

approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization, and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH

process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: <http://www.ich.org>.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 1, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on April 24, 2006, on the Internet at http://www.fda.gov/cder/meeting/ICH_20060508.htm.

Dated: April 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; ODS Assessment of Dietary Supplement Education

SUMMARY: The proposed information collection described below will be submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. In compliance with the requirement of Section

3506(c)(2)(A) of the Paperwork Reduction Act, for opportunity for public comment on proposed data collection projects, the Office of Dietary Supplements (ODS), at the National Institutes of Health (NIH) is soliciting public comments on the subject proposal.

Proposed Collection

Title: ODS Assessment of Dietary Supplement Education.

Type of Information Collection

Request: New data collection.

Need and Use of Information

Collection: 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. To assist ODS in prioritizing educational and training needs for researchers in the field, ODS is requesting OMB Clearance for a survey of members of academic health institutions. This effort involves a dual method (mail/Web) survey consisting of nine questions (including four two-part questions), which will be attempted with an estimated 2600 individuals at approximately 1000 academic institutions, yielding an annual total of approximately 1820 respondents (based on a 70 percent response rate). The survey results will help ODS in measuring the scope of higher education's curriculum on dietary supplements, identifying gaps in dietary supplement education, and determining the level of interest in potential ODS seminars and programs, and the specific content needs.

Frequency of Response: This is a one-time data collection.

Affected Public: Academic institutions.

Type of Respondents: Faculty members at academic institutions.

The annual reporting burden is as follows.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Telephone or web survey completion				
Individuals at academic institutions	1820	1	0.12	218
Review of course information for survey completion				
Individuals at academic institutions	1820	1	0.25	455

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Collection and submission of materials				
Individuals at academic institutions	910	1	0.50	455
Annualized totals	1820			1128

The annualized cost to respondents is estimated at \$31,978.86, \$6,189.46 for survey completion, and \$12,894.70 for the review of course information and collection and submission of materials, respectively.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Paul M. Coates, Director, Office of Dietary Supplements, National Institutes of Health, Suite 3B01, 6100 Executive Boulevard, Bethesda, MD 20892-7517; or fax your request to 301-480-1845; or e-mail ods@nih.gov. Dr. Coates can be contacted by telephone at 301-435-2920.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: April 13, 2006.

Paul M. Coates,

*Director, Office of Dietary Supplements,
National Institutes of Health.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Liaison and Scientific Review Office; Meeting of the NTP Board of Scientific Counselors

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Meeting announcement and request for comments

SUMMARY: Pursuant to Public Law 92-463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (NTP BSC). The NTP BSC is composed of scientists from the public and private sectors and provides primary scientific oversight to the Director for the NTP and evaluates the scientific merit of the NTP's intramural and collaborative programs.

DATES: The NTP BSC meeting will be held on June 13, 2006. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the Executive Secretary for the NTP BSC by May 31, 2006 (see **FOR FURTHER INFORMATION CONTACT** below). Written comments should also be received by May 31, 2006, to enable review by the NTP BSC and NIEHS/NTP staff prior to the meeting. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919-541-2475 (voice), 919-541-4644 TTY (text telephone), through the Federal TTY Relay System at 800-877-8339, or by e-mail to niehsoeeo@niehs.nih.gov. Requests should be made at least 7 days in advance of the event.

ADDRESSES: The NTP BSC meeting will be held in the Rodbell Auditorium, Rall Building at the National Institute of Environmental Health Sciences, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Public comments and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP Board (NTP Liaison and

Scientific Review Office, NIEHS, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709; telephone: 919-541-4253, fax: 919-541-0295; or e-mail: shane@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda Topics and Availability of Meeting Materials

Preliminary agenda topics are as follows:

- NIEHS Strategic Plan.
- Update of NTP Activities.
- NTP BSC's Technical Report Review Subcommittee Report.
- NTP Testing Nominations.

A copy of the preliminary agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site or may be requested in hardcopy from the Executive Secretary for the NTP BSC (see **FOR FURTHER INFORMATION CONTACT** above). Following the meeting, summary minutes will be prepared and made available on the NTP Web site.

Attendance and Registration

The meeting is scheduled for June 13, 2006, from 8:30 a.m. to adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP Web site by May 31, 2006, to facilitate access to the NIEHS campus. Please note that a photo ID is required to access the NIEHS campus. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/external/video.htm>.

Request for Comments

Time is allotted during the meeting for the public to present comment to the NTP BSC and NTP staff on the agenda topics. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.