The number of respondents in Table 1 of this document are the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006. (156 x hours per response (.08) = 12.5 total hours.)

Dated: February 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2579 Filed 2–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0016]

Sentinel Network To Promote Medical Product Safety; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of registration period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 28, 2007, registration for the public meeting that will be held on March 7 and 8, 2007, regarding FDA's exploration and development of an integrated national network to link private sector and public sector postmarket safety efforts, creating a virtual, integrated, electronic ''Sentinel Network''. Such a network would integrate existing and planned efforts to collect, analyze, and disseminate medical product safety information to health care practitioners and patients at the point-of-care. It would be established through multiple, broad-based, public-private partnerships.

Dates and Times: The public meeting will be held on March 7 and 8, 2007, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at the University System of Maryland Shady Grove Center, 8630 Gudelsky Dr., Rockville, MD 20850.

ADDRESSES: Submit written registration to Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20852, 301–827–3360, FAX: 301–594–6777. Submit electronic registration to *Erik.Mettler@fda.hhs.gov*.

For Registration to Attend and/or Participate in the Meeting: Seating at the meeting is limited. People interested in attending should e-mail or submit written registration to Erik Mettler (see **ADDRESSES**) by close of business on February 28, 2007. Registration is free and will be on a first-come, first-serve basis. All individuals wishing to speak during the open session of the meeting must indicate their intent, the question to be addressed, and provide an abstract of the presentation by February 28, 2007.

We have set aside a portion of the agenda (*http://www.fda.gov/oc/op/sentinel/*) for individuals who would like to make presentations at the meeting. If you wish to make an oral presentation during the open session of the meeting, you must state your intention on your registration submission (see **ADDRESSES**). To speak, submit your name, title, business affiliation, address, telephone number, fax number, and e-mail address. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you require special accommodations due to a disability, please inform Erik Mettler (see **ADDRESSES**) when you register.

For Information On the Meeting Contact: Erik Mettler (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 18, 2007 (72 FR 2284), FDA announced a public meeting to explore opportunities to link private sector and public sector postmarket safety efforts to create a virtual, integrated, electronic ''Sentinel Network''. Such a network would integrate existing and planned efforts to collect, analyze, and disseminate medical product safety information to health care practitioners and patients at the point-of-care. It would be established through multiple, broad-based, public-private partnerships. We are seeking input on a number of specific questions, included in the original **Federal Register** notice, regarding opportunities for collaboration, the efficient use of information technology, and the collection and analysis of medical product safety information. A tentative agenda for the 2-day meeting has been posted on FDA's Web site and can be viewed at *http://www.fda.gov/oc/op/sentinel/*. We will post a final agenda by March 1, 2007, at the same Web site.

During the course of the registration period, FDA became aware that some registrations were not properly recorded. Because of this and because of the strong interest being expressed in this meeting, the agency has decided to reopen and extend the registration period to February 28, 2007.

In light of the fact that we have experienced some registration difficulties, individuals who have already registered can contact Erik Mettler (see **ADDRESSES**) if they wish to receive confirmation that their registration has been recorded.

Interested parties who have not yet registered may, on or before February 28, 2007, submit to Erik Mettler (see **ADDRESSES**) an electronic or written registration. Please include your name, title, business affiliation, address, telephone number, fax number, and e-mail address. Please also indicate if you wish to speak during the open public session or if you would like to register to make a presentation.

Dated: February 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–710 Filed 2–12–07; 2:59 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0040]

Draft Guidance for Industry on Developing Products for Weight Management; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Developing Products for Weight Management.'' FDA is interested in updating the September 1996 draft guidance entitled ''Guidance for the Clinical Evaluation of Weight-Control Drugs'' by incorporating the latest scientific and clinical advances in the drug development field of obesity, including 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 action is expected to provide clear and consistent advice to those in industry who are interested in developing weight-management products.

DATES: Submit written or electronic comments on the draft guidance by

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.

[FR Doc. E7–2581 Filed 2–14–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Proposed Collection; Proposed Reinstatement of Collection With Changes; Comment 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) Uunderstand if innovative projects supported through the NIH SBIR Program are being commercialized and if so, to classify the types of