OFFICE OF DIETARY SUPPLEMENTS

National Institutes of Health

BACKGROUND PAPER

for

STRATEGIC PLANNING: 2004-2009

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

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Department of Health and Human Services

Preface

The following information about the research, educational, and related programs of the Office of Dietary Supplements (ODS) was compiled by ODS staff. The document summarizes what ODS has initiated in the past 5 years based on the guidance provided by the stakeholder communities as identified in the first ODS Five-Year Strategic Plan.

The purpose of this background paper is twofold: to bring together brief summaries of what the ODS has accomplished from its origin in 1995 to 2003 and to set the stage for identifying the research opportunities and needs that ODS should explore in the next 5 years. It is intended to stimulate discussion and comment from the wide range of interested parties that constitute the ODS stakeholder community. The background paper is available publicly and is posted on the ODS web site.

Research, education, communication, and related opportunities and needs that ODS should consider in its strategic plan for 2004–2009 will be the subject of a public meeting to be held at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland, on May 8–9, 2003. Persons wishing to attend this planning meeting are invited to register on the ODS web site. There is no registration fee. However, because of space limitations, registration must be received by April 25, 2003.

Persons who are unable to attend the meeting are encouraged to contact ODS at http://ods.od.nih.gov for further information on the strategic planning process. All interested parties are invited to submit suggestions and comments on aspects of the original Five-Year Strategic Plan that need further attention. In addition, ODS is interested in identifying other topics and areas with opportunities and needs related to research and education on as well as communication about the efficacy and safety of dietary supplements. E-mail submissions should be directed to ODSplan@od.nih.gov.

ODS will consider all written submissions and comments as well as discussions at the stakeholder meeting on the development of the draft Second Five-Year ODS Strategic Plan. Contributors and participants will receive the draft plan for additional comment. Development of the strategic planning process and this background paper by ODS has been assisted by a steering group composed of representatives of several institutes and centers of the National Institutes of Health as well as other federal agencies (see Appendix A). Based on input to the review of the draft strategic plan, ODS, with the assistance of the steering group, will finalize and publish its Second Five-Year ODS Strategic Plan in late 2003.

Paul M. Coates, Ph.D., Director
Office of Dietary Supplements, NIH

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Introduction

DSHEA and the Organization of the Office of Dietary Supplements

In November 1994, Congress passed Public Law 103-417, the Dietary Supplement Health and Education Act (DSHEA). This bill amended the Food, Drug, and Cosmetic Act and focused on further defining aspects of that law relating to the definition, regulation, and labeling of dietary supplements. DSHEA included authorization for the creation of the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) and a Presidential Commission on Dietary Supplement Labels.

In DSHEA, Congress stated specific activities or mandates for the ODS, including

- 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 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 related to dietary supplements.

ODS was formally established on November 27, 1995 within the Office of Disease Prevention, Office of the Director, NIH. The overall mission of NIH is "… to uncover new knowledge that will lead to better health for everyone." NIH works toward that mission by "… conducting and supporting research, helping to train research investigators; and fostering communication of biomedical information." ODS embraces the NIH mission with particular reference to the possible role of dietary supplements in better health for everyone.

1995–1998 Activities

In early 1995, the NIH Associate Director for Disease Prevention met with representatives of professional, scientific, and trade organizations interested in dietary supplements to determine the state of scientific knowledge on substances, ingredients, and preparations considered to be dietary supplements. Discussions were also held on approaches to developing the several dietary databases on these topics that were mandated by DSHEA.

ODS began formal operations in November 1995 with the appointment of the first director, Bernadette M. Marriott, Ph.D. In setting up the ODS, Dr. Marriott met with NIH institute and center (IC) directors to present the purposes and possible activities of ODS and to identify areas of common interest. She also enlarged the dialogue with representatives of the scientific community, industry, other agencies of the federal government, and the public in an effort to enlist their cooperation in the future development of ODS. These efforts led to a description of

the ODS mission and to a Five Year Strategic Plan for implementation of that mission (*Merging Quality Science with Supplement Research*. NIH Publ. No. 99-4356. September 1999, http://ods.od.nih.gov/showpage.aspx?pageid=69#plan).

One of the first steps of the strategic planning process was the development of a statement describing the ODS mission.

ODS Mission: 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.

1998 Status Report and Strategic Plan

Because the mandate for and establishment of ODS in DSHEA represented a departure for NIH, the scope of activities undertaken in 1995–1998 were summarized in a status report, *The First Years of the Office of Dietary Supplements 1995-1998* (NIH Publ. No.99-4383. May 1999, http://ods.od.nih.gov/showpage.aspx?pageid=69#status).

The status report reviewed the history of how and why ODS was established by Congress, identified the pertinent sections of DSHEA that relate to what ODS was to accomplish within the context of DHHS and NIH, explained the methods and mechanisms used by ODS in conduct of its activities, and briefly described the progress made in the first 3 years of its existence.

The ODS Strategic Plan had three major components: foundation, methods, and scientific goals:

Three sets of statements were the foundation for the ODS Strategic Plan:

- The Congressional mandates were set forth by the 103rd Congress. This section presents the Congressional mandates in the context of ODS as an office of NIH within DHHS.
- The term *dietary supplements* was defined by DSHEA, and the activities of ODS are guided by this definition.
- The ODS mission statement succinctly stated the purpose and mandates of ODS.

Throughout its first several years of operation, ODS used five general methods to conduct its activities:

- *Operating principles* described the underlying approaches of all ODS activities, such as emphasis on supporting the highest quality science in regard to conducting research and in communicating research findings to the public.
- *Criteria* defined what ODS used to evaluate competing scientific priorities; for example, relevance to the ODS mission and funding of the highest quality of research.
- *Types of activities* outlined the approaches ODS used to accomplish its goals; for example, through research support, research dissemination, partnering programs, and education.

- *Emerging science* described how ODS identified and promoted new or developing scientific topics of merit.
- *Plan evaluation process* outlined ways in which ODS would review its progress toward meeting the five scientific goals.

Scientific Goals

The ODS Strategic Plan identified five equally weighted scientific goals and within each goal, several proposed objectives. Each scientific goal was considered a pivotal role for ODS and the objectives were specific scientific areas where the participants in the strategic planning process suggested research priorities for the next 3–5 years. ODS has focused its efforts on the five scientific goals and many of the objectives within each (see Appendix B for the complete list).

The Strategic Plan Scientific Goals

- 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.

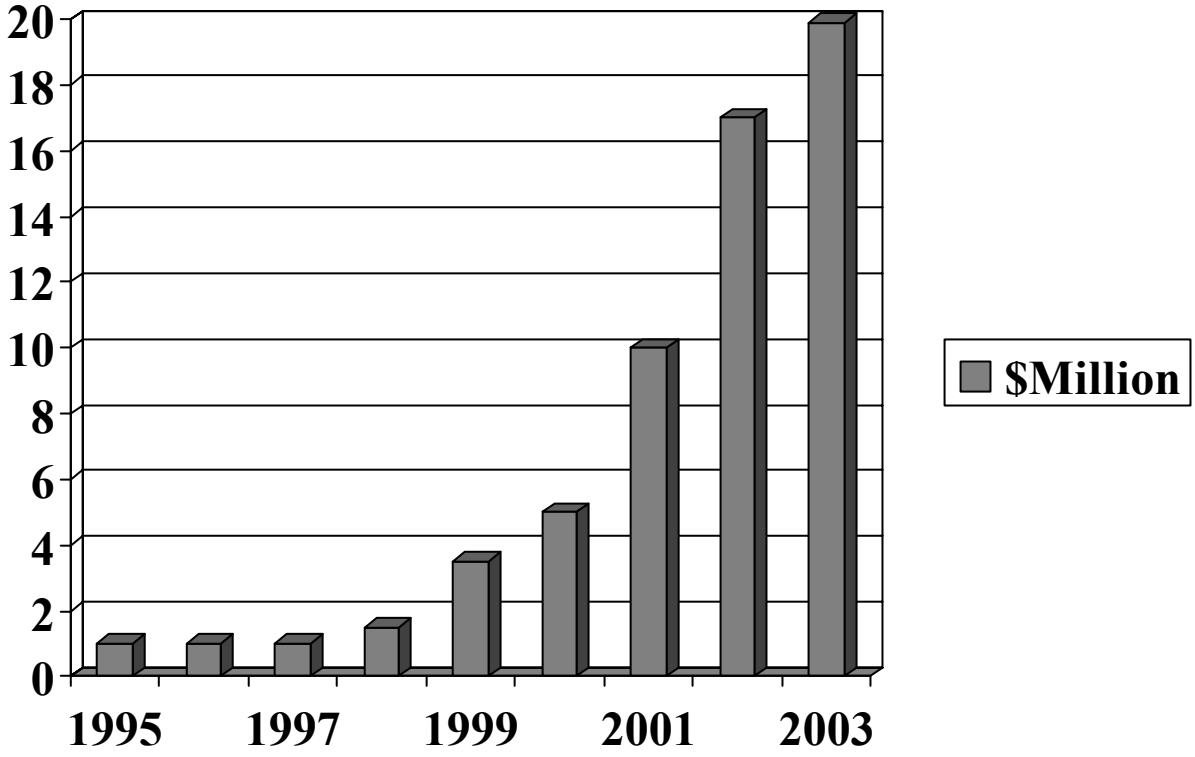
ODS Resources in Support of the Strategic Plan Scientific Goals

Since its modest beginnings in 1995 with the appointment of the director and employment of temporary staff, ODS has grown as programs have been initiated and developed. By 2003, ODS had seven full-time senior scientific and two full-time support staff federal government employees as well as seven persons and organizations under contract.

In addition to the director and deputy director, each of the five senior scientific staff manages one or more of the ODS programs. Since its inception, ODS has used 22 part-time and full-time individual and organizational contractors to augment the staff. Appointed for specific duties, contract personnel have served in several roles such as science writers, copy editors, meeting coordinators, and scientific consultants. In addition, ODS has benefited from the advice and counsel of over 300 professionals who have assisted in the drafting of scientific documents, peer review of research proposals and manuscripts, as well as program development and evaluation.

The trend of fiscal support for programmatic efforts of ODS from 1995 to 2003 is shown in **Figure 1.**

Figure 1. Trend of fiscal support for ODS.



Programs and Activities: 1998–2003

Research Support and Related Activities

Botanical Research Centers

ODS currently supports Botanical Research Centers for Dietary Supplement Research in collaboration with the National Center for Complementary and Alternative Medicine (NCCAM) and the National Institute of Environmental Health Sciences (NIEHS), with additional support from the National Institute of General Medical Sciences (NIGMS) and the Office of Research on Women's Health (ORWH). The centers program marked an important milestone for ODS, being the first major research effort initiated and coordinated by ODS.

The Botanical Research Centers are the direct result of a Congressional mandate for the ODS "to establish a botanical research initiative with major research institutions in the United States." The Congressional directive, in large part, reflected recognition that botanicals were becoming widely used as dietary supplements but their role in health and health care was difficult to evaluate because the research base was inadequate.

After meeting with representatives of the NIH ICs, a request for applications (RFA) was announced to the research community. Applicants were required to propose multidisciplinary centers with specific core activities as well as research projects ranging from basic to clinical research. A fully integrated center was required to develop the capacity to 1) identify, characterize, and authenticate botanicals; 2) assess the bioavailability and bioactivity of botanical ingredients; 3) identify active constituents of botanicals and explore their mechanisms of action; 4) conduct both preclinical and clinical evaluation of botanicals; and 5) serve as an information resource for the public. The formation of multidisciplinary teams to perform the research of this initiative was also an essential requirement of each applicant.

Applicants were also required to have a designated organizational structure that included an administrative and planning core headed by the center director. An independent advisory committee was established within the administrative core to provide scientific oversight and to advise the Center Director. Each center also included a research resource core to provide shared resources (e.g., botany or plant science facilities and analytical chemistry laboratories) that would enhance productivity or in other ways benefit investigators working to accomplish common research goals of the center.

Since 1999, six grant awards have been made, with funding provided by ODS, NCCAM, NIEHS, NIGMS, and ORWH. (See Appendix C for a synopsis of activities of the Botanical Research Centers.) In addition to providing scientific input and funding, NCCAM and NIEHS provide grants management oversight of the centers.

An expert panel has evaluated the Botanical Centers Program in 2003. The evaluation was conducted to determine whether the research centers have successfully advanced the mission of ODS and also contributed to the research goals of NCCAM and NIEHS. The panel was asked to

consider scientific productivity, efficiency of the existing organizational structure, and whether current funding mechanisms are appropriate. The evaluation will be used to guide the development of the next RFA or program announcement (PA) supporting multidisciplinary research on botanicals.

Summary: ODS is meeting the Congressional mandate to encourage and support NIH-funded research on botanicals. The centers contribute to each of the five scientific goals of the first ODS Strategic Plan. Congress allocated funds sufficient to fund three centers. Six institutions received grant awards as a result of substantial support from other NIH ICs, particularly NCCAM and NIEHS. An expert panel was convened in early 2003 to assist in the evaluation of the Botanical Research Center. The evaluation will be used to guide the development of the next announcement to fund existing or new botanical centers.

Other Research Support

As an office in the Office of the NIH Director, ODS does not have the authority to fund investigator-initiated research grant applications directly. However, ODS supports investigator-initiated research projects by means of funding awards, interagency agreements, and contracts in collaboration with NIH ICs.

Since 1996, ODS has participated in the NIH Research Enhancement Awards Program (REAP). This is a mechanism by which investigator-initiated grant applications are received and reviewed through the standard NIH peer review process. Meritorious applications that are outside an IC's funding resources but within the research interests of participating offices in the Office of the NIH Director can be nominated by ICs to receive funding by these offices. REAP is coordinated by the NIH ORWH. From 1996 to 2002, ODS, in conjunction with several NIH institutes has provided funding or cofunding for 24 REAP studies to explore the potential role of dietary supplements in health promotion and disease prevention.

As the budget for ODS has increased, so have the opportunities for funding research grants and contracts with the ICs. For example, in fiscal year (FY) 2002 ODS was able to cofund 54 research projects in conjunction with 18 ICs (see Appendix D). This number includes applications awarded in response to REAP. The data in Appendix D indicate several aspects of the ODS efforts to encourage a wide diversity of research and training. Examination of the project titles provides a perspective of the range of the research topics supported. Similarly, the data show that ODS has been able to cofund research and training needs of mutual interest to 21 NIH ICs and other federal agencies. This ability to cofund such a diverse array of important research studies has substantially increased the visibility of ODS and made it an effective partner for NIH ICs.

Another way in which ODS has collaborated with ICs is in the cosponsorship on research initiatives, such as RFAs, PAs, and requests for proposals. Since 1998, ODS has participated in 14 NIH RFAs and PAs associated with the possible roles of dietary supplements in health promotion and disease prevention (see Appendix E). A significant number of these RFAs and PAs have resulted from workshops and conferences jointly sponsored by ODS and ICs (see

Appendix F). Similarly, ODS engages in interagency agreements with other federal agencies in meeting their research goals (see Appendix D). Examination of the topics of the several RFAs, PAs, and interagency agreements reveals a broad range of investigative topics of mutual interest to both the funding ICs and agencies and ODS.

Summary: Since its formation, ODS has used various existing NIH mechanisms to encourage investigator-initiated research. In many cases, ODS has provided incremental support for ongoing research projects of mutual interest to ICs and ODS. In other instances, promising topics of investigation or preliminary studies of interest have received funding. By this means, investigators have had opportunities to obtain further data and seek multiyear research support from NIH or other agencies. These approaches have added to the efforts of ODS to stimulate research related to the five goals of the original strategic plan.

Evidence-based Reviews

In language supporting the ODS budget appropriation for FY 2001, Congress encouraged ODS, in consultation with NCCAM, the Agency for Healthcare Research and Quality (AHRQ), and the Food and Drug Administration to review the current scientific evidence on the safety and efficacy of dietary supplement ingredients now on the market. This review could then form a basis for further research. ODS responded by developing an evidence-based review program, using the AHRQ Evidence-Based Practice Center (EPC) program to conduct systematic reviews of the scientific literature. ODS will use these reviews to help NIH establish research agendas for dietary supplements.

The Senate also noted that the number of Americans taking dietary supplements containing ephedra has risen dramatically and encouraged ODS to enhance support for clinical research on the safety and efficacy of the products. As the starting point for this task, ODS and NCCAM commissioned an evidence-based report on the safety and efficacy of ephedra using AHRQ's EPC program. Originally scheduled to be completed at the end of summer 2002, results of the preliminary review of the report and the availability of additional data required additional effort on the part of the EPC. The final report was completed recently. Information about the report is available through the AHRQ web site (http://www.ahrq.gov) and a summary of the report has been published (JAMA 298:1537-1570). ODS and NCCAM organized an ad hoc working group of experts in the field to provide NIH with options for future research on ephedra. The working group used the ephedra report as one of its resources for its recommendations to NIH.

In Senate report language supporting the ODS FY 2002 appropriation, ODS was urged to begin work on a major assessment of the health benefits of omega-3 fatty acid consumption. To begin this task, in late October 2002 ODS commissioned an evidence-based review on the health benefits of omega-3 fatty acids through the AHRQ EPC program.

ODS is working with eight NIH institutes (National Heart, Lung, and Blood Institute, National Cancer Institute [NCI], National Institute of Mental Health, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Allergy and Infectious Disease, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health

and Development, and National Eye Institute) to develop a set of questions on the relationship between omega-3 fatty acids consumption and cardiovascular disease, cancer, child and maternal health, asthma, gastrointestinal conditions, renal conditions, transplantation, autoimmune disorders, eye diseases, neurological disorders, and mental health. The report will address a broad range of questions on these topics. Upon completion of the report, a working group will be convened to provide NIH with options for research on omega-3 fatty acids.

To select topics for future reviews, ODS is developing a process for NIH ICs to nominate topics for ODS-sponsored evidence-based reviews. ODS will establish a review board to prioritize the nominations. Nominations must include both the rationale and supporting evidence on the clinical relevance and importance of the topic. In addition, the nomination must identify how the nominating organization will incorporate the report into its research agenda.

The following criteria will be used by ODS in determining approval of nominations for evidence-based reviews:

- Knowledge from existing science of the risks and benefits, including controversies or uncertainties, about the effectiveness or safety.
- Availability of scientific data to support the systematic review and analysis of the topic in regard to 1) effect on prevalence, incidence, and mortality of a condition or disease; 2) potential to improve safety outcomes of a condition, disease; 3) potential to improve consumer, patient, or provider decision making; 4) availability of research resources or organizations to address the results of the topic review; 5) whether the topic is already being addressed by ongoing NIH research programs; 6) Congressional interest; and 7) consumer interest.

AHRQ has completed several evidence-based reports that are available on the AHRQ web site (http://ahrq.gov/clinic/epcix.htm).

Summary: By establishing an evidence-based review program, ODS has met the Congressional mandate to review current scientific evidence on the safety and efficacy of dietary supplements. The program also forms a basis for further research and education of practitioners and consumers. The evidence-based review program contributes to Goals 1, 2, and 5 of the original ODS Strategic Plan. A review of the scientific evidence related to the safety and efficacy of ephedra for weight loss and athletic performance enhancement was completed in early 2003. It will support the development of an NIH research agenda on ephedra. An evidence-based review on the health effects of omega-3-fatty acids has been initiated and will be completed in October 2004. A series of reports will evaluate the health effects of omega-3-fatty acids in a variety of conditions. NIH will use the findings of this review to determine future research on omega-3-fatty acids.

Conferences and Workshops

The ODS plans, organizes, and supports conferences, workshops, and symposia on scientific topics related to dietary supplements. These are designed to identify research opportunities and needs as well as stimulate investigation. Although such activities can be initiated by ODS alone, most are initiated in collaboration with NIH ICs, other government agencies, and professional and scientific organizations because of the underlying mutual interests concerning the scientific issues. Since its inception, ODS has sponsored over 100 such scientific meetings on various topics that have not only been focused on research promotion and dissemination but also responsive to the broad scope of the ODS mission.

A complete list of the workshops and conferences that ODS has organized or cofunded and their outcomes is given in Appendix F. ODS has used support of conferences and workshops not only to identify specific research needs and opportunities for existing or new NIH and other agency programs, but also to stimulate investigators to develop research proposals of interest to potential sponsoring organizations. One significant outcome of several workshops and conferences has been the development of a number of RFAs and PAs on topics of mutual interest to various ICs and ODS (see Appendix E).

Conference and workshop topics have been both diverse and far-reaching in terms of basic and applied research issues of mutual interest to both ODS and other funding ICs and agencies. Some topics have concerned research needs and opportunities more closely associated with specific populations. For example, beginning in 2001, ODS has participated in sponsoring a series of conferences examining issues related to the use of dietary supplements throughout the lifespan, (e.g., children, women, and the elderly).

Summary: Initiation and cofunding of conferences and workshops has been a useful mechanism to stimulate not only the awareness of the need for research on dietary supplements among investigators but also the development of programs for research support among both public and private sector sources that fund research.

Information Resources

Databases

CARDS

Computer Access to Research on Dietary Supplements (CARDS) is an online database of federally funded research projects pertaining to dietary supplements. CARDS was developed in response to a congressional mandate to compile a database of scientific research on dietary supplements and individual nutrients. This mandate was part of DSHEA. The information in CARDS is useful to Congress, agencies of the federal government, and the NIH ICs for budgetary considerations. In addition, CARDS provides useful information for researchers, health care providers, industry, and the general public.

At the start of the CARDS development process, ODS staff discussed the database project with the NIH ICs, including the National Institute of Diabetes and Digestive and Kidney Diseases, which includes the NIH Nutrition Coordinating Committee. This committee is charged with the maintenance of the Human Nutrition Research and Information Management (HNRIM) system. This resource is a federal government-wide, online database created for fiscal accounting, management, and control of cross-agency nutrition research activities. In FY 1999, two new nutrition classification codes were added to HNRIM to identify first-time research related to dietary supplements. With the addition of these new codes, HNRIM provided a readily accessible source of information that could be used to populate the CARDS database.

Because the CARDS database has a more narrow focus than the HNRIM system, CARDS provides greater detail for each research project. For example, CARDS identifies the specific dietary supplement or ingredient being studied. CARDS also identifies the health outcome and research methodology being used.

CARDS has been online and available to the public since October 2001 from the ODS web site (http://ods.od.nih.gov/databases/cards.html). Since its release, CARDS has consistently been one of the top 10 web pages accessed from the ODS web site, averaging about 1000 visits per month. The initial CARDS release contained projects funded by the NIH ICs during FY 1999, the first year that NIH ICs began reporting research related to dietary supplements through the HNRIM database. Regular updates to CARDS will be completed to add projects funded in subsequent years and by other federal agencies. Projects funded during FY 2000 were added to CARDS in 2002 and those from 2001 were added in early 2003. ODS will post notices on its web site and listserv as CARDS updates are completed.

The CARDS search screen is designed to be user friendly to allow individuals at all levels of computer expertise to quickly and effectively search the database. The main CARDS search screen allows users to enter a variety of search criteria to find research projects of interest. In addition to the search boxes containing lists of terms, search boxes for fields such as Project ID or Researcher allow users to search for specific projects by typing a partial or full project ID or researcher name. Text search options are also available to search for words contained in the abstract or title of a research project.

Codes assigned to each research project allow the CARDS user to identify

- research related to specific dietary supplement ingredients (e.g., vitamin E or St. John's wort),
- type of study (e.g., a Phase III clinical trial or an animal study),
- health outcomes or biological effects (e.g., osteoporosis or antioxidant function), and
- whether the research is directly related or indirectly related to dietary supplements (e.g., a clinical trial comparing bone density in women given a daily calcium supplement versus a placebo would be classified as directly related to dietary supplements; conversely, a study examining the mechanisms of enzyme-catalyzed reactions of thiamin would be classified as indirectly related to dietary supplements because the research pertains to thiamin but is not directly examining the effects of thiamin supplementation).

A search of the CARDS database can be used to identify, sort, and tabulate information for a variety of purposes. For example, a researcher may want to know which NIH ICs fund research on herbal supplement ingredients. A consumer may want to know whether the federal government is supporting research on a popular dietary supplement ingredient such as vitamin C. Anticipating that a wide variety of dietary supplement ingredients eventually will be studied, the list of substances was intentionally designed to be extensive. As a consequence of developing an inclusive ingredient list, some searches of the current CARDS database will not return any research projects.

Summary: The development of the CARDS database is a component of the ODS effort to meet the Congressional mandate to compile a database of scientific research on dietary supplements and individual nutrients. The CARDS database contributes to Goal 5 of the original ODS Strategic Plan. CARDS has been online and available to the public since October 2001. It currently contains research project data from FYs 1999, 2000, and 2001. During 2003 and subsequent years, the CARDS database will be enhanced to improve its utility to all users. For example, research grants will be linked with subsequent publications from the investigations.

IBIDS

One of the activities mandated by DSHEA is to "collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine" (Public Law 103-417, Section 13.[a]). ODS completed a database that addresses this mandated activity in 1998. This database, International Bibliographic Information on Dietary Supplements (IBIDS), is designed specifically to assist both researchers and the general public in locating scientific literature on dietary supplements.

Available to the public via the ODS web site (http://ods.od.nih.gov/databases/ibids.html), IBIDS is a database of published, peer-reviewed, international, scientific literature on dietary supplements. IBIDS allows the user to search transparently multiple existing sources including peer-reviewed journal publications from major medical, botanical, agricultural, chemical, and pharmaceutical databases. IBIDS was developed and is maintained in collaboration with the Food and Nutrition Information Center (FNIC) of the National Agricultural Library, United States Department of Agriculture (USDA).

ODS initiated an interagency agreement with USDA in FY 1996 to develop the database. The first phase included the published, peer-reviewed, international, scientific literature on dietary supplements from 1986 to 2001. To validate the peer-reviewed status of journals for the first phase of IBIDS, the FNIC staff used ULRICH's *International Periodicals Directory*. This directory lists journals that have indicated they are peer-reviewed.

The IBIDS team developed a search strategy to identify the appropriate scientific literature for the IBIDS database (see IBIDS background on the ODS web site for details). Because of copyright and database vendor restrictions, IBIDS was initially launched with contents from three databases: AGRIS International, AGRICOLA, and MEDLINE. Citations from CAB

international have been added since then and discussions are ongoing with additional database vendors. IBIDS is updated quarterly with new citations and abstracts. In addition, new search terms are being added continually to reflect emerging areas in dietary supplement research.

The search interface was designed to be user-friendly so that users with all levels of expertise can quickly search the database; an easy-to-use keyword list is available. ODS staff work closely with FNIC staff to ensure that IBIDS and CARDS have similar formats and a similar thesaurus. The information available to the user depends on the availability of information from the original databases and the copyright policies of each journal. Since its release, IBIDS has consistently been one of the top five web pages accessed from the ODS web site, averaging about 10,000 visits per month.

Summary: With IBIDS, ODS has met its DSHEA mandate to compile and make available a database of scientific literature on dietary supplements. IBIDS supports Goal 5 of the original ODS Strategic Plan. The database continues to grow through the inclusion of relevant citations on a quarterly basis and through continued addition of new and unique journal collections.

ODS Web Site

The ODS web site (http://ods.od.nih.gov) was developed shortly after ODS was established in order to provide an effective and inexpensive method for widespread communication. The primary goal during its development was to ensure that information of interest would be provided to a broad spectrum of individuals, including scientists, health care professionals, industry members, educators, policy makers, the media, and the general public. Traffic on the ODS web site continues to grow each year. Between 2000 and 2002, the number of visits increased by 50% from about 22,000 to 33,000 per month.

The ODS web site provides information about ODS, including its origins, mandates, mission statement, and strategic plan. It also provides access to ODS databases, fact sheets and publications, current funding opportunities, conferences and workshops, and news releases as well as other activities, programs, and scientific resources. Links are provided to web sites providing relevant information on dietary supplements, including sites at NIH and other federal agencies, dietary supplement–related databases, scientific and professional organizations, trade associations, and other sites of interest.

A listserv was developed in 2000 to provide current information about ODS to interested parties. Individuals who subscribe to the listserv receive an e-mail message from ODS approximately monthly notifying them of significant changes to the ODS web site and other news from ODS. Listserv notices contain information such as the availability of new fact sheets on dietary supplements, updates to ODS databases, information about upcoming workshops and conferences, announcements of funding opportunities, and availability of proceedings or presentations from previously held conferences. The ODS listserv currently has over 4800 subscribers.

To keep pace with available web technology, the ODS web site is undergoing a major redesign. During this effort, the web site will be modified to reorganize content; improve navigation; enhance its appearance; provide printer-friendly pages where appropriate; and ensure compliance with Section 508 requirements, a federal ruling on electronic and information technology accessibility standards. The web site is continually updated and redesigned to enhance user friendliness.

Summary: The ODS web site provides an effective and cost-effective method for widespread communication. It contributes to Goal 5 of the original ODS Strategic Plan. The ODS web site is updated regularly to provide current information about ODS and its activities. A listserv supplies over 4800 subscribers with an additional means of communication at no cost. A redesign of the ODS web site will be completed in early 2003 and is expected to enhance its utility to all users.

Fact Sheets

As one mechanism to achieve Goal 5 of the ODS Strategic Plan, the fact sheet project provides scientifically credible and publicly useful fact sheets that summarize the current knowledge on selected vitamin, mineral, and botanical supplements. Each fact sheet contains information on the supplement: sources, composition, and availability; administration and dosages; data from scientific study of use and safety; and health issues and concerns (if any). Each fact sheet has a summary and pertinent references. Health professionals and consumers need information they can trust to help make thoughtful decisions about using vitamin, mineral, and botanical supplements. The purpose of the fact sheets is to provide accurate information to help make those decisions.

To date several fact sheets have been prepared on vitamins and minerals. Registered dietitians at the Warren Grant Magnuson Clinical Center at NIH developed these fact sheets in conjunction with ODS. Each vitamin and mineral fact sheet in this series has undergone extensive scientific review by recognized experts from the academic and research communities. The information has also been reviewed for scientific accuracy and for consistency with the Dietary Guidelines for Americans by the Nutrition Education Subcommittee of the NIH Nutrition Coordinating Committee, the USDA Dietary Guidance Working Group, and the DHHS Nutrition Policy Board Committee on Dietary Guidance.

Initially, a total of 12 fact sheets on vitamins and minerals were planned. Fact sheets on magnesium, selenium, iron, and zinc and vitamins A, D, E, B-6, and B-12 and folic acid are currently available. Fact sheets on vitamins K and C and calcium are expected to be available in 2003. Planned fact sheets on chromium and copper will bring the number of web accessible fact sheets to 15.

ODS, in collaboration with NCCAM, is developing fact sheets on 10 commonly used botanical dietary supplements. Each fact sheet will present a summary of information on the use and safety of a botanical. Written for health professionals, botanical fact sheets are meant to help readers make health care decisions for their patients. Experts in the field prepare drafts that are reviewed

by ODS and other experts for accuracy, consistency, and scientific objectivity. The first of the series, on black cohosh, was released in October 2002; additional fact sheets will be available publicly in 2003. ODS is also developing an electronic glossary that will provide hypertext links from technical terms in the fact sheets to their definitions.

ODS recognizes that for fact sheets to be meaningful, they must be updated regularly to reflect emerging science. The fact sheets are available at the ODS web site (http://dietary-supplements.info.nih.gov/), NIH Clinical Center web site (http://www.cc.nih.gov/supplements/intro.html), and NCCAM web site (http://nccam.nih.gov).

Summary: ODS fact sheets are an effort to meet the mandate of Goal 5 of the original ODS Strategic Plan. The rigorously peer-reviewed series is designed to disseminate accurate current scientific information to the public.

Annual Bibliography of Significant Advances

In 1999, ODS and the Consumer Healthcare Products Association implemented a program to publish an annual bibliography of scientific papers of significance to the understanding of biology, chemistry, safety, and efficacy of dietary supplements. The bibliography is intended to help develop an overall perspective on how knowledge of dietary supplements is advancing through quality research. A secondary goal is to provide peer recognition to investigators whose work is cited in the bibliography.

To this end, peer-reviewed journal editors are asked to nominate articles of original work published in their respective journals dealing with dietary supplements or dietary supplement ingredients. Submitted articles are forwarded to a panel of experts who evaluate each article with regard to clarity of presentation, appropriateness of methodology, validity of results, accuracy of conclusions, and overall importance to furthering our understanding of dietary supplements. Reviewers are asked to score each article, and the 25 with highest overall scores constitute the Annual Bibliography of Significance Advances in Dietary Supplement Research.

Since its inception in 1999, approximately 6000 copies of the bibliography have been distributed annually to health professionals; the media; and scientific, legislative, regulatory, and consumer organizations. Copies of the 1999, 2000, and 2001 bibliographies can be downloaded from both the ODS and Consumer Healthcare Products Association web sites.

Summary: The Annual Bibliography of Scientific Advances is primarily a contribution to Goal 5 of the original ODS Strategic Plan. In addition, it contributes to efforts of ODS to disseminate research conducted under Goals 1 and 2 of the original strategic plan.

Dietary Supplement Use and Surveys

In theory, dietary supplements supply amounts of dietary constituents that may not be adequate in foods that are consumed or offer a health benefit when consumed in quantities greater than those normally provided by diets. The ODS in collaboration with other NIH ICs supports research that focuses on developing a knowledge base from which public health recommendations about use of particular dietary supplements may be made. In many cases, the research involves diet interventions, dietary supplement interventions, or both. However, it is frequently difficult to interpret experimental results when intake of targeted constituents is from both foods and dietary supplements. For example, in studies of dietary intake, intake of nutrients from dietary supplements may far exceed amounts furnished from the diet alone. Similarly, in dietary supplement studies, the nutrient contribution of the diet itself may overwhelm any possible enhancement of intake from supplements. ODS has undertaken a series of initiatives that will lead to the development of a dietary supplement database capable of being merged with the food composition database for tabulation of nutrient and other bioactive dietary components.

In July 2001, ODS sponsored a workshop on the assessment of dietary supplement use and the potential need for a national database of dietary supplements. Participants included domestic and international researchers, members of the dietary supplement industry, and government officials. A summary of the meeting is posted on the ODS web site (http://dietary-supplements.info.nih.gov/conferences/Dietary_Supplement_Use_Summary.html).

In June 2002, ODS and USDA cosponsored a workshop entitled, "Future Directions for What We Eat in America–NHANES: The Integrated CSFII-NHANES." The workshop was designed to bring together representatives of the major stakeholder communities including federal agencies involved in research, surveillance and policy, academia, and others involved in the management and use of the dietary aspects of the survey. Current survey methodology, data needs, and the analyses required to capture usual dietary intake from both foods and dietary supplements was covered. The proceedings of this workshop appeared in the *Journal of Nutrition* in 2003 and are available via the ODS web site. One of the significant recommendations made by the participants was that a comprehensive database system for foods and dietary supplements should be developed and maintained; each part of the system should be built on a foundation of analytical chemical data that can be integrated so that a complete estimate of daily intakes of nutrients and other substances of interest in both foods and dietary supplements can be achieved.

The National Center for Health Statistics of the National Centers for Disease Control and Prevention (CDC) has developed and maintains a database for dietary supplements based on label information. This database is used to tabulate intakes of dietary supplements by subjects enrolled in the National Health and Nutrition Examination Survey (NHANES). Since FY 2001 ODS has supported this activity. Efforts are underway to consider how to validate this database by analysis.

The nutrient databank for foods is maintained by USDA; its analytical data are continually reviewed and evaluated. ODS and USDA signed an interagency agreement in 2003 for the development of a dietary supplement database analogous to the USDA nutrient databank for foods. The supplements to be included first in the database are those reported to be taken most

often by NHANES respondents as well as those included in clinical trials funded by NIH. ODS also supports the National Food and Nutrition Analysis Program for phytochemicals and methods development.

ODS has entered into an interagency agreement with CDC to fund the addition of three questions to the National Physical Activity and Weight Loss Survey of its Behavioral Risk Factor Surveillance System to assess the use of dietary supplements for weight loss.

ODS is funding the collection of various biomarkers (folate and vitamins B-6, B-12, and D) in the continuous NHANES to assess whether and to what extent dietary supplements may be furnishing these nutrients of potential public health significance to vulnerable populations.

Summary: ODS has developed and supported initiatives to promote collection of data on patterns of dietary supplement usage by the U.S. population and its subsets. Data on use based on demographic, economic, and other related characteristics are critical to the understanding of the roles that dietary supplement usage has in health maintenance and disease prevention and in their influence on physical and mental health as well as physical performance. These efforts contribute to stimulation of research as specified in Goals 1, 2, and 3 of the original ODS Strategic Plan. More importantly, these initiatives contribute to the objectives of Goal 4.

Methods and Reference Materials

The rapid post-DSHEA expansion of the dietary supplement marketplace has resulted in a proliferation of ingredients and products that has outstripped the pace of development of reliable analytical methods for verifying ingredient identity and for measuring the amounts of declared ingredients in raw materials and finished products. To accelerate the rate of methods development and validation, in its FY 2002 appropriation to NIH, Congress called for "…ODS to allocate sufficient funds to speed up an ongoing collaborative effort to develop and disseminate validated analytical methods and reference materials for the most commonly used botanicals and other dietary supplements." (Senate Report 107-84-Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill). Senate Report comments in the FY 2003 budget states that the Appropriation Committee expects ODS to allocate sufficient funds to continue this initiative.

Responding to the Congressional mandate, ODS held two meetings in 2002. The meetings included representatives of the supplement industry (manufacturers, suppliers, and trade associations), the contract analytical laboratories industry, regulatory and other governmental entities, nongovernmental organizations, and consumers. Attendees at the first meeting strongly supported the program and recommended that the program pay attention to basic quality issues such as botanical identification and determination of contaminants; accept the recommendations of the Association of Official Analytical Chemists, International (AOAC) Dietary Supplements Task Group for prioritization of ingredients for methods development (http://www.aoac.org/pubs/storyarchives/botanicals.htm); and accept the role of existing organizations as a framework for methods validation.

The discussion at the second meeting reiterated the recommendations made at the previous meeting and focused on analytical methods selection as well as policy issues such as costs of methods selection, validation process costs, and public and media credibility. The AOAC "ring testing" approach was proposed for selecting the methods to be submitted for AOAC validation. Technical discussions emphasized the need for methods for identification and analysis of raw materials with a focus on the top 20-25 herbs in commerce. Participants recognized the tension between the need for uniform public methods and in-house proprietary methods and agreed that a potential solution would involve a consensus process for methods selection involving both experts and stakeholders.

Participants also cited numerous methods for identifying and measuring some constituents of certain supplements but noted that for some ingredients no generally accepted published analytical methods meet the criteria of being sufficiently rugged, accurate, and precise. At present, there are no universally acceptable and appropriately validated AOAC Official Methods of Analysis for botanical ingredients and very few highly characterized reference materials. Thus, even if methods are available, the means to routinely evaluate whether methods are performing as expected do not exist. Participants concluded that timely output is essential; the program should reward innovation; qualitative methods (e.g., fingerprinting) for establishing and documenting plant identity are important; and efforts to define appropriate phytochemical markers and underlying mechanisms of action are also critically important.

Part of the reason for deficiencies in the scientific basis of supplement quality is a lack of basic information (and access to information) on the ingredients themselves. Highly technical solutions to complex analytical issues may be useless in the absence of an infrastructure for simple botanical identification. The early stages of the ODS collaborative program involve locating and collating sources of information and identifying potential collaborators as well as building the infrastructure for development and validation of analytical methods and reference materials. As the infrastructure becomes available, the pace of solicitation of research proposals for reference material and analytical methods development and validation will accelerate. Specific provisions of the solicitations will require that the methods be suitable for submission to the AOAC Official Methods Program and that they be so submitted.

ODS has also funded several research initiatives. The first is a collaboration between ODS and the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN), to cofund a contract with AOAC to validate analytical methods for determination of ephedrine-type alkaloids and aristolochic acid in supplements. The contract calls for development and validation of a liquid chromatography–mass spectrometry method and a high-performance–non-mass spectrometry method for ephedra analysis. ODS and FDA extended and broadened the scope of the AOAC contract to expedite methods approval and to offer formal training on requirements for conduct of in-house validation. The contract calls for validation of 20 additional methods via the collaborative study process under the extended contract.

The second initiative was to cofund with CFSAN an interagency agreement with the National Institute of Standards and Technology (NIST) that calls for production of an *Ephedra sinica* standard reference material, a reference material for an *Ephedra* extract used as a raw material in the manufacture of ephedra products, and two ephedra finished product reference materials. The

agreement with NIST has been expanded for an additional 5 years to develop reference materials for other botanicals, including St. John's wort, ginkgo, and saw palmetto.

In a third project, ODS is providing supplemental funds to an interagency agreement between USDA's Food Composition Laboratory and the NIH's National Heart, Lung and Blood Institute entitled "A Research Resource Laboratory for Food Composition Methodology." The funds for FY 2002 through FY 2005 are to be used to facilitate development and validation of analytical methods for determination of selected flavonoids.

Two nonlaboratory projects have been initiated that are intended to expand the infrastructure for supplement quality evaluation. The first includes funding for investigating the feasibility of developing a virtual herbarium that will provide on-line access to digital images of the collections of a number of academic herbaria. The second provides support to the American Herbal Pharmacopoeia for publication of a practical handbook on microscopic evaluation of herbs in commerce.

Summary: The Methods and Reference Materials Program is based on results and issues raised by recent ODS research efforts as well as increased support for ODS. It focuses directly on the central purpose of Goal 4 of the 1998 ODS Strategic Plan. The program is a broad-based approach supporting the technical and scientific aspects of analytical methods development through critical laboratory research as well as building the infrastructure necessary for scientific evaluation and wide dissemination of new methods and reference materials. The information collection and collation component will ensure that vital techniques and knowledge accumulated over the past century are readily accessible publicly. The initial efforts of the program, the increased support by Congress, and the continuing dialogue with the stakeholder community have resulted in recognition of complex issues and logical goals that can be attained by collaborative efforts. Continued expansion of this program is anticipated as emerging science identifies new needs and opportunities.

Training and Career Development Activities

The purpose of the ODS training and career development efforts is to create opportunities for dietary supplement and nutrition research training and career development using existing systems within both the NIH intramural and extramural programs.

Intramural Activities

Within the intramural programs of the several NIH ICs, research scientists serve as research mentors for aspiring young scientists both at the predoctoral and postdoctoral levels. In cooperation with investigators in the NIH intramural programs engaged in nutrition or dietary supplement research or in areas of interest to ODS, ODS has supported three young scientists in the National Institute of Child Health and Development, National Eye Institute, and National Institute of Diabetes and Digestive and Kidney Diseases. Their studies include, respectively, research on the role of dietary supplements in the metabolic regulation of body weight; in proliferative retinopathy and ocular inflammation using animal models; and on flavonoid intake,

glucose tolerance, and vitamin C bioavailability and the role of supplemental vitamin C in cancer treatment and in maintaining adequate intakes in disease such as diabetes, pregnancy, and sickle cell anemia.

Extramural Activities

NIH supports training programs at academic centers throughout the country. These extramural programs include opportunities for research training and career development across most scientific and medical disciplines. By partnering with the ICs and supporting targeted additional slots in existing programs, ODS has supported three extramural programs in nutrition and dietary supplement research.

At Harvard University an ODS research training grant provides for the education and training of a pediatric gastroenterology and nutrition fellow who is investigating mechanisms by which omega-3 fatty acids, nucleotides, and glutamine affect the gastrointestinal tract by providing protection against the immature infant's excessive gastrointestinal response to colonizing bacteria.

ODS provides a training and career development supplement to the NIH-funded Botanical Centers. Currently, 11 trainees are being supported by this effort. The possibility of providing supplemental funding of training and career development to two additional Botanical Centers is being explored.

In collaboration with the National Institute of Child Health and Development and ORWH, ODS cofunds the career development award program entitled "Building Interdisciplinary Research Careers in Women's Health (BIRCWH)." ODS provides funds for a BIRWCH award at Tulane University that supports a research career development program of junior faculty members (Interdisciplinary Women's Health Research Scholars) who have recently completed clinical or postdoctoral training and are initiating independent research programs relevant to women's health.

Other ODS activities in support of training and career development include participation in ongoing NIH programs:

- Young Investigator Travel Awards, which enhance participation and provide hands-on learning opportunities for trainees in nutrition and dietary supplement research. To date, about 100 trainees have received travel awards.
- An initiative (Off Campus Interagency Program) that funds training positions at other governmental agencies engaged in collaborative activities to further the ODS mission. Such positions include a postdoctoral fellow at NIST for research on reference material development and a postdoctoral fellow at the USDA Agricultural Research Service for methods development research on bioactive components of foods and dietary supplements.
- The NIH Global Health Research Initiative Program for New Foreign Investigators (GRIP). This program promotes productive reentry of NIH-trained foreign investigators into their home countries as part of a broader program to enhance the scientific research infrastructure in developing countries, stimulate research on a wide

variety of high-priority health-related issues in these countries; and advance NIH efforts to address health issues of global import. ODS is cofunding three research efforts in Brazil, Peoples Republic of China, and Thailand.

- The NIH Extramural Loan Repayment Program for Pediatric Researchers. This NIH-wide program provides a mechanism to encourage and enhance the training of pediatric clinical research investigators, an area where qualified investigators are urgently needed.

Teaching Module: Dietary Supplements

ODS collaborated with NCI in supporting development of a teaching module CD-ROM on dietary supplements that was completed in late 2001. This module consists of approaches to evaluating supplements including information necessary to determine efficacy and safety; use of this information to make informed decisions on supplement use; comparison of regulations governing supplements, foods, and drugs; and common misconceptions about the role of supplements in health and disease and the appropriate basis for nutrient supplementation.

This module is a part of the NCI Cancer Education Grant Program that focuses on development of unique educational approaches to teaching nutrition in medical schools that will have an effect on reducing cancer incidence, morbidity, and mortality. Since 1995 the University of North Carolina has received support under this program to create interactive CD-ROMs for teaching nutrition and nutritional biochemistry to medical students. The program, Nutrition in Medicine (NIM)^{TM}, has prepared nine such modules (http://www.med.unc.edu/nutr/nim/GllyMods.htm). ODS is providing both scientific input and peer review for a 10th module that focuses on sports nutrition.

Summary: To meet a major objective of Goal 5 of the original ODS Strategic Plan, ODS has focused its efforts on using existing NIH intramural and extramural systems and programs for training and career development, especially those for young and emerging research scientists. These involve collaboration with several NIH ICs that have such programs and mutual interests in furthering educational opportunities. ODS supported development of a teaching module on dietary supplements in the NCI Cancer Education Grant Program. More recently, support for training and career development has been added to the ODS Botanical Centers Program and to joint efforts with other federal agencies; in addition, a program of travel grants for young scientists has been initiated. Support for training and career development will be expanded in the future because a larger cadre of qualified research scientists will enhance the research community's ability to meet the basic and clinical research objectives of Goals 1, 2, and 3 of the original ODS Strategic Plan.

Other Activities

ODS has begun to expand its research opportunities to the international arena. Beginning in FY 2001, ODS has participated in the following international initiatives:

- In FY 2001, ODS cosponsored a workshop with the Fogarty International Center in Guatemala to help build research capacity related to food fortification and micronutrient supplementation.
- In FY 2001, ODS worked with the Fogarty International Center and the National Institute of Child Health and Development to develop an NIH position paper on enhancing food fortification and supplementation strategies around the world. The paper was presented at a meeting of a global consortium led by the Bill and Melinda Gates Foundation. The consortium initiated a program called the Global Alliance to Improve Nutrition, now underway with government, nongovernment, and private sector organizations.
- ODS was a charter member of the NIH Subcommittee for International Nutrition Research, a subcommittee of the NIH Nutrition Coordinating Committee. The NIH Coordinating Committee holds quarterly meetings to explore opportunities for research, particularly in micronutrient supplementation in developing countries.
- ODS cofunded the Institute of Medicine's International Food and Nutrition Forum with other agencies within and outside NIH. This forum brings together organizations in both public and private sectors to discuss opportunities for research collaboration in the international nutrition setting.

Future Directions and Opportunities

Introduction

The initial activities of the ODS in 1995 were directed toward informing various stakeholder groups about the existence of the office. Beginning in 1996 ODS focused on developing a strategic plan to meet the Congressional mandates in DSHEA. This 2-year effort involved a comprehensive and coordinated effort to consider the concerns and suggestions of all interested parties as to what the role of ODS should be.

The first ODS Strategic Plan was the result of this activity. It reflects both the Congressional mandates and the collective wisdom of the 129 representatives of the public and private sectors who participated in its development. DSHEA states that the purposes of ODS 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 the scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions."

The ODS Strategic Plan identifies five equally weighted goals (see Appendix B) and each goal represents a pivotal role for ODS. The five goals focus on disease prevention (Goal 1), health maintenance (Goal 2), effects on biological systems effects throughout the life cycle (Goal 3), improvement of scientific methodology for supplement study (Goal 4), and education and information dissemination (Goal 5). Within each of the five goals are more specific objectives for initiation, exploration, promotion, investigation, and facilitation. The concluding paragraphs of the first ODS Strategic Plan identified the need for reevaluation of the goals after 3–5 years as scientific priorities shifted.

ODS has made significant progress toward meeting these scientific and informational strategic goals over the past several years. Scientific knowledge about and interest in dietary supplements and their influence on maintaining health and reducing disease risks has grown substantially during this time. The current reexamination of the ODS goals and objectives was initiated for these reasons and because of substantial increases in the ODS budget over the past 3 years.

A broad range of interested parties significantly influenced the development of the original strategic plan. ODS recognizes the continuing importance of recommendations and guidance that can be provided by the broad community of persons and organizations concerned with the safety and utility of dietary supplements. For this reason, ODS is making a concerted effort to obtain public input into its strategic planning process during the next several months. All comments, suggestions, and recommendations will be considered in the development of the second strategic plan. Thus, the anticipated outcome of this comprehensive evaluation is expected to be the publication of the Second ODS Strategic Plan, which will cover the period 2004–2009. This revised plan for research, information dissemination, and educational programs will allow ODS to focus its efforts appropriately.

Original Goals

The 1996–1998 strategic planning process identified goals that were intentionally weighted equally. All five address aspects of the Congressional mandate in DSHEA. Development of ODS programs since then has been focused on programs that contribute to one or more of these goals. During the past several years both intramural and extramural discussions have identified additional topics that ODS should consider in its research portfolio. ODS has initiated research on several of these topics.

Within the context of scientific interest and progress as well as increased fiscal resources, ODS programs have expanded beyond the specific objectives but always within the original five goals. Therefore, reexamination and assessment of the need or desirability of creating additional goals for the broad range of ODS programs is appropriate.

One of the purposes of the current strategic planning process is to determine whether there is a need or opportunity for additional overarching goals for ODS. As a corollary, are there reasons or justification for modifying the priorities for allocation of resources to the original five goals?

Objectives within ODS Goals

Initially, 33 specific objectives were identified under the five goals (see Appendix B). During the past several years, ODS has attempted to address most the specific objectives. Appendixes D, E, and F document the exploratory workshops and conferences, research grants, database development, educational efforts, and other programs that have addressed a number of the objectives.

A second purpose of the current strategic planning effort is to evaluate the original 33 objectives individually to address the following questions:

- Within the framework of the existing 33 objectives, are there any where current knowledge, opportunities, or needs suggest that additional efforts or changes in priority should be made? If so, documentation and justification should be provided.
- Within the framework of the existing 33 objectives, are there additional aspects of specific topics that should be added? If so, documentation and justification should be provided.
- Beyond the original 33 objectives, are there newly identified needs and opportunities that suggest additional objectives for increased emphasis in ODS programs in the future? If so, documentation and justification should be provided.

Approaches to Meeting ODS Goals and Objectives

Since the establishment of ODS in 1995 and the development of the original strategic plan in 1997–1998, ODS has used a number of approaches to implement its goals and objectives. Many of these methods included existing NIH mechanisms for initiating research, supporting ongoing investigations, and enhancing scientific collaboration.

ODS has used a broad array of accepted scientific means of communication and dissemination of information. For example, the REAP grants enabled investigators to explore promising areas for research. Conferences and workshops brought interested parties together to discuss research needs and opportunities, develop collaboration and cooperation, and generate interest in support of research on the five ODS goals.

Creation of the botanical centers was intended to establish groups of knowledgeable investigators with a series of common purposes to stimulate research on botanical dietary supplements. Similarly, significant emphasis was placed on the development of the ODS web site, several databases, and mechanisms for generation of data on dietary supplement efficacy and safety and on use of supplements.

A third purpose of this current strategic planning effort is to seek comments and suggestions about the various approaches that ODS has used in addressing the goals and objectives of its first strategic plan. For example, among the several approaches used by ODS, should there be greater emphasis on certain ones with regard to support for basic and applied research; communication and information dissemination; databases; and training and career development? Are there additional methods and techniques that ODS should consider in implementing its goals and objectives in the future?

Goals and Objectives for 2004–2009

The fundamental purpose of the current reexamination of the ODS strategic goals and objectives is not only to solicit suggestions on emerging needs and opportunities within the context of the ODS legislative mandate, but also to elicit information on possible reprioritization of existing programs. Scientific knowledge about and interest in dietary supplements and their influence on health and disease has grown significantly in the past several years. Concomitantly, knowledge and techniques of study in many areas of the biomedical sciences are also expanding rapidly. Application of these advances in other fields can lead to exploration, useful research investigations, and increased communication on topics and issues related to the efficacy and safety of dietary supplements.

Request for Comments

Within NIH ICs, advisory committees make recommendations on research and other programs. This is not the case for NIH offices. Therefore, ODS is using this strategic planning process to obtain information, views, and suggestions from concerned persons and organizations directly. ODS will use this information in formulating revisions to its goals and objectives for the next 5 years. The strategic planning process is an open one and suggestions and comments are earnestly solicited from all segments of the public and private sectors. It is hoped that a large number of ODS clients, users, and interested parties will take advantage of this opportunity to submit comments in response to this background paper.

This background paper and information about the strategic planning process are available on the ODS web site. These documents may be copied and freely distributed. In addition, the background paper is available in hard copy from ODS and has been announced in the Federal Register and by news releases.

An open public meeting will be held on May 8–9, 2003 at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland. The meeting will explore needs and opportunities for modifying the existing ODS Strategic Plan and developing the ODS Strategic Plan for 2004–2009. Additional details of this meeting will be posted on the ODS web site (http://ods.od.nih.gov).

Persons wishing to comment directly may respond to the ODS web site or may send comments to ODS via e-mail to ODSplan@od.nih.gov. All comments, suggestions, and other submissions received by June 27, 2003 will be considered in the development of the draft of the ODS Strategic Plan for 2004–2009.

Summary: The overall purpose of this strategic planning effort is to identify both new opportunities and emerging needs for possible incorporation in the ODS programs. To address this purpose, ODS is soliciting comments and suggestions from the stakeholder community on these important issues:

- Is there a need or opportunity for additional overarching goals for ODS? As a corollary, are there reasons or justification for modifying the priorities for allocation of resources to the original five goals?
- Is there a need or opportunity to reexamine the original 33 objectives individually in order to answer the questions, Are there objectives where current knowledge, opportunities, or needs that suggest expanded efforts or changes in priority for study are appropriate? Are there additional aspects of specific topics that should be added? Beyond the original 33 objectives, are there newly identified needs and opportunities that suggest additional objectives for increased emphasis in ODS programs in the future? If so, documentation and justification should be provided.

An additional purpose of this current strategic planning effort is to seek comments and suggestions about the various approaches that ODS has used in addressing the goals of its first strategic plan.

- Among the approaches used by ODS, should there be greater emphasis on certain ones in regard to research support, communication and information dissemination, database development, and training and career development?
- Are there other methods and techniques that ODS should consider in implementing its goals and objectives in the future?

Comments and suggestions on any or all of the above issues as well as others of interest to ODS stakeholders will be appreciated. ODS can only meet its mandated purposes by considering the interests and concerns of all interested parties.

Appendix A
Strategic Planning Steering Group
Office of Dietary Supplements
National Institutes of Health

Members

Paul M. Coates, Ph.D.
Director
National Institutes of Health
Office of Dietary Supplements
Bethesda, MD 20892-7517

Darla Danford, Ph.D.
Nutrition Coordinator
NHLBI/NIH
Bethesda, MD 20892-2480

Joanne Holden, M.S.
Research Leader
Nutrient Data Laboratory
USDA, ARS
Beltsville, MD 20705-2350

Clifford L. Johnson, M.S.P.H.
Director
Division of Health Examination Statistics
National Center for Health Statistics
Hyattsville, MD 20782

Jane F. Kinsel, Ph.D., M.B.A.
Associate Director for Science Policy and Operations
NCCAM/NIH
Bethesda, MD 20892

Barnett S. Kramer, M.D., MPH
Associate Director for Disease Prevention
National Institutes of Health
Bethesda, MD 20892

Michael Ken May, Ph.D.
Director, Nutrient Metabolism Program
NIDDK/NIH
Bethesda, MD 20892

Michael McClure, Ph.D.
Chief, Organs & Systems Toxicology Branch, NIEHS
Research Triangle Park, NC 27709

John Milner, Ph.D.
Chief, Nutritional Science Research Group
National Cancer Institute/NIH
Rockville, MD 20892

Daniel Raiten, Ph.D.
NICHD/Office of Prevention Research and International Programs
National Institutes of Health
Rockville, MD 20853

Susan J. Walker, M.D.
Associate Director for Clinical Affairs
Office of Nutritional Products, Labeling, and Dietary Supplements
CFSAN/Food and Drug Administration
College Park, MD 20740

Alternates

Vicki Burt, M.S. (*for C. Johnson*)
Chief, Planning Branch, NHANES Program
National Center for Health Statistics
Hyattsville, MD 20782

Elizabeth Yetley, Ph.D. (*for S. J. Walker*)
Senior Regulatory Scientist
Office of Science HFS-006
Food and Drug Administration
College Park, MD 20740

ODS Staff

William Harlan, M.D.
Senior Medical Consultant
Office of Dietary Supplements
Chevy Chase, MD 20815-4001

Kenneth D. Fisher, Ph.D.
Senior Scientific Consultant
Office of Dietary Supplements
Phone: 301-435-2920
Fax: 301-480-1845
Email: FisherK@od.nih.gov

Donna F. Allen
Office Manager
Office of Dietary Supplements
Phone: 301-435-2920
Fax: 301-480-1845
Email: Allend@od.nih.gov

Appendix B
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 supplement 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.

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

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

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.

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

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.

- 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 published, peer-reviewed, scientific literature on 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.

Appendix C
Synopsis of Botanical Center Activities

University of Illinois at Chicago (established 1999)
Center for Botanical Dietary Supplements Research
www.uic.edu/pharmacy/research/diet
Principal Investigator: **Norman R. Farnsworth, Ph.D.**

Description: The University of Illinois at Chicago center is studying 11 botanicals and focusing on their possible role in women's health, such as treatment of menopausal symptoms. The center supports an active research-training program in pharmacognosy (the study of natural products, including botanicals). It also provides information on botanicals to consumers and health professionals; educational activities with continuing educationcredits currently include an interactive web site for pharmacists.

University of California, Los Angeles (established 1999)
UCLA Center for Dietary Supplements Research: Botanicals
Center Director: David Heber, M.D., Ph.D

Description: The University of California, Los Angeles center conducts basic and clinical research to explore the potential mechanisms of action of yeast-fermented rice for cholesterol reduction with implications for heart disease prevention. Other research projects include studies of green tea extract and other herbs for inhibition of tumor growth with implications for the prevention and treatment of cancer. As is the case with most centers, this center is comparing the biological effects of isolated active constituents with those of less refined extracts.

University of Missouri (established 1999)
Missouri University for Phytonutrient and Phytochemical Studies
http://www.phyto-research.org
Principal Investigator: Dennis Lubahn, Ph.D.

Description: The University of Missouri center conducts preclinical research to elucidate molecular mechanisms of action of selected phytochemicals. Scientists are exploring the role of phytoestrogens in prostate cancer. Plant estrogens are also being studied to determine the effects of supplementation on immune function. The molecular basis for purported neuroprotective effects of plant polyphenols, including resveratrol from grapes and quercetin in Ginkgo, is being explored. Studies include assessment of both efficacy and safety of botanicals. This center maintains an active collaboration with scientists from the Missouri Botanical Garden.

Purdue University (established 2000)
Botanical Center for Age-Related Diseases
http://www.fn.cfs.purdue.edu/bot
Principal Investigator: Connie M. Weaver, Ph.D.

Description: This center is conducting research on the health effects of polyphenols (a diverse group of chemical components widely distributed in plants), many of which are consumed both for their nutritive value and medicinal properties. Examples include soy, grapes, green tea, and several herbs. The health-promoting effects of polyphenols are generally attributed to their antioxidant action, but other biological mechanisms may be involved and are being explored. Soy isoflavones, for example, function as phytoestrogens that may play a role in bone metabolism. The research agenda of the center is clinically relevant to heart disease and cancer as well as osteoporosis and cognitive decline with aging. The Purdue researchers collaborate closely with investigators at the University of Alabama at Birmingham.

University of Arizona (established 2000)
Arizona Center for Phytomedicine Research
www.acprx.pharmacy.arizona.edu
Principal Investigator: Barbara N. Timmermann, Ph.D.

Description: This center's activities are focused on three botanicals (ginger, turmeric, and boswellia) widely used in Ayurvedic medicine for inflammatory diseases. Ayurveda, a medical system primarily practiced in India over the past 5000 years, includes diet and herbal remedies while emphasizing the body, mind, and spirit in disease prevention and treatment. Researchers at this center seek to identify the active constituents of these three herbs and study their pharmacological activity. This research will lead to clinical studies of arthritis and other chronic inflammatory conditions, including respiratory diseases such as asthma.

Iowa State University (established 2002)
Iowa Center for Dietary Supplement Research: Botanicals
Principal Investigator: Diane Birt, Ph.D.
Description: The Iowa center was recently established and will focus on two widely used botanicals, echinacea and St. John's wort. Center investigators propose to identify the active constituents of each and determine the factors (genetic, growth, environmental, and harvest) that influence quantity and quality of bioactive constituents. They are particularly interested in identifying plant compounds that modulate immunity, prevent viral infection, or prevent inflammation and cellular proliferation.

Appendix D
Cofunded Grants, Contracts, and Interagency Agreements: FY 2002

Co-Funding IC[1]	Project Title	Principal Investigator	Institution
FIC	Omega-3 Fats, Immune Functions, and Behavioral Disorders	Thienprasert, A.	Silpakorn Univ, Thailand
FIC	Biomarkers for Detection of Bladder Cancer	Ribeiro-Filho, L.A.	Univ of Sao Paulo, Brazil
FIC	China Childhood Obesity Survey	Du, S.	Chinese Ctr for Dis Cont Prev, China
NCCAM	UCLA Center for Dietary Supplement Research: Botanicals	Heber, D.	Univ of California Los Angeles
NCCAM	Training Grant Supplement	Heber, D.	Univ of California Los Angeles
NCCAM	Botanical Dietary Supplements for Women's Health	Farnsworth, N.	Univ of Illinois at Chicago
NCCAM	Training Grant Supplement	Farnsworth, N.	Univ. of Illinois at Chicago
NCCAM	Arizona Center for Phytomedicine Research	Timmermann, B.	Univ of Arizona
NCCAM	Training Grant Supplement	Timmermann, B.	Univ of Arizona
NCCAM	Botanical Center for Age-Related Diseases	Weaver, C.	Purdue Univ
NCCAM	Training Grant Supplement	Weaver, C.	Purdue Univ
NCCAM	SAMe Treatment of Depression in Parkinson's Disease	DiRocco, A.	Beth Israel Medical Center
NCCAM	Creatine in Amyotrophic Lateral Sclerosis	Rosenfeld, J.	Carolinas Med Center
NCCAM	Long-Term Efficacy and Safety of Atkins Diet	Foster, G.	Univ of Pennsylvania
NCCAM	Comparing Effects of 3 Sources of Garlic on Serum Lipids	Gardner, C.	Stanford Univ
NCCAM	Chromium Enhancement of Insulin Signaling	Brautigan, D. L.	Univ of Virginia
NCCAM	Chromium Analysis and Diabetes	Paul, K. G.	Biophysics Assay Lab, Inc.
NCCAM	Genomic Bioresponse: Quality Control for Botanical Drugs	VanEyndhoven, W.	Phytoceutica, Inc.
NCCAM	A HTS Gene Expression Assay for Screening Nutraceuticals	Olson, M.	Third Wave Technologies
NCI	Biologic Activity of B-Carotene Metabolites	Russell, R.	Tufts Univ
NCI	Mechanism of Tea Catechin's Inhibition of Angiogenesis	Meydani, M.	Tufts Univ
NCI	Computer-Based Nutrition Curriculum	Zeisel, S.	Univ of North Carolina
NHLBI	INTERMAP-Dietary Supplement Substudy	Archer, S.	Northwestern Univ
NEI	Postdoctoral Fellowship Training	SanGiovanni, J.P.	NIH
NIAAA	Molecular Mechanisms of SAMe in Hepatic Stellate Cells	Schrum, L.W.	UNC Charlotte
NIAAA	SAMe, RXR alpha-Mediated Pathways and Alcoholic Liver Disease	Wan, Y.-J. Y.	Harbor-UCLA
NIAAA	Effect of Hepatotoxins and Adomet on Liver Gene Expression	Kruger, W.D.	Fox Chase Cancer Center
NIAAA	SAMe Inhibits Inflammatory-Mediated Enhanced Toxicity	Maddox, J.F.	Michigan State University
NIAAA	Mitochondrial GSH and SAM in ALD	Fernandez-Checa, J.C.	Fundacio Clinic, Spain

Co-funding IC[1]	Project Title	Principal Investigator	Institution
NIAAA	Mitochondrial rRNA Methylation and Effects of Ethanol/SAMe	Cahill, A.	Thomas Jefferson University
NIA	Supplemental B-Vitamin Atherosclerosis Intervention Trial	Hodis, H.	Univ of Southern California
NIA	Melatonin Enhancement of Elderly Blind Free-Runners	Lewy, A. J.	Univ of Oregon
NICHD	Youth Environment for Promoting Nutrition and Activity	Dzewaltowski, D.	Kansas State Univ
NICHD	Postdoctoral Fellowship Training	Parikh, S.	NIH
NICHD	Tulane BIRCWH	Welton, P.K.	Tulane University
NIDA	Anabolic Androgenic Steroid Effects on Brain and Behavior	McGinnis, M. Y.	Mt. Sinai School of Medicine
NIDCR	N-3 Fatty Acids and Host Responses to Oral Infection	Kesavalu, L.	Univ of Kentucky
NIDCR	Folate Receptors in Craniofacial Malformations	Finnell, R. H.	Texas A & M Univ
NIDDK	Alternative Therapies for Benign Prostatic Symptoms: Clinical Trial	Andriole, G.L.	Washington Univ St. Louis
NIDDK	Alternative Therapies for Benign Prostatic Symptoms: Clinical Trial	Kreder, K.J.	University of Iowa
NIDDK	Alternative Therapies for Benign Prostatic Symptoms: Clinical Trial	Naslund, M.J.	University of Maryland
NIDDK	Alternative Therapies for Benign Prostatic Symptoms: Clinical Trial	Dixon, C.M.	New York University
NIDDK	Alternative Therapies for Benign Prostatic Symptoms: Clinical Trial	Avins, A.L.	Kaiser Foundation Research Institute
NIDDK	Homocysteine Lowering in Renal Transplant Patients	Bostom, A. G.	Mem Hosp of RI
NIDDK	Magnesium and Sickle Cell Disease	Brugnara, C.	Children's Hospital, Boston
NIDDK	Pediatric GI/Nutrition Training	Walker, W. A.	Harvard Univ
NIDDK	Elucidating the Biochemistry of Chromium III	Vincent, J.	University of Alabama
NIDDK	Pinitol in Human Nutrition	Ostlund, R.	Washington Univ
NIDDK	Measurement of Folate in Fortified Cereal Grain Products	Selhub, J.	Tufts Univ
NIDDK	Antiobesity Mechanism of CLA Isomer in Human Adipocytes	McIntosh, M.	Univ of N Carolina Greensboro
NIEHS	Center for Research on Botanical Dietary Supplements	Birt, D. F.	Iowa State Univ
NIGMS	Analysis of Phenolic Phytochemicals	Brodbelt, J.	Univ of Texas at Austin
NIGMS	Regulation of Cellular Zinc Distribution	Maret, W.	Harvard Univ
NIMH	Pharmacotherapy for Minor Depression	Nierenberg, A. A.	Massachusetts General Hosp
NIMH	Pharmacotherapy for Minor Depression	Howland, R. H.	Univ of Pittsburgh
NIMH	Pharmacotherapy for Minor Depression	Rapaport, M. H.	Veteran's Admin San Diego
NIMH	St. John's Wort and CYP3A Metabolism	Frye, R. F.	Univ of Pittsburgh
OD/NIH	Loan Repayment Program: Training and Career Development	Weber, W.	Bastyr Univ
	Botanical Pharmacognosy & Microscopic Characterization	Upton, R.	American Herbal Pharmacopoeia
	National Inventory of Plant Authentication Resources	Flaster, T.	Botanical Liaisons

Co-funding Agency[1]	Title	Contact	Organization
FDA	AOAC International Analytical Methods Validation Program	Smith, M.	CFSAN
CDC	NHANES Dietary Supplement Data Collection and Biochemical Measures	Johnson, C.	NCHS
CDC	Surveillance of Physical Activity/Weight Control	Blanck, H.	NCCDPHP/DNPA
AHRQ	Evidence-Based Review Program	Besteman, J.	CPTA
Commerce	Standard Reference Materials Development	Wise, S.	NIST
Commerce	Postdoctoral Training in Reference Materials	Wise, S.	NIST
USDA	Development of a Dietary Supplement Ingredient Database	Holden, J.	ARS
USDA	National Food and Nutrient Analysis Program: Phytochemicals	Holden, J.	ARS
USDA	National Food and Nutrient Analysis Program: Methods Development	Harnly, J.	ARS
USDA	Development and Maintenance of IBIDS Database	Frierson, E.	NAL
DEA	Guinea Pig Study for the Evaluation and Testing of Steroids	Tolliver, J.	
NICHD	International Food and Nutrition Forum	Raiten, D.	IOM
NCCAM	CAM Practices	Straus, S.	IOM

[1] AHRQ, Agency for Healthcare Research and Quality; CDC, Centers for Disease Control and Prevention; Commerce, Department of Commerce; DEA, Drug Enforcement Administration; FDA, Food and Drug Administration; FIC, Fogarty International Center; IC, Institute and Center; NCCAM, National Center for Complementary and Alternative Medicine; NCI, National Cancer Institute; NEI, National Eye Institute; NHLBI, National Heart, Lung, and Blood Institute; NIA, National Institute on Aging; NIAAA, National Institute on Alcohol Abuse and Alcoholism; NICHD, National Institute of Child Health and Development; NIDA, National Institute on Drug Abuse; NIDCR, National Institute of Dental and Craniofacial Research; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; OD/NIH, Office of the Director, National Institutes of Health; USDA, U.S. Department of Agriculture.

Appendix E
ODS Partnerships on RFAs and PAs, 1999–2003[1]

Year		Issuing IC[2]	RFA/PA Title	RFA/PA Number	Date (open/close)
1999	1	NCCAM	Centers for Dietary Supplements Research - Botanicals	RFA-AT-99-007	03/08/99 - 05/13/99
2000	2	NCCAM	Centers for Dietary Supplements Research – Botanicals	RFA-AT-00-004	02/24/00 – 04/25/00
2001	3	NIGMS	Metals in Medicine	PA 01-071	03/19/01 – 06/01/04
	4	NIDDK	The Role of Antioxidants in the Prevention of Diabetic Complications	PA-01-112	06/27/01 – 10/01/04
	5	NCCAM/NIDDK	Chromium as Adjuvant Therapy for Type 2 Diabetes and Impaired Glucose Tolerance	PA-01-114	07/02/01 – 10/01/04
	6	NIDCR	Mechanisms in Nutrition and Infection	PA-01-133	08/29/01 – 09/01/04
	7	ORWH + ICs	Building Interdisciplinary Research Careers in Women's Health	RFA-OD-02-001	12/05/01 – 03/14/02
	8	ORWH + ICs	Pathophysiology and Treatment of Chronic Fatigue Syndrome (CFS)	PA-OD-02-034	12/11/01 – 01/10/05
	9	FIC	Global Health Research Initiative Program for New Foreign Investigators (GRIP)	RFA-TW-02-002	01/29/02 – 04/19/02
2002	10	NIAAA	S-Adenosyl-L-Methionine (SAMe) and Liver Disease	RFA-AA-02-011	01/30/02 – 05/15/02
	11	NIDDK	Alternative Therapies for Benign Prostate Symptoms – CT Consortium	RFA-DK-02-026	01/16/02 – 04/15/02
	12	NCI	Diet, DNA Methylation and other Epigenetic Events, and Cancer Prevention	RFA-CA-03-016	09/27/02 – 03/18/03

	13	NCI	" " competing supplements	PAR-CA-02-175	09/27/02 – 03/19/04
		FIC	Brain Disorders in the Developing World: Research Across the Lifespan	TW-03-007	11/07/02 – 03/11/03
2003					
	14	NCCAM	Cranberry: Urinary Tract Infection and Other Conditions	RFA-AT-03-004	01/30/03 – 04/21/03
	15	OD / Multiple ICs	Ruth L. Kirschstein National Research Service Awards for Individual Postdoctoral Fellows (F32)	PA-03-067	02/06/03 – 02/06

[1] RFA, request for application; PA, program announcement.
[2] FIC, Fogarty International Center; IC, Institute and Center; NCCAM, National Center for Complementary and Alternative Medicine; NIAAA, National Institute on Alcohol Abuse and Alcoholism; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NIGMS, National Institute of General Medical Sciences; OD, Office of the Director; ORWH, Office of Research on Women's Health.

Appendix F
ODS-Supported Workshops and Conferences, 1996–2003

Date	Meeting Topic	ODS Cosponsors[1]	Outcomes
1996			
Mar 17-18	Approach to the Prevention of Orofacial Cleft	NIDCR	Workshop cited in discussion of Use of Folic Acid in Improving Reproductive Outcomes at http://ods.od.nih.gov/news/conferences/folic.html
Mar 18-19	Genetic and Environmental Determinants of Copper Needs Across the Life Span	FIC	Proceedings published: *Am J Clin Nutr* 1998 67:951-1102 or www.ajcn/contents/vol67/issues5/#SUPPLEMENTS.
June 3-4	Workshop: The Role of Dietary Supplements for Physically Active People	11 Institutes & Centers	Proceedings published in *Am J Clin Nutr* 2000; (72): 503S-674S and at http://www.ajcn.org/content/vol72/issue2/#SUPPLEMENTS. Conference program and abstracts at http://ods.od.nih.gov/publications/abstract.html. NLM Bibliography - *The Role of dietary supplements for physically active people: January 1966 through 1996* for the US Dept of Health & Human Services, Public Health Service, NIH, NLM Reference Section and at http://www.nlm.nih.gov/pubs/cbm/dietsup.html.
Aug 12-13	Melatonin and Sleep	NIA	Summary published in *JAMA* 276(13):1011-1014.
Aug 14-16	Melatonin and Aging	NIA	Identified research gaps and opportunities for IC program planning
Sept 8-10	Of What Importance are Phospholipids in Health and Disease?, 7th Annual Conference of Phospholipids in Health and Disease		Identified research gaps and opportunities for OD program planning. Summary at ODS web site http://ods.od.nih.gov/news/conferences/lipids.html
1997			
Jul 29	Identifying The Role of Dietary Supplements in Brain Function - ODS initiated poster workshop		Scientific exchange at the 16th International Congress on Nutrition, Montreal, Quebec Canada.
1998			
Jan 19	Frontiers in Antioxidant Research (in conjunction with ASPEN 22nd Annual Clinical Congress)	NIDDK	Education session

Feb 10	Lutein and Zeaxanthin: Safety and Procedural Issues for Supplementation in Relation to the Development of Macular Degeneration	NEI	Identified research gaps and opportunities for IC program planning
Apr 18	Nutritional Supplements, Botanical Products and Functional Foods		Minisymposium & poster session at Experimental Biology 1998 in San Francisco. Abstracts in *FASEB J* 1998, 12;375-389 or at http://www.fasebj.org/cgi/content/full/12/3/375?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=nutritional+supplements&searchid=1042151287438_1974&stored_search=&FIRSTINDEX=0&volume=12&fdate=1/1/1998&tdate=12/31/1998&journalcode=fasebj#SEC4
May 5-7	The Path to Maternal and Child Health: The PVO Role in Improving Iron and Vitamin A Status	FIC	Scientific exchange
May 18-19	Conference: Nutritional and Health Benefits of Inulin and Oligofructose		Conference Proceedings published in *J Nutr* 1999 July; 129(7)
June 15-19	Human Selenium Deficiency in the Russian Federation & The Problem of Overcoming Selenium Deficiency in the Russian Federation	FIC / NIDDK	Scientific exchange & Identified research gaps and opportunities for IC program planning
Jul 1	Dietary Supplements for Wasting in AIDS related conditions	NIAID / NIDDK	Identified research gaps and opportunities for IC program planning
Aug 1-6	Folic Acid, Vitamin B_{12}, and One Carbon Metabolism	NIDDK	Scientific exchange in conjunction with FASEB sponsored workshop.
Aug 3-4	Metabolic, Endocrine and Gastrointestinal (MEG) Disorders in Drug Abuse and HIV/AIDS	NIDA	Workshop Proceedings published in *J Acquir Immune Defic Syndr Oct* 2000; 25(Suppl 1).
Aug 31-Sep 1	Workshop: Coenzyme Q_{10} and Aging	NIA	Identified research gaps and opportunities for IC program planning
Sept 1-3	Linking Environmental Agents to Autoimmune Diseases	NIEHS	Summary published in *Environ Health Perspect,* Dec 12, 1998 106:A592-A593
Sept 2-3	NIH Workshop on Omega-3 Essential Fatty Acids & Psychiatric Disorders	NIMH	Workshop mentioned in the NIMH 1998 Director's Report to the National Advisory Mental Health Council at http://www.nimh.nih.gov/council/dir998.cfm

Sept 16-17	Factors Influencing the Need for Dietary Supplements for Pregnancy	NICHD	Identified research gaps and opportunities for IC program planning
Sept 23-24	International Workshop to Evaluate Research Needs on the Use and Safety of Medicinal Herbs	NIEHS	Summary published in *Environ Health Perspect* Dec 12, 1998 106: A590-A592
Oct 29-30	Emerging Issues in Microbial Infections and Cardiovascular Disease	NIAID	Identified research gaps and opportunities for IC program planning
Nov 4-5	Scientific Workshop: Zinc and Health: Current Status and Future Directions	6 Institutes & Centers	Proceedings published as a supplement to the *J Nutr*, May 2000 130: 1341S-1519S at http://www.nutrition.org/content/vol130/issue5/#SUPPLEMENT. Proceedings at http://ods.od.nih.gov/publications/abstract_zn_ws.html
Nov 6	Conference: Zinc: What Role Might Supplements Play?	6 Institutes & Centers	Abstract at http://ods.od.nih.gov/publications/abstract_zn_conf.html
1999			
April 7–9	Workshop on the Essentially of and Dietary Reference Intakes (DRIs) for Omega-6 and Omega-3 Fatty Acids	NIAAA	Proceedings published at ODS web site http://ods.od.nih.gov/news/conferences/w6w3_abstracts.html
Apr 14	Nutritional Implications of Cephalic Phase Responses (at Annual meeting of the Association for Chemoreception Sciences)	NIDCD	Symposium proceedings published in *Appetite* April 2000: 34(2) 177-182 and at www.idealibrary.com/servlet/useragent?func=showAllIssues&curIssueID=appe
May 10–12	International Collaborative Research Project on Fluorides: Research Needs	NIDCR	Proceedings published in J. Dent. Res. Special report 79(4) 2000, 893-904.
May 24-25	Workshop: Nutrient Metabolism in the Genetic Anemias and Dietary Supplements of Potential Benefit to Patients with Sickle Cell Disease	NHLBI	Agenda on web:ods.od.nih.gov/news/conferences/sickle.html. Identified research gaps and opportunities for IC program planning
June 3-4	Phytoestrogens and Healthy Aging: Gaps in Knowledge	NIA	Proceedings published in *Menopause* 2001May-June. 8: 157-70 at web site http://www.menopausejournal.com/
July 14-16	Antioxidants: Strategies for Interventions in Aging and Age-Related Diseases	NIA	Summary published in *Antioxid Redox Signal,* Fall 2000 3:375-377

September 13-14	Workshop: Dietary Supplements for People Infected with HIV	NIAID	Identified research gaps and opportunities for IC program planning
September 16-17	Micronutrients and Infectious Diseases: Cellular and Molecular Immunomodulatory Mechanisms	NIAID	Workshop summary on web: http://www.cdc.gov/ncidod/eid/vol6no1/newsnotes.htm#. Proceedings in *J Infect Dis* Sept 2000, (182) Suppl 1.
September 22-23	Workshop: Prevention of Craniofacial Anomalies	NIDCR	Identified research gaps and opportunities for IC program planning
Nov 4	Chromium and Diabetes		Overview at http://ods.od.nih.gov/news/conferences/chromium_diabetes.html. Initiative Chromium as Adjuvant Therapy for Type 2 Diabetes and Impaired Glucose Tolerance released July 2001 PA#: PA-01-114
2000			
January 5-6	Conference / Workshop: Bioavailability of Nutrients and Other Bioactive Components of Dietary Supplements - Defining the Research Agenda		Proceedings in the *J Nutr* April 2001 131(4S): 1329S-1400 S. Also on line at http://www.nutrition.org/content/vol131/issue4/index.shtml
Feb 10-12	Indo-U.S. Workshop on Health and Nutrition of Women, Infants and Children in Hyderabad, India	NICHD	Proceedings published in *Nutr Rev* May 2002, 60:Part 2.
March 2-3	The Efficacy and Safety of Medicinal Herbs	NIEHS	Proceedings published in *Public Health Nutr*, Dec 2000 3(4A) 435-535. Summary at http://ehpnet1.niehs.nih.gov/docs/1998/106-12/niehsnews.html
Mar 20	Essential Fats in Foods	NIAAA	Interactive Workshop & videocast of program at http://ods.od.nih.gov/eicosanoids and at http://videocast.nih.gov/ PastEvents.asp?1
May 30-31	National Nutrition Summit		Summit agenda with content details at http://summit.iqsolutions.com/. Bibliography at http://www.nlm.nih.gov/pubs/cbm/nutritionsummit.html.
June 28-29	Metals in Medicine: Targets, Diagnostics, and Therapeutics	NIGMS	Conference videocasts and proceedings at http://www.nigms.nih.gov/news/meetings/metals.html. Initiative released March 2001 PA#: PA-01-071
September 17-22	Symposium: Eighth International Symposium on Biological and Environmental Reference Materials (BERM 8), including workshop on	DHHS / USDA	Initiative planned for National Institute of Standards & Technology (NIST) to develop reference materials for botanicals.

	(BERM_8), including workshop on Botanical and Dietary Supplement Standard Materials		
Sep 18	The Importance of Omega-3 Fatty Acids in the Attenuation of Immune-Mediated Diseases	NIAID	Proceedings published and new initiatives identified. Agenda and abstracts at http://ods.od.nih.gov/news/conferences/omega3.html
Sept 28-29	ODS sponsored Science Panel,		Educational session at Consumer Healthcare Products Association (CHPA) Annual Dietary Supplements Symposium. Objectives, agenda and speakers slides at http://ods.od.nih.gov/news/conferences/CHPA_SciencePanel.html
Oct 16	Is There a Role for Dietary Supplements in the Management of Diabetes? Lessons from Clinical Studies		Educational session at American Dietetic Association (ADA) Annual meeting 2000. Objectives, agenda and speakers' presentations at http://ods.od.nih.gov/news/conferences/ada_diabetes.html
Oct 23	Vitamin E in the Prevention of Diabetes Complications	NIDDK	Identified research gaps and opportunities for IC program planning Initiative released June 2001 PA#: PA-01-112
November 5-7	Nutrition and Oral Infectious Diseases Workshop (co-sponsored with the Forsyth Institute)	NIDCR	Program agenda at www.forsyth.org/uti/uti%5Fnoidw%5Fagenda.htm; recommendations at http://www.forsyth.org/nutrition/recommendations.htm Initiative released as Mechanisms in Nutrition and Infection August, 2001 PA#: PA-01-133
Nov 30 - Dec 2	Omega-3 Fatty Acids, Diabetes & Cardiovascular Risk An International Workshop	NHLBI	Identified research gaps and opportunities for IC program planning
2001			
February 12-13	Conference - Dietary Supplement Use in Children: Who, What, Why, and Where Do We Go From Here?	NICHD	Executive Summary published in *Nutrition Today* 2002 May/June 37: 118-129. Summary on web www.nichd.nih.gov/prip/
March 13-14	Diets, Antioxidants & Environmental Influences on Health and Disease	NIEHS	Identified research gaps and opportunities for IC program planning. Summary at Division of Extramural Research & Training (DERT) http://www.niehs.nih.gov/dert/council/2001/staff501.htm.
March 13-14	Use of Quantitative Polymerase Chain Reaction (PCR) to Identify and Quantitate Botanicals in Dietary	NIEHS	Identified research gaps and opportunities for IC program planning

	Supplements		
Mar 20	Workshop: Essential Fatty Acids in Health Maintenance and Disease Prevention		Summary and links to video at http://ods.od.nih.gov/news/conferences/omega3_2001.html. Workshop was in addition to information at a similar workshop on March 20, 2000 with video of program sessions of 2000 program at http://videocast.nih.gov/PastEvents.asp?1
March 24-25	Shape Up America's Diabesity™ Conference	Shape-up America	Conference program at http://www.shapeup.org/diabesity/prelprog.htm
May 13-16	Melatonin and the Biology of Serotonin N-Acetyltransferase	NICHD	Scientific exchange
May 14	Colloquium: Exploring Opportunities for Collaboration with Industry	NCCAM	Summary, agenda and speakers presentations on NCCAM web site at http://nccam.nih.gov/news/pastmeetings/051401/index.htm. Summary published in *J Altern Complement Med 2001: 7(15): 579-82.*
June 2-6	Evidence-Based Clinical Reviews	ISTAHC	ODS participation in program planning
June 4-8	Micronutrients in Central America: Beyond Vitamin A Iodine and Iron	FIC	Identified research gaps and opportunities for IC program planning
Jul 25	Assessment of Dietary Supplement Use, Workshop on Database Needs		ODS program planning. Summary at http://ods.od.nih.gov/news/conferences/Dietary_Supplement_Use_Summary.html
July 30	Antioxidant Use and Concurrent Chemotherapy and Radiotherapy	NCCAM	Planning workshop for future conferences.
August 6-8	Diet, DNA Methylation Processes and Health	NCI	Summary posted on web http://www3.cancer.gov/prevention/methylation/index.html. Proceedings published: *J Nutr.* 2002: 132:2329S-2332S. Initiative released September, 2002: RFA #CA-03-016
September 7	Symposium: Role of S-Adenosyl-L-Methionine (SAMe) in the Treatment of Alcoholic Liver Disease	NIAAA	Summary published in *Alcohol*, 27 (2002) 151-154. RFA for S-Adenosyl-L-Methionine (SAMe) & Liver Disease. Initiative released: RFA-AA-02-011.

Oct 22	Do Herbal Products Affect Quality of Life Issues for Women?		Educational session at American Dietetic Association (ADA) Annual meeting 2001. Session objectives and program agenda and slides at http://ods.od.nih.gov/news/conferences/ada_herbal.html
November 26-27	Interventions for Metabolic and Endocrine Complications of HIV/AIDS and Drug Abuse	NIDA	Executive Summary at www.nida.nih.gov/whatsnew/meetings/Endocrine/default.html
2002			
Jan 8-9	Symposium: Conference on the The Science and Policy of Performance-Enhancing Products	CRN	Proceedings in *Medicine & Science in Sports & Exercise* Oct 2002, 34: 1685-1690. Video webcast at http://ods.od.nih.gov/news/conferences/pep.html and conference report at http://www.crnusa.org/PEP_recap.html.
Jan 28-29 Jul 27-31	Dietary Supplement Use in Women: Current Status and Future Directions	NICHD	Educational session at Society for Nutrition Education Annual meeting 2002. Preconference summary & agenda at http://www.nichd.nih.gov/prip/. Proceedings to be published in J Nutr.
Feb 8	Stakeholders Meeting: ODS Dietary Supplements Methods and References Materials Program		Identified research gaps and opportunities for IC program planning.
Feb 10-15	Gordon Conference - Pineal Cell Biology	NICHD	Scientific exchange
Feb 23	Research Workshop 2002: Functional Foods (in conjunction with ASPEN sponsored workshop)	NIDDK	Educational Session
Apr 18	Dietary Supplements Analytical Methods Workshop	CHPA / AOAC	ODS program planning. Program as PDF file from http://ods.od.nih.gov/news/conferences/conferences.html#2001.
Apr 22	Botanical Dietary Supplements: Health Effects and Mechanism of Action		Minisymposium & poster session at Experimental Biology 2002 in New Orleans. Educational session and scientific exchange. Abstracts published in *FASEB J* March 2002, 16:A610-11.
May 10	Conference on Lipids in Immune Function (a workshop sponsored in conjunction with the International Society for the Study of Fatty Acids and Lipids)	NIAID	Executive summary prepared. Follow-up workshop held at International Society for the Study of Fatty Acids and Lipids 5th Congress. 5/7-11, 2002 at web site http://www.issfal.org.uk/issfal_5th_congress.htm.

May 15-16	Workshop: Perspectives on Conjugated Linoleic Research: Current Status and Future Directions	NIDDK	Conference summary, program, speaker abstracts & conference presentations at http://ods.od.nih.gov/news/conferences/cla/cla.html
Jun 2-6	The 11th International Symposium on Trace Elements in Man and Animals (TEMA 11)	NIDDK	Proceedings to be published in J Nutr.
Jun 20-21	Future Directions for What We Eat in America-NHANES: The Integrated CSFII-NHANES		Proceedings published in *J Nutr* Feb 2003, 133:573S-635S. Also at http://www.nutrition.org/current.shtml#SUPPLEMENT__FUTURE_DIRECTIONS_FOR_WHAT_WE_EAT_IN_AMERICA_NHANES__THE_INTEGRATED_CSFII_NHANES
Aug 22-23	Mechanistic Studies of Cardiovascular Effects of Botanicals	NHLBI	Identified research gaps and opportunities for future IC program planning. Proceedings to be published in *Circulation.*
Sep 5-6	Nutritional Genomics and Proteomics in Cancer Prevention	NCI	Proceedings to be published in *J Nutr.*
Sep 18-19	The Role of Nutrition in the Etiology of Cardiomyopathies and Heart Failure	NHLBI	Identified research gaps and opportunities for future IC program planning; summary report with recommendations, pending
Sep 26	Prevention of Asthma and Allergy with Probiotics	NIAID	Identified research gaps and opportunities for future IC program planning
Sep 27-28	Dietary Supplements For Reduction of Risk for Chronic Obstructive Pulmonary Disease	NHLBI	Identified research gaps and opportunities for future IC program planning
Oct 21	Antioxidants and Concurrent Cancer Therapies: To Use or Not to Use?		Educational session at American Dietetic Association (ADA) Annual meeting 2002. Summary and speaker presentations at http://ods.od.nih.gov/news/conferences/ada2002/ada_antioxidants.html.
Oct 25	Role of Iron Supplements in Alcoholic Liver Disease	NIAAA	Proceedings to be published in *ALCOHOL.*
2003			
January 14-15	Dietary Supplements and the Elderly	NIA	Proceedings to be published. On-line bibliography at National Library of Medicine web site http://nihlibrary.nih.gov/resourceindex.htm. Agenda at http://www.scgcorp.com/dsuse/index2.asp.

May 22	Nutrition and Susceptibility to Infectious Diseases: A Genomics Approach		Scientific exchange; encourage use of genomic and proteomic technology in the advancement of micronutrient studies; encourage "bench to bedside" concepts.
2003	Safety and Efficacy of Weight Loss Supplement	NHLBI	To Identify research gaps and opportunities for future IC program planning
2003	Free Radicals: The Pros and Cons of Antioxidants	NCCAM	To identify research gaps and opportunities for future IC program planning
2003	Understanding Micronutrients and Susceptibility to Infections: A Genomics Approach	NIAID	To identify research gaps and opportunities for future IC program planning
2003	Malnutrition and Parasitic Diseases: Host Pathogen Interactions	NIAID	To identify research gaps and opportunities for future IC program planning

[1] AOAC, Association of Official Analytical Chemists, International; CHPA, Consumer Healthcare Products Association; CRN, Council for Responsible Nutrition; DHHS, Department of Health and Human Services; FIC, Fogarty International Center; ISTAHC, International Society of Technology Assessment in Health Care; NCCAM, National Center for Complementary and Alternative Medicine; NCI, National Cancer Institute; NEI, National Eye Institute; NHLBI, National Heart, Lung, and Blood Institute; NIA, National Institute on Aging; NIAAA, National Institute on Alcohol Abuse and Alcoholism; NIAID, National Institute of Allergy and Infectious Diseases; NICHD, National Institute of Child Health and Development; NIDA, National Institute on Drug Abuse; NIDCD, National Institute on Deafness and Other Communication Disorder; NIDCR, National Institute of Dental and Craniofacial Research; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NIEHS, National Institute of Environmental Health Sciences; NIGMS, National Institute of General Medical Sciences; NIMH, National Institute of Mental Health; USDA, U.S. Department of Agriculture.