

April 16, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Eric Colman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3340, Silver Spring, MD 20993-0002, 301-796-1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Developing Products for Weight Management," which revises the September 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."

In 1996, following input from an expert advisory panel, FDA issued the September 1996 draft guidance. The September 1996 draft guidance provides general recommendations on the development of drugs for the long-term treatment of obesity. Important areas discussed in that guidance include patient-selection criteria, size and duration of phase 3 trials, and definitions of efficacy of a weight-control drug.

On January 26, 2004, FDA issued a notice in the **Federal Register** requesting public comment on the September 1996 draft guidance for the purpose of incorporating the latest scientific and clinical advances in weight-management drug development (69 FR 3588). In September 2004, FDA convened an advisory committee meeting to discuss the public comments received and to identify specific scientific, clinical, and regulatory issues that should be incorporated into an updated guidance document.

As a result, this revised draft guidance discusses several key areas of interest that are not covered in the September 1996 draft guidance. These areas

include recommendations on the development of products for weight management in pediatric patients and in patients with medication-induced weight gain, and recommendations on the development of combinations of weight-management products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing products for weight management. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Proposed Collection; Proposed Reinstatement of Request; Second National Survey To Evaluate the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) Program

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), Office of Extramural Research (OER), Office of Extramural Programs (OEP), National

Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Second National Survey to Evaluate the Outcomes of the NIH SBIR Program. Type of Information Collection Request: Reinstatement with changes.

Need and Use of the Information Collection: The NIH, Office of the Director, (OD), Office of Extramural Research (OER), Office of Extramural Programs (OEP) will seek OMB approval to reinstate with changes a prior approved collection to conduct a second survey to evaluate the outcomes of the NIH Small Business Innovation Research (SBIR) Program. The SBIR Program, established by Congress in 1982 (Pub. Law No. 97-219), and reauthorized through September 30, 2008 (Pub. Law No. 106-554; 15 U.S.C. § 638), provides research support to small businesses for innovative technology. OMB approved the information collection associated with the initial National Survey to Evaluate the NIH SBIR Program on March 15, 2002 (OMB Control No. 0925-0499), expiration April 30, 2003. Through the first National Survey to Evaluate the NIH SBIR Program, NIH was able to obtain data demonstrating significant SBIR programmatic results. For example, seventy-three percent of the 768 awardee respondents reported commercializing new or improved products, processes, usages, and/or services in health-related fields. Other evidence of commercialization from the survey were that SBIR projects developed 48 drugs and medical devices receiving FDA approval; 281 awardees received additional funding from non-SBIR sources; and 436 awardees engaged in ongoing or completed marketing activities.

NIH will seek OMB approval to reinstate this information collection with changes with the primary objective to assess the extent to which the SBIR program goals continue to be met, particularly those dealing with the commercialization of research products, processes or services and the uncovering of new knowledge that will lead to better health for everyone. With outcome data, NIH will be able to more accurately assess the results of its large financial investment in funding innovative research conducted by small business concerns. Findings will help NIH to (1) Understand if innovative projects supported through the NIH SBIR Program are being commercialized and if so, to classify the types of

products, processes or services that are derived through SBIR funding; (2) determine if other measures of success defined within the NIH mission are being achieved; and (3) enhance NIH's administration of the SBIR Program and the support that it provides to small business concerns. Overall, the NIH will use the evaluation results to assess the outcomes from NIH-supported SBIR awards. The evaluation results will provide OD with the information necessary to make quality improvements to the SBIR program and enhance program performance in generating significant outcomes. The Government Performance and Results Act of 1993 (GPRA) mandates that Federal programs improve their effectiveness and public accountability

by focusing on results. The OMB developed the Program Assessment Rating Tool (PART) to monitor compliance with the GPRA and to rate federal programs for their effectiveness and ability to show results. It is anticipated that results from a second survey will assist NIH in demonstrating that it is meeting its GPRA goals for the NIH SBIR Program. Using an Internet survey OD will collect information Phase II SBIR awardees from fiscal years (FY) 2002 through 2006. The online survey will be implemented using Secure Socket Layer (SSL) encryption technology and password access. OD will use e-mail messages to advise awardees that they have been selected to participate in the survey.

Frequency of Response: One time.

Affected Public: Small business concerns supported by NIH through the SBIR Program.

Type of Respondents: For-profit small business concerns that received a NIH SBIR Phase II award from (FY 2002–2006). The annual reporting burden is as follows:

Estimated Number of Respondents: 1,000; *Estimated Number of Responses Per Respondent:* 1; *Averaged Burden Hours Per Response:* .5; and *Estimated Total Annual Burden Hours Requested:* 500. The annualized cost to the public is estimated at \$37, 500. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
For-profit small business concerns that have received an NIH SBIR Phase II award from (FY 2002–2006)	1000	1	0.5	500

Requests for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed information collection; (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 respondents, including through 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: Ms. Jo Anne Goodnight, NIH SBIR/STTR Program Coordinator, Rockledge I Bldg., Room 3538, 6705 Rockledge Drive, Bethesda, MD 20892–7910, or call non-toll-free number (301) 435–2688 or E-mail your request, including your address, to: jg128w@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before April 13, 2007.

Dated: February 7, 2007.

Jo Anne Goodnight,

Coordinator, Small Business Innovation Research/Small Business Technology Transfer Program Office of Extramural Programs, Office of Extramural Research, Office of the Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908),

on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified,