, directs the training and career development program. "We hope to expand the number of well-qualified researchers who undertake investigations on dietary supplements," she notes, "with particular emphasis on young investigators, minorities, and women." More detailed information about this program is available at <http://dietary-supplements.info.nih.gov/Research/Training.aspx>.

Information Resources

A primary goal of ODS is to provide information about dietary supplements to its various audiences, ranging from academic researchers who might wish to know what studies have been published on ginkgo, for example, to an individual wanting an objective overview of whether valerian might help with insomnia. Such information is provided in several ways.

IBIDS Database

The International Bibliographic Information on Dietary Supplements (IBIDS) database provides access to scientific citations and abstracts on dietary supplements from more than 3,200 journals and over 50 consumer publications. ODS began work with USDA in 1996 to develop this database in response to a direct mandate in the 1994 DSHEA law. Easy to use and now more consumer friendly, it boasts almost 1 million citations and is periodically updated. Reference citations can be emailed and/or downloaded into an EndNote reference program.

Deputy Director Rebecca B. Costello, PhD, directs the IBIDS project. Further information about the program and the actual database are available at http://dietary-supplements.info.nih.gov/Health_Information/IBIDS.aspx.

CARDS Database

Computer Access to Research on Dietary Supplements (CARDS) is an online database of federally funded research projects pertaining to supplements. Online and publicly available since October 2001 from the ODS website, it, like IBIDS, was developed in response to the 1994 DSHEA law. Currently, CARDS provides information on research funded by NIH, USDA, and the U.S. Department of Defense beginning with FY 1999. Each

record, for example, notes the specific dietary supplement or ingredient being studied, health outcome, and research methodology being used.

Nutritionist Karen S. Regan, MS, RD, who directs the CARDS project, notes that "CARDS was designed to be user friendly and is updated regularly." Further information about the program and the actual database are available at http://dietary-supplements.info.nih.gov/Research/CARDS_Database.aspx.

ODS Website

The databases described above and much more are available on the ODS web site (<http://dietary-supplements.info.nih.gov/index.aspx>). It was developed shortly after ODS was established as an effective, inexpensive method for communication, providing information of interest to a broad spectrum of individuals, including scientists, healthcare professionals, industry members, educators, policymakers, the media, and public. The number of visits to the site continues to grow each year, from about 22,000 per month in 2000 to 210,000 in 2005. Individuals may also subscribe to the ODS listserv to receive occasional email messages about significant changes to the ODS web site and other news from ODS.

Fact Sheets

Fact sheets provide scientifically credible and useful summaries of the current knowledge on selected vitamin, mineral, botanical, and other supplements that can help people to make thoughtful decisions about using these products. Many of them are prepared by ODS with various partners and reviewers and follow a similar outline of topics. In addition, ODS provides links to summary documents of various supplements authored by other NIH and government offices. ODS continues to prepare new fact sheets, update existing ones, and plans to prepare more consumer-friendly summaries of them in

the future. The complete listing and links to dietary supplement fact sheets can be found at http://dietary-supplements.info.nih.gov/Health_Information/Information_About_Individual_Dietary_Supplements.aspx.

Annual Bibliography of Significant Advances in Dietary Supplement Research

Since 1999, ODS has published an annual bibliography with abstracts of exemplary research papers that increase our understanding of the biology, chemistry, safety, and efficacy of dietary supplements. It is intended to highlight how knowledge of these products and dietary ingredients is advanced through quality research. Each year, a panel of experts chooses approximately 25 published articles to highlight and summarize. More than 20,000 copies of the six bibliographies published to date have been distributed to health professionals, industry groups, the media, and others. Copies of the 1999-2004 editions can be downloaded at http://dietary-supplements.info.nih.gov/Research/Annual_Bibliographies.aspx.

Other Activities

Here is a sampling of other programs and projects that occupy the ODS staff:

Dietary Supplement Databases

In July 2001, ODS sponsored a workshop to assess dietary supplement use and the potential need for a national database of supplements. ODS has begun initiatives that will ultimately lead to the development of a database providing the composition of dietary supplements taken from labels and/or derived from analytical chemical data. Collaborating agencies include the Agricultural Research Service at USDA, the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC), and NIST. Senior Nutrition Scientist Johanna T. Dwyer, DSc coordinates these initiatives

Other ODS Publications

- **Office of Dietary Supplements Update**

A periodic newsletter (of which this is the most recent issue) that announces fact sheets, publications, databases, exhibits, conferences, workshops, and symposia of the office as well as feature stories on timely projects and initiatives. All issues are available at http://dietary-supplements.info.nih.gov/News/ODS_Update.aspx

- **What Dietary Supplements Are You Taking? It Matters and Here's Why**

Together with the FDA, ODS developed this consumer brochure to share with your health professional (or doctor). It can be downloaded at <http://ods.od.nih.gov/pubs/partnersbrochure.asp>

- **How to Evaluate Health Information on the Internet: Questions and Answers**

Another consumer-directed ODS publication available at <http://ods.od.nih.gov/EvaluatingHealthInfo>

and notes that "ultimately, the data will be integrated with food composition databases so that the daily nutrient intakes of individuals from both foods and supplements can be determined with greater precision."

Online Analysis Tool

An accurate, easy-to-use, web-based analysis tool is being developed that will enable users to determine nutrient intakes from foods and supplements by various population groups and their related biomarkers. Based on data derived from the National Health and Nutrition Examination Surveys (NHANES), the pilot phase focuses on folate and vitamin B12 and will be online later in 2006.

Expanding International Focus

ODS recognizes that involvement in international food- and nutrition-related initiatives provides unique opportunities for scientific investigation and allows for the sharing of expertise and scientific capacity building. For example, ODS is collaborating with other NIH units to co-fund research grants to better understand the impact of zinc malnutrition on infant growth and cognitive performance as well as the role of probiotics in maintaining infant health and reducing risk for diarrheal disease.

To aid the building of scientific capacity in developing countries, ODS works with NIH's Fogarty International Center, through the Global Research Initiative Program, to provide funding opportunities for career development of foreign investigators to advance critical issues in global health, including the role of dietary supplements. To facilitate the use of sound science in the development of international nutrition reference values, ODS co-funded (with several other national states) a recent

workshop sponsored by the World Health Organization and the Food and Agriculture Organization (WHO/FAO) of the United Nations to develop an internationally-relevant model for establishing upper levels of intake for nutrients and related substances.

According to Senior Nutrition Research Scientist Elizabeth A. Yetley, PhD, "Our international activities are a win-win for both ODS and for the countries with which we are collaborating. ODS benefits by being able to better understand diet and health/disease relationships through access to populations with widely varying dietary patterns and nutritional status. At the same time, our international partners benefit from our direct funding of in-country research projects, the sponsoring of training for their most promising scientists, and our sharing of expertise and experiences in using scientific knowledge to promote population-based public health programs."

Assessing the Health Effects of Bioactive Food Components

ODS has participated in an ad-hoc government working group to define bioactive components in food and explore approaches to evaluating their significance in health promotion and disease prevention. This cross-agency effort led to two public meetings in 2005 to address the challenges of defining and identifying bioactives in foods, to review existing approaches and techniques for evaluating their health effects, and

to identify other study approaches and techniques that might aid research in this area.

Improving Outreach Efforts

ODS is in the process of evaluating its communications and information programs to better meet their goals, which are to increase the range of ODS information products available to all constituent groups, enhance awareness of ODS and its mission, and to establish ODS as a source of accurate and credible information on dietary supplements. An assessment prepared last year by the Aspen Systems Corporation will serve as a basis for improving the ways ODS communicates and provides information to its stakeholders.

The Future

During these first ten years of ODS's life, scientific knowledge about, use of, and interest in dietary supplements and their influence on maintaining health and reducing disease risks has grown substantially. ODS Director Paul Coates pledges that "implementing the mission of ODS—to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public—will continue to be the basis for ODS programs and activities as the office addresses the challenges and opportunities over the next ten years and beyond."

ODS – Current Staff

Scientific and Professional Staff

Paul M. Coates, PhD; *Director*

Rebecca B. Costello, PhD; *Deputy Director*

Richard A. Bailen, MBA, MHA; *Senior Program Analyst*

Joseph M. Betz, PhD; *Director, Dietary Supplements Methods and Reference Materials Program*

Johanna T. Dwyer, DSc, RD; *Senior Nutrition Scientist*

Mary Frances Picciano, PhD; *Senior Nutrition Research Scientist*

Karen S. Regan, MS, RD; *Nutritionist*

Christine Swanson, PhD, RD; *Director, Dietary Supplements Research Centers Program*

Anne L. Thurn, PhD; *Director, Evidence-Based Review Program*

Elizabeth A. Yetley, PhD; *Senior Nutrition Research Scientist*

Donna F. Allen, *Office Manager*

Leslie Johnson, *Program Assistant*

Scientific Staff Consultants

Kenneth D. Fisher, PhD; *Senior Scientific Consultant*

Leila Saldanha, PhD, RD; *Scientific Consultant*

Paul R. Thomas, EdD, RD; *Scientific Consultant*

Staff Consultants

Judith M. Chamot, MS, RD; *Coordinator, Technical Projects*

Carol Haggans, MS; *Scientific and Health Communications Consultant*

Christopher J. Hinkle; *Information Technology Specialist*

Amy Mobley, MS, RD; *Health Communications Assistant*

Sheryl Rosenthal, MSPH, RD; *Health Communications Specialist*

Edwina Wambogo, MS; *Research Assistant*

Since its inception, ODS has used dozens of contractors to augment the staff as science writers, copy editors, meeting coordinators, and scientific consultants. It has benefited from the advice and counsel of hundreds of professionals who have helped to draft scientific documents, peer review research proposals and manuscripts, and assist in program development and evaluation.