Volume 2, Issue 1

Winter 2004

Office of Dietary Supplements Update

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

ODS Strategic Plan: 2004-2009

Special points of interest:

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The NIH Office of Dietary Supplements (ODS) has released its five-year strategic plan entitled, "Promoting Quality Science in Dietary Supplement Research, Education and Communication: A Strategic Plan for the Office of Dietary Supplements 2004-2009."

"The first ODS strategic plan, developed in 1998, provided a sound basis for program development and support of ODS activities related to conduct of basic and clinical research, development of education and communication programs directed to all segments of the public and private sectors with an interest in dietary supplements. But times have changed and another leap forward is needed", said Paul Coates, Ph.D., ODS Director.

In 2003, ODS initiated a strategic planning process involving several efforts to obtain input on future needs and opportunities from the ODS constituency including the public. The goals and initiatives presented in this plan for 2004-2009, just as those developed in the original plan in 1998, emphasize the important role of ODS in research on disease prevention and health promotion, education, and communication of scientific information about dietary supplements.

The ODS Strategic Plan for 2004-2009 incorporates the vision and thrust of the recently published HHS Strategic Plan for 2004-2009 and the NIH Roadmap. ODS is committed to furthering the guiding principles and goals developed

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Paul Coates, Ph.D,
ODS Director

ODS Strategic Goals: 2004-2009

ODS will focus on these five goals in 2004-2009 :

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

Goal 2: Foster research that evaluates the role of dietary supplements in maintaining

and improving optimal physical and mental health and performance.

Goal 3: Stimulate and support research to further understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.

Goal 4: Promote and support the development and improvement of methodologies appropriate to the scientific study of dietary supplement ingredi-

Goal 5: Expand and conduct outreach activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.

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The Science of Pharmacognosy

Pharmacognosy is a branch of science that deals with drugs in the crude or natural state. It is concerned with the physical, botanical biological and chemical properties of bioactive substances of natural origin. There are currently 20 pharmacy schools in the U.S. with a specialization in pharmacognosy or natural products chemistry as well as close to 2,000 members of the American Society of Pharmacognosy (http://www. phcog.org).

Forty percent of all medications on the market are derived from natural products. Penicillin, morphine, atropine, cocaine (for dental and ocular surgery) and several anti-cancer drugs (e.g., taxol, vinblastine, and vincristine) are all examples of drugs made from natural, plant-based sources and the use of pharmacognosy in modern medicine.

In today's marketplace with so many botanical and other dietary substances available over-the-counter (e.g., ephedra, kava, ginkgo biloba, etc.), the science of pharmacognosy is more important than ever in order to verify and ensure the quality and safety of ingredients.

To accelerate the rate of development and validation of analytical methods for botanicals and other dietary supplements, Congress included language in its fiscal year 2002 appropriation to NIH that 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 these ingredients."

As a result, the Office of Dietary Supplements established

the Dietary Supplement Methods and Reference Development Program, which is directed by Joseph Betz, Ph.D. It is a broadbased approach supporting the technical and scientific aspects of analytical methods development through critical laboratory research as well as for the scientific evaluation and wide dissemination of new methods and reference materials.

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Database Updates: IBIDS Celebrates Five Years—1999-2004

This year marks the fifth anniversary of the International Bibliographic Information on Dietary Supplements (IBIDS) database from the Office of Dietary Supplements (ODS), NIH.

IBIDS was launched in January 1999 as a result of the Dietary Supplement and Health Education Act (DSHEA) 1994, whereby Congress mandated that ODS create a tool to assist both scientists and the public

in locating credible, scientific literature on dietary supplements.

IBIDS is available to the public free of charge through a search engine on the ODS homepage. It was designed to be user-friendly so individuals with all levels of expertise may use it easily.

Keeping with their commitment to work together with other federal agencies, the ODS initiated an interagency cooperative agreement with the Food and Nutrition Information Center (FNIC), National Agriculture Library (NAL), Agricultural Research Service, U.S. Department of Agriculture to develop and maintain the IBIDS database.

Since its inception five years ago, the database has grown to include more than 700,000 scientific citations and abstracts.

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Tips for Older Dietary Supplement Users

The FDA published a new online educational brochure, "Tips for Older Dietary Supplement Users" to accompany its 2002 online brochure, "Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information."

The ODS contributed to the development of the material along with several other fed-

eral agencies, health professional associations and nonprofit health organizations.

The brochure provides information on dietary supplements specific to older consumers, including:

 Working with your healthcare team to manage intake of medications, overthe-counter drugs and other dietary supplements.

- How to spot a false claim
- Key "Points to Ponder" before buying
- Resource list

The brochure is available on both the ODS and FDA Web sites. The direct URL is http://www.cfsan.fda.gov/~dms/ds-savv2.html.



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The Science of Pharmacognosy (cont.)

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In its first two years, the Methods and Reference Materials Program focused on building its infrastructure and capabilities.

Some of the early program achievements included:

- Development of a program with the Association of Official Analytical Chemists (AOAC) on methods validation; publication of five articles in the Journal of the AOAC.
- Partnership with National Institute for Standards and Technology (NIST) on development of certified refer-

ence materials for ephedra.

"The rapid development of the dietary supplement marketplace has resulted in a proliferation of ingredients and products, many of which contain ingredients whose amounts and quantity in finished products cannot be verified using existing technology. The development of reliable analytical methods is needed to verify ingredient identity and measure amounts of declared ingredients in raw materials' finished products," explains Dr. Betz.

Current projects include:

Continuation of the AOAC methods validation program

- Continuation of NIST project with plan for developing additional reference materials for ginkgo, St. John's wort, saw palmetto, and others
- Developing a "Handbook of Microscopy" with the American Herbal Pharmacopoeia
- Initiating a "virtual herbarium" feasibility study for identity testing and a "virtual herbarium" pilot
- Developing reference materials for U.S. Pharmacopoeia monographs
- Developing a Black Cohosh adulteration test kit

 Developing methods and references materials for other marker compounds and for plant identification

For more on pharmacognosy or the Methods and Reference Materials Program, visit the Office of Dietary Supplements Web site, http://dietary-supplements.info.nih.gov/showpage.aspx?pageid=25.

Calendar Exhibits

Apr 17-21, Experimental Biology Washington, D.C.

Apr 21-24, American College of Physicians, New Orleans

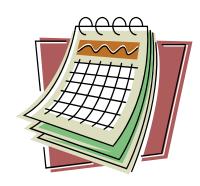
May 5-7, Supply Side East, Baltimore

Symposia Calendar

Mar 18, 1-3pm: Women's Health Research for the 21st Century. Women and Heart Disease. (ORWH) - Lipsett Amphitheater (Bldg 10). http://www4.od.nih.gov/orwh/2004 Seminars.pdf.

Mar 26-27, 8-4pm: Carnitine: the Science Behind a Conditionally Essential Nutrient. (ODS, NICHD, NCCAM, NIMH) - *Lister Hill Auditorium* (Bldg 38) http://www.scgcorp.com/

carnitine2004/index.htm



IBIDS Celebrates Five Years (cont.)

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Over time, a sophisticated search strategy was developed and revised to adequately extract appropriate citations from four major bibliographic databases: biomedical-related articles from MED-LINE, botanical and agricultural science from AGRI-COLA, worldwide agricultural literature from AGRIS, and selected nutrition journals

from CAB Abstracts and CAB Health. Overall, a list of over 2,000 journals exists with links to their Web sites for access to articles.

IBIDS is utilized around the world by researchers, consumers, health professionals and the media and is the central location for research-based journal articles and citations on a variety of dietary supplements, including vita-

mins, mineral and botanicals. Users have typically commended the site on its ease of use, ability to email citations and abstracts, amount and quality of information, and uniqueness of site as a source of information on dietary supplements and alternative medicine.

Plans for the next five years include, adding more databases to increase search capabilities, searching keywords of health outcomes, viewing photos of selected substances, possibility of creating a specialty Clinical IBIDS site, and expanding Consumer IBIDS to include more consumer-oriented articles and links directly to journals.

You can access IBIDS at http://dietary-supplements.info.nih.gov/databases/ibids.html.

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WE'RE ON THE WEB! HTTP://DIETARY-SUPPLEMENTS.INFO.NIH.GOV

Upcoming Features and Announcements

Next Issue:

- New ODS Website Launch
- Vitamin and Mineral Fact Sheet Update
- Carnitine Symposium

ODS Strategic Plan continued from page 1...

by its parent organizations. The new strategic plan includes ongoing evaluation of existing ODS programs, needs for new programs, and prioritization of resource allocation. This effort, initiated in 2004, will include annual consultative meetings with representatives of the ODS constituency and formation of an ODS Steering Group.

"I commend the NIH Office of Dietary Supplements in looking to the future and leading the way in the field of dietary supplement research, says NIH Director, Elias A. Zerhouni, M.D.

"ODS has made significant progress in advancing the recognition of the need for and the conduct of quality scientific research on dietary supplements. In addition, these efforts have increased markedly the availability of objective evidencebased information useful to the public in making decisions about efficacy and safety of dietary supplements. The ODS strategic plan for 2004-2009 provides a roadmap intended to catalyze research that will expand the scientific knowledge base to improve

health of the public," said Paul Coates, Ph.D. ODS Director.

The ODS Strategic Plan for 2004-2009 is available on the ODS Web site (http://ods.od.nih.gov/strategicplan2004). Copies of the printed version will be available later this year. Check the Web site for information on how to receive a copy (http://dietary-supplements.info.nih.gov/).