caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 of this document is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device reporting (MDR) requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

The annual burden for recordkeeping to respondents follows. Under § 803.17, FDA estimates 220 respondents will spend approximately 3.3 hours to complete the requirements for this section. The number of respondents was estimated by consolidating the total of all new reporting entities together. The 3.3 hours was estimated by FDA, as this section deals with a respondent creating new MDR procedures and is a one-time function. The ''total hours'' for this section equals approximately 726 hours.

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1 1/2 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4426 Filed 3–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0118]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Reagents for Detection of Specific Novel Influenza A Viruses'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0584. The approval expires on September 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4427 Filed 3–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0508]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Health Care Practitioners Regarding Their Preferences for Public Health Notifications

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 April 27, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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.

Survey of Health Care Practitioners Regarding Their Preferences for Public Health Notifications (PHNs)

The PHN is one of the tools that the Center for Devices and Radiological Health (CDRH) uses to get an important message to the user community about risks associated with the use of medical devices. This particular tool is meant to serve a specific purpose not served by the other communication tools at our

disposal—to be a source of information for health care practitioners, immediately recognizable as a statement from FDA, about a device risk with information on how to avoid or mitigate the risk. The purpose of this project is to evaluate the current notification format and distribution process for CDRH, with the goal of determining what is necessary to assure that the notifications reach, and are acted upon by, the target audience. The center needs to know that it is using the most effective approach to formatting and to disseminating PHNs to assure that they are received, recognized, understood, and acted upon quickly and effectively by medical practitioners and institutions. Considerations include, but are not limited to, design, terminology, nomenclature, distribution, utility of standardization, relationship with other medical product notifications (e.g., recalls), use of electronic transmission, and use of plain language.

The intent of this project is to determine the preferences of the health care community for learning from FDA about risks associated with medical devices and to compare the current process against the approach identified by the research to be ''preferred'' with the intent of improving our format and process.

CDRH will conduct a survey of a sample of health care providers who receive a new PHN from FDA. Most recently, FDA has been using intermediary organizations, such as professional associations, to help us distribute notifications to the appropriate target audiences and we are assuming that any new PHN will be disseminated in this way, using the appropriate association to distribute the PHN to their members. Generally, the PHN is distributed to the target audience electronically, either as a link embedded in a news article or sent directly via e-mail from either the professional association or FDA using the e-mail listing provided by the professional association. As part of the notification, we will provide a link to a Web-based questionnaire that will collect information related to the health care providers' preferences for learning about risks associated with medical devices.

The information collected in this survey will help FDA identify the most effective format(s) and distribution method(s) for CDRH PHNs.

In the **Federal Register** of January 9, 2006 (71 FR 1428), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey of health care providers in relevant specialty	300	1	300	.1666	50
Survey of health care providers in another relevant specialty	300	1	300	.1666	50
Total					100

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions and completing the questionnaire.

Dated: March 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4440 Filed 3–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0489] (formerly Docket No. 01D–0489)

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated March 2006. The guidance is intended to assist sponsors of clinical trials in determining when a data monitoring committee (DMC) is needed for study monitoring, and how such committees should operate. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800; or the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; Robert Temple,