Survey, OMB No. 0920–0214) and other federally sponsored surveys. The QDRL conducts cognitive interviews, focus groups, mini field-pretests, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common questionnaire evaluation method is the cognitive interview. In a cognitive interview, a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews; ideally, the questionnaire is re-worked between rounds and revisions are tested iteratively until interviews yield relatively few new insights. When possible, cognitive interviews are conducted in the survey's intended mode of administration. For example, when testing telephone survey questionnaires, participants often respond to the questions via a telephone in a laboratory room. Under this condition, the participant answers without face-to-face interaction. QDRL staff watch for response difficulties from an observation room, and then conduct a face-to-face debriefing with in-depth probes. Cognitive interviewing provides useful data on questionnaire performance at minimal cost and respondent burden. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. NCHS is requesting 3 years of OMB Clearance for the project. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents per year	Number of responses/ respondent	Avg. burden response (in hours)	Total burden hours
2007 test volunteers	500	1	1.2	600

Dated: April 25, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–6501 Filed 4–28–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0273] (formerly 03N–0273)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Research Study Complaint Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Research Study Complaint Form'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 16, 2005 (70 FR 74817), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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 0910–0579. The approval expires on March 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6457 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0166]

Agency Emergency Processing Under the Office of Management and Budget Review; MedWatch—The Food and Drug Administration Safety Information and Adverse Event Reporting Program; Proposal to Survey MedWatch Partners Organizations

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on a proposal for the MedWatch program to deploy and conduct a web-based customer satisfaction survey of certain health care professional trade and specialty organizations that voluntarily have chosen to participate in the FDA MedWatch's Partners program. The survey will solicit information about the utility of the FDA MedWatch safety alerts and monthly safety labeling changes that are posted on the MedWatch Web site and disseminated to partner organizations for sharing with members of the organizations.

DATES: Fax written comments on the collection of information by May 31, 2006. FDA is requesting approval of this emergency processing by May 31, 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 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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this

proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed immediately so that the agency can effectively assess and re-evaluate its FDA MedWatch risk communication efforts in drug safety as part of a broader center level (the Center for Drug Evaluation and Research (CDER)) reorganization action to enhance its risk communication activities for CDER-regulated products, and address public expectations for timely dissemination of clinically useful safety information to both providers and their patients at the point of care.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 automated collection techniques, when appropriate, and other forms of information technology.

MedWatch—The FDA Safety Information and Adverse Event Reporting Program; Proposal to Survey MedWatch Partners Organizations

The MedWatch Partners program is an FDA outreach effort directed at health care provider professional organizations. The effort facilitates the timely dissemination of clinically important new safety information on the drugs, devices, and other human medical care products regulated by FDA and prescribed, dispensed, or used by the membership of these professional societies. In voluntarily agreeing to work with FDA MedWatch, these partner organizations disseminate this important safety information to their members and their members' patients so that medical products necessary to efforts to improve a patient's health may be used more safely and reduce the risk of harm.

Risk communication is one of the essential elements in the risk management paradigm accepted as a framework within CDER since described in the ''Report to the FDA Commissioner from the Task Force on Risk Management'' in May 1999. As an agency that regulates a broad range of clinical medical products—drugs, therapeutic biologics, blood products, medical devices, and dietary supplements—FDA's public health mission includes the timely dissemination of new safety information identified during post-marketing surveillance activities. This information includes class 1 recalls, public health advisories, notice of counterfeit drug product, and labeling changes such as new black box warnings or contraindications to drug product use. In recent years, there has been a public commitment to actively disseminating this new safety information, both to health care providers and their patients, and to leveraging this risk communication activity by developing partnerships and alliances with non-governmental organizations. This commitment was explicitly identified as an objective in the strategic plan for ''Improving Patient Safety'' of former Commissioner of Food and Drugs, Mark McClellan. That objective states that FDA will ''take appropriate actions to communicate risks and correct problems associated with medical products'' and ''will identify new ways to inform physicians, pharmacists, nurses, and patients about the safety of FDA-regulated products.''

The MedWatch program is currently located in the Office of Drug Safety, CDER. MedWatch disseminates safety information on FDA-regulated medical products to both health care professional and consumer/patient audiences. MedWatch maintains a comprehensive Web site at *http://www.fda.gov/medwatch* for this purpose. The FDA MedWatch program has about 120 Partner organizations that represent clinical care providers (doctors, nurses, pharmacists, etc.). As a ''Partner,'' the organization has agreed to support the goals of the MedWatch program: Participating in the dissemination of FDA-approved safety information and promoting the voluntary reporting to FDA of adverse events. In order to communicate quickly with MedWatch Partner organizations, a listserve, supported by the National Institutes of Health, is maintained, with contacts for each MedWatch Partner group. Partner organizations have voluntarily agreed to receive these FDA MedWatch safety alerts and monthly safety labeling changes. Each organization receives e-mail notification of two types of FDA MedWatch safety information at the time it is added to the MedWatch Web site—safety alerts for individual products and, once a month, a listing of the 30 to 60 drugs that have had safety labeling changes for that month.

The FDA MedWatch program, in order to implement this safety information dissemination process effectively, needs to evaluate satisfaction of these customer groups so that FDA MedWatch can improve the dissemination process and content of this safety information and increase its use and application to direct patient care and to the public's health.

The purpose of the survey is to fulfill phase one of Executive Order 12862, ''Setting Customer Service Standards,'' which directs agencies to continually reform their management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector. There is no duplication of effort. The MedWatch program is the only one planning to perform this survey. By actively gathering this survey information from MedWatch partner customers, the agency will achieve a better understanding customer satisfaction with this program, and be able to direct limited resources to produce an improved program that is most useful to both health care provider customers and, secondarily, their patients.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Partner Organizations	120	1	120	.5	60

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

This burden estimate of total hours was developed by using: (1) The number of known MedWatch partner health care organizations, (2) the number of times the survey will be deployed, and (3) the expected time to complete the response

based on internal pilot testing of the survey instrument at the agency.

Dated: April 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6461 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Research Review Subcommittee of the Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of the Subcommittee: Research Review Subcommittee of the Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 19, 2006, from 8 a.m. to 4:30 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 19, 2006, the subcommittee will listen to presentations about the research program at the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). The program is intended to provide dynamic, responsive, cutting edge research to contribute to OVRR's regulatory mission and facilitate development of safe and effective biological products. The subcommittee will discuss the program and make recommendations to the Vaccines and Related Biological Products Advisory Committee at a future open meeting of the full committee. Information regarding CBER's scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: *http://www.fda.gov/cber/inside/mission.htm*. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: *http://www.fda.gov/oc/initiatives/criticalpath/*.

Procedure: On May 19, 2006, from 8 a.m. to 1 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 12, 2006. Oral presentations from the public will be scheduled between approximately 12 p.m. to 1 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 12, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 19, 2006, from 2 p.m. to 4:30 p.m., the meeting will be closed to the public. The meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4). The subcommittee will discuss internal research programs in the Office of Vaccines Research and Review, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 21, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–6508 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 18, 2006, from 9 a.m. to 4:45 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and make recommendations on the safety and efficacy of GARDASIL (Human Papillomavirus [Types 6,11,16,18] Recombinant Vaccine) manufactured by Merck.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 11, 2006. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral