TABLE 2. —ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	Number of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.22(a)	6	1	6	1	6		
900.22(d)	6	1	6	1	6		
900.22(e)	6	1	6	1	6		
900.22(f)	3	1	3	1	3		
900.22(g)	6	1	6	1	6		$60
900.25(b)	6	1	6	1	6		
Total					242,225	$25,000	$60

This request for OMB approval now serves to consolidate previously issued information collection, OMB control number 0910–0580 into 0910–0309. The hourly burden as well as the associated operating costs were increased to better represent the actual burden and costs on facilities and accreditation bodies.

The following regulations were not included in the above burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.12(c)(1) and (c)(3) and § 900.3(f)(1) (21 CFR 900.3(f)(1)).

The following regulations were not included in the above burden tables because they were not considered applicable during the information collection period or their burdens were reported under other regulatory requirements. Therefore, they resulted in no additional reporting or recordkeeping burden: § 900.3(c), 21 CFR 900.11(b)(1) and (b)(2), and 900.24(c).

Dated: February 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2578 Filed 2–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office Of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office Of New Animal Drug Evaluation—21 CFR 10.65 (OMB Control Number 0910–0452)—Extension

The Center for Veterinary Medicine (CVM) holds meetings and /or teleconferences when a sponsor requests a presubmission conference under 21 CFR 514.5, or requests a meeting to discuss general questions. Generally, meeting requests are submitted to CVM on paper. However, CVM now allows registered sponsors to submit information electronically, and to request meetings electronically, if they determine this is more efficient and time saving for them. CVM's guidance ''On How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation'' provides sponsors with the option to submit a request for a meeting or teleconference as an e-mail attachment via the internet.

In the **Federal Register** of November 8, 2006 (71 FR 65535), FDA published a 60-day notice soliciting comments on the proposed collection of information requirements. In response to that notice, no comments were received.

The likely respondents are sponsors for new animal drug applications.

CVM estimates the burden for this information collection activity as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDA Form #	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
10.65/FDA Form 3489	25	6.24	156	.08	12.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between July 1, 2005 and June 30, 2006.

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