EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Screening form	124	1	3/60	6
Self-administered questionnaire	84	1	6/60	8
Focus group with parents of children <8 years of age (4 groups of 8 participants)	32	1	1.5	48
Focus group with adults (4 groups of 8 participants)	32	1	1.5	48
Semi-structured interviews with adolescents (13 to 20 years of age)	20	1	30/60	10
Semi-structured interviews with primary care physicians	20	1	20/60	7
Semi-structured interviews with pharmacists	20	1	20/60	7
Total	332			134

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening form	124	6	$10.30	$62
Self-administered questionnaire	84	8	10.30	82
Focus groups with parents of children <8 years of age (4 groups of 8 participants)	32	48	10.30	494
Focus groups with adults (4 groups of 8 participants)	32	48	10.30	494
Semi-structured interviews with adolescents (13 to 20 years of age)	20	10	10.30	103
Semi-structured interviews with primary care physicians	20	7	61.10	428
Semi-structured interviews with pharmacists	20	7	48.22	338
Total	332	134		2,001

* Patient average hourly wage based on the average per capita income of $21,435 (computed into an hourly wage rate of $10.30) in Harris County, Texas where the study will take place. Provider hourly wage based on the following estimates from National Compensation Survey: Occupational wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics: Primary care physician = $61.10/hour; pharmacist = $48.22/hour.

Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated cost to the Federal Government for this six month project.

The total cost is $164,440. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost
Project Development	$13,250
Data Collection Activities	61,699
Data Processing and Analysis	14,080
Publication of Results	750
Project Management	17,000
Overhead	57,661
Total	164,440

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 17, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–3959 Filed 2–25–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0631]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

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 30, 2009.

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, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0432. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432)—Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810) for the medical device recall authority provisions. Section 518(e) of the act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death to: (1) Immediately cease distribution of such device, (2) immediately notify health professionals and device-user facilities of the order, and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518 (e) of the act sets out a three- step procedure for issuance of a mandatory device recall order which are: (1) If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately: (a) Cease distribution of the device, (b) notify health professionals and device user facilities of the order, and (c) instruct those professionals and facilities to cease use of the device, (2) FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device and, (3) after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to: (1) Ensure that all devices entering the market are safe and effective, (2) accurately and immediately detect serious problems with medical devices, and (3) remove dangerous and defective devices from the market.

In the **Federal Register** of December 19, 2008 (73 FR 77719), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a-b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a-c)	2	1	2	12	24
810.15(d)	2	1	2	4	8
810.15(e)	10	1	10	1	10
810.16(a-b)	2	12	24	40	960
810.17(a)	2	1	2	8	16
Total					1,082

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

TABLE 2.—ESTIMATED ANNUAL RECODKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
810.15(b)	2	1	1	8	8

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

Explanation for Burden Estimates:

The burden estimates for tables I and II of this document are based on FDA's experience with voluntary recalls under part 810 of the regulations. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily. Since the last time this collection of information was submitted to OMB for renewal/approval, there have been no mandatory recalls.

Dated: February 18, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4137 Filed 2–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Oral and Dental: Small Business.

Date: March 5–6, 2009.

Time: 9 a.m. to 12 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016K, MSC 7814, Bethesda, MD 20892, 301–451–1327, *tthyagar@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Pathogens and their Vectors.

Date: March 12, 2009.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–402–4454, *kostrikr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Quick Trials on Imaging and Image-guided Intervention.

Date: March 12, 2009.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: John Firrell, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Infectious Agent Detection/Diagnosis, Food Safety, Sterilization/Disinfection and Bioremediation.

Date: March 13, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, (301) 435–1149, *elzaataf@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Specials of Genes, Genomes, and Genetics.

Date: March 13, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Michael A. Marino, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2216, MSC 7890, Bethesda, MD 20892, (301) 435–0601, *marinomi@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, BTSS Member Conflict.

Date: March 16, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–2204, *matusr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Immune Mechanisms.

Date: March 19, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Jian, Wang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095D, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Health of the Population SBIR–2.

Date: March 23, 2009.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301–435–1017, *helmersk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Data Ontologies and Sharing Data and Tools.

Date: March 24–25, 2009.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 5144, MSC 7812, Bethesda, MD 20892, 301–435–2902, *gubina@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Digestive Sciences.

Date: March 24–25, 2009.

Time: 8 a.m. to 6 p.m.