TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Instrument(s) tested	Frequency of response	Average time per response (minutes/hour)	Number of respondents	Annual hour burden
Read Invitation (Attachments 3)	1.00	1/60 (0.017)	16,667.00	278
Pre-Enrollment (Attachment 6)	1.00	10/60 (0.167)	2,312.00	385
Enrollment Process (Attachment 7)	1.00	5/60 (0.083)	2,288.00	191
ASA24 (Attachments 4–1)	2.00	30/60 (0.500)	1,944.00	1,944
ACT–24 (Attachments 4–2)	2.00	15/60 (0.250)	1,944.00	972
LHQ (Attachments 4–3)	1.00	20/60 (0.333)	1,944.00	648
DHQ (Attachments 4–4)	1.00	45/60 (0.750)	1,944.00	1,458
Web Re-entry (Attachment 8)	6.00	5/60 (0.083)	1,944.00	972
Evaluation Survey (Attachment 9)	1.00	1/60 (0.017)	2,288.00	38
Totals			33,275.00	6,886

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Arthur Schatzkin, M.D., Dr.P.H, Chief, Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, Executive Plaza South, Room 3040, 6120 Executive Blvd., EPS–MSC 7242, Bethesda, MD 20892–7335 or call non-toll-free number 301–594–2931 or e-mail your request, including your address to: *schatzka@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: October 12, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–26187 Filed 10–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Quality System Regulations

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 November 17, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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 Devices: Current Good Manufacturing Practice Quality System Regulations—21

CFR Part 820 (OMB Control Number 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice (CGMP), as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/quality system (QS) regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the FD&C act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies

requirements for product acceptance activities quality data evaluations and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards "ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing." The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with QS requirements encompassing design, production, installation, and servicing processes.

Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review the following topics: (1) The quality policy, (2) the organizational structure, (3) the quality plan, and (4) the quality system procedures of the organization.

Section 820.22 requires the conduct and documentation of QS audits and re-audits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j), requires in respective order, the establishment, maintenance, and/or documentation of the following topics: (1) Procedures to control design of class III and class II devices and certain class I devices as listed therein; (2) plans for design and development activities and updates; (3) procedures identifying, documenting, and approving design input requirements; (4) procedures defining design output, including acceptance criteria, and documentation of approved records; (5) procedures for formal review of design results and documentation of results in the design history file (DHF); (6) procedures for verifying device design and documentation of results and approvals in the DHF; (7) procedures for validating device design, including documentation of results in the DHF; (8) procedures for translating device design into production specifications; (9) procedures for documenting, verifying, and validating approved design changes before implementation of changes; and (10) the records and references constituting the DHF for each type of device.

Section 820.40 requires manufacturers to establish and maintain procedures controlling approval and distribution of required documents and document changes.

Section 820.40(a) and (b) requires the establishment and maintenance of procedures for the review, approval, issuance, and documentation of required records (documents) and changes to those records.

Section 820.50(a)(1), (a)(2), (a)(3), and (b) requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers, and purchasing data describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a)(1) through (a)(5), (b) through (e), (g)(1) through (g)(3), (h), and (i) requires the establishment, maintenance, and/or documentation of the following topics: (1) Process control procedures; (2) procedures for verifying or validating changes to specification, method, process, or procedure; (3) procedures to control environmental conditions and inspection result records; (4) requirements for personnel hygiene; (5) procedures for preventing contamination of equipment and products; (6) equipment adjustment, cleaning, and maintenance schedules; (7) equipment inspection records; (8) equipment tolerance postings, procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and (9) validation protocols and validation records for computer software and software changes.

Sections 820.72(a), (b)(1), and (b)(2) and 820.75(a) through (c) require, respectively, the establishment, maintenance, and/or documentation of the following topics: (1) Equipment calibration and inspection procedures; (2) national, international or in-house calibration standards; (3) records that identify calibrated equipment and next calibration dates; (4) validation procedures and validation results for processes not verifiable by inspections and tests; (5) procedures for keeping validated processes within specified limits; (6) records for monitoring and controlling validated processes; and (7) records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80(a) through (e) and 820.86, respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for incoming acceptance by inspection, test, or other verification; (2) procedures for ensuring that in process products meet specified requirements and the control of product until inspection and tests are completed; (3) procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests or other verifications; (4) procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; (5) records in the device history record (DHR) showing acceptance dates, results, and equipment used; and (6) the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90(a), (b)(1), and (b)(2) and 820.100 require, respectively, the establishment, maintenance and/or documentation of the following topics: (1) Procedures for identifying, recording, evaluating, and disposing of nonconforming product; (2) procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; (3) procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; (4) procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes, and results; and (5) records for all corrective and preventive action activities.

Section 820.100(a)(1) through (a)(7) states that procedures and requirements shall be established and maintained for corrective/preventive actions, including the following: (1) Analysis of data from process, work, quality, servicing records; investigation of nonconformance causes; (2) identification of corrections and their effectiveness; (3) recording of changes made; and (4) appropriate distribution and managerial review of corrective and preventive action information. Section 820.120 states that manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, and document those procedures.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150(a) and (b), 820.160(a) and (b), and 820.170(a) and (b), respectively, require the establishment, maintenance, and/or documentation of following topics: (1) Procedures for controlling and recording the storage, examination, release, and use of labeling; (2) the filing of labels/labeling used in the DHR; (3) procedures for controlling product storage areas and receipt/dispatch authorizations; (4) procedures controlling the release of products for distribution; (5) distribution records that identify consignee, product, date, and control

numbers; and (6) instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181(a) through (e), 820.184(a) through (f), and 820.186 require, respectively, the maintenance of records that are: (1) Retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; (2) contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; (3) contained in a DHR and demonstrate the manufacture of each unit, lot, or batch of product in conformance with DMR and regulatory requirements, include manufacturing and distribution dates, quantities, acceptance documents, labels and labeling, control numbers; and (4) contained in a quality system record (QSR), consisting of references, documents, procedures, and activities not specific to particular devices.

Sections 820.198(a) through (c) and 820.200(a) through (d), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Complaint files and procedures for receiving, reviewing and evaluating complaints; (2) complaint investigation records identifying the device, complainant, and relationship of the device to the incident; (3) complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; (4) procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and (5) service reports that record the device, service activity, and test and inspection data. Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, which are written and based on valid statistical rationale; and procedures for ensuring adequate sampling methods. The CGMP/QS regulation amends and revises the CGMP requirements for medical devices set out under part 820. The regulation adds design and purchasing controls; modifies previous critical device requirements; revises previous validation and other requirements; and harmonizes device CGMP requirements with QS specifications in the international standard "ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing." The rule does not apply to manufacturers of components or parts of finished devices, nor to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class I devices listed in § 820.30(a)(2) of the regulation. The rule imposes burden upon: (1) Finished device manufacturer firms, which are subject to all recordkeeping requirements; (2) finished device contract manufacturers, specification developers; and (3) repacker, relabelers, and contract sterilizer firms, which are subject only to requirements applicable to their activities. In addition, remanufacturers of hospital single-use devices (SUDs) will now be considered to have the same requirements as manufacturers in regard to this regulation. The establishment, maintenance and/or documentation of procedures, records, and data required by this regulation will assist FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

The CGMP/QS regulation applies to approximately 8,924 respondents. These recordkeepers consist of 8,945 original respondents and an estimated 18 hospitals that remanufacture or reuse SUDs. They include manufacturers, subject to all requirements and contract manufacturers, specification developers, repackers, relabelers, and contract sterilizers, subject only to requirements applicable to their activities. Hospital remanufacturers of SUDs are now defined to be manufacturers under guidelines issued by FDA's Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics. Respondents to this collection have no reporting activities, but must make required records available for review or copying during FDA inspection. The regulation contains additional recordkeeping requirements in such areas as design control, purchasing, installation, and information relating to there manufacture of SUDs. The estimates for this burden are derived from those incremental tasks that were determined when the new CGMP/QS regulation became final as well as those carryover requirements. The carryover requirements are based on decisions made by the agency on July 16, 1992, under OMB Control Number 0910–0073, which still provides valid base line data.

Explanation of Recordkeeping Burden Estimate

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,105,552 hours. This figure also consists of approximately 143,052 hours spent on a startup basis by 734 new firms.

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG), in 1996 when the CGMP/QS regulation became final. Additional factors considered in deriving estimates included the following:

- Establishment type: Query has been made of CDRH's registration/listing databank and the current count was 7,748 domestic firms subject to CGMPs. It was also calculated that each year, the number of new domestic firms subject to CGMPs is 734. The average amount of firms therefore subject to CGMPs over the 3 years is therefore 8,924 and this figure has been used to calculate the total burden. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden.
- During the last report it was estimated that this number was 8,963. When the last set of numbers was calculated, FDA was still using a paper based system to register and list firms. On October 1, 2007, FDA switched to an electronic system for registration and listing. Also at that time the Food and Drug Administration Amendments Act of 2007 instituted an establishment registration fee for some types of facilities. FDA believes that during the fiscal year 2008 annual registration cycle, establishments that had previously registered but were not required to do so, removed themselves from inventory of active establishments. FDA believes that the current figures reported by the electronic system more accurately reflect the inventory of registered establishments.
- Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to subpart C, Design Controls. The type of firm

subject to each requirement was identified by the ERG.

• FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act Control Number 0910–0073. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,924 respondents), which compensates for differences in methodology.

In the **Federal Register** of June 24, 2010 (75 FR 36092), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments, however only one was regarding the information collection. One part of the comment questioned a technical reference found within the 60-day notice, stating not that the reference was incorrect, but that it may be somewhat misleading since the reference is updated on a regular basis and this was not communicated in the notice. While the commenter is correct that ISO 9001 is on version 2008 and ISO/DIS 13485 is on version 2003, the standard ISO 9001 and ISO/DIS 13485 are referenced because they are the standard regardless of version.

Another part of the comment maintains that the term "collect" is misleading as it pertains to recordkeeping requirements because relevant documents are only submitted if requested; however, the comment agrees that the information collection is necessary. Under the PRA regulations, records retention is considered "information collection," as defined by the PRA 5 CFR 1320.3

A third part of the comment stated that it was not clear to whom the regulations applied based on the statement, "[e]xcept for manufacturers, not every type of firm is subject to every CGMP/QS requirement." FDA believes the scope of the regulations found at part 820.1 makes it clear to whom the requirements are applicable.

The commenter questioned the validity and availability of a study that was conducted by the ERG in 1996, claiming that without benefit of the study itself, comments regarding burden estimates were too difficult to make. As a basis for its burden estimates, the agency relied in part on certain pieces of information found in the 1996 study and recommends that FDA make this document part of the docket. The study was submitted to OMB as part of the original PRA approval and is part of the Federal docket.

The commenter states that FDA assumes that the burden for each firm is the same, i.e., each of the 8,924 firms has exactly the same burden. The flexibility of the system suggests that the "one size fits all" approach in the **Federal Register** is not appropriate. The PRA burden placed on the 8,924 firms is an average burden on respondents.

The commenter believes that the estimates the agency provides are too low, but does not offer an alternative methodology for estimating that the agency may review. The comment goes on to suggest, however, that a new analysis similar to the 1996 study be conducted and serve as the basis for future burden estimates because our estimates have not changed in several years. While FDA agrees that additional analysis is always helpful in determining burden, the agency does perform ongoing reviews of the burden associated with PRA burden as required under the PRA for purposes of evaluating burden associated with its information collection requests, and has done so for purposes of renewing these CGMP/QS regulations.

Finally, the commenter suggests that the agency's regulation regarding electronic signatures found at part 11 (21 CFR part 11) is overly cumbersome to many firms. Part 11 is a separate regulation from part 820, and it is only mentioned for reference purposes in the preamble. The record keeping for part 11 is not within the scope of this paperwork analysis.

Also, CDRH is proactive in ensuring that the medical device industry and other affected individuals are made aware of on-going issues relating to the CGMP/QS regulations. FDA's Medical Device GMP/QS experts have participated in numerous conferences and seminars relating to the CGMP/QS regulatory requirements. During these sessions, our GMP/QS experts share information through speeches and panel discussions that provide a forum for open discussion. During these discussions guidance and direction is often given to the audience to help them understand their regulatory responsibilities under the GMP/QS regulation. In addition, issues are sometimes identified by the audience that provides the agency areas that we may need to clarify to affected individuals.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
820.20(a)	8,924	1	8,924	7	62,468
820.20(b)	8,924	1	8,924	4	35,696
820.20(c)	8,924	1	8,924	6	53,544
820.20(d)	8,924	1	8,924	10	89,240
820.20(e)	8,924	1	8,924	10	89,240
820.22	8,924	1	8,924	33	294,492
820.25(b)	8,924	1	8,924	13	116,012
820.30(a)(1)	8,924	1	8,924	2	17,848
820.30(b)	8,924	1	8,924	6	53,544
820.30(c)	8,924	1	8,924	2	17,848
820.30(d)	8,924	1	8,924	2	17,848
820.30(e)	8,924	1	8,924	23	205,252
820.30(f)	8,924	1	8,924	37	330,188
820.30(g)	8,924	1	8,924	37	330,188
820.30(h)	8,924	1	8,924	3	26,772
820.30(i)	8,924	1	8,924	17	151,708
820.30(j)	8,924	1	8,924	3	26,772

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
820.40	8,924	1	8,924	9	80,316
820.40(a) and (b)	8,924	1	8,924	2	17,848
820.50(a)(1) through (a)(3)	8,924	1	8,924	22	196,328
820.50(b)	8,924	1	8,924	6	53,544
820.6	8,924	1	8,924	1	8,924
820.65	8,924	1	8,924	1	8,924
820.70(a)(1) through (a)(5)	8,924	1	8,924	2	17,848
820.70(b) and (c)	8,924	1	8,924	2	17,848
820.70(d)	8,924	1	8,924	3	26,772
820.70(e)	8,924	1	8,924	2	17,848
820.70(g)(1) through (g)(3)	8,924	1	8,924	1	8,924
820.70(h)	8,924	1	8,924	2	17,848
820.70(i)	8,924	1	8,924	8	71,392
820.72(a)	8,924	1	8,924	5	44,620
820.72(b)(1) and (b)(2)	8,924	1	8,924	1	8,924
820.75(a)	8,924	1	8,924	3	26,772
820.75(b)	8,924	1	8,924	1	8,924
820.75(c)	8,924	1	8,924	1	8,924
820.80(a) through (e)	8,924	1	8,924	5	44,620
820.86	8,924	1	8,924	1	8,924
820.90(a)	8,924	1	8,924	5	44,620
820.90(b)(1) and (b)(2)	8,924	1	8,924	5	44,620
820.100(a)(1) through (a)(7)	8,924	1	8,924	12	107,088
820.100(b)	8,924	1	8,924	1	8,924
820.120(b)	8,924	1	8,924	1	8,924
820.120(d)	8,924	1	8,924	1	8,924
820.130	8,924	1	8,924	1	8,924
820.140	8,924	1	8,924	6	53,544
820.150(a) and (b)	8,924	1	8,924	6	53,544
820.160(a) and (b)	8,924	1	8,924	1	8,924
820.170(a) and (b)	8,924	1	8,924	2	17,848
820.180(b) and (c)	8,924	1	8,924	2	17,848
820.181(a) through (e)	8,924	1	8,924	1	8,924
820.184(a) through (f)	8,924	1	8,924	1	8,924
820.186	8,924	1	8,924	1	8,924
820.198(a) through (c)	8,924	1	8,924	5	44,620
820.200(a) and (d)	8,924	1	8,924	3	26,772
820.25	8,924	1	8,924	1	8,924
Totals					3,105,552

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

Dated: October 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26102 Filed 10–15–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0344]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

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 November 17, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and the title "Testing Communications on Medical Devices and Radiation-Emitting Products." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Testing Communications on Medical Devices and Radiation-Emitting Products—(OMB Control Number 0910–NEW)

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs