

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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.

Threshold of Regulation for Substances Used in Food-Contact Articles—(OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j), (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive that meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or

an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical

composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of April 9, 2010 (75 FR 18209), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	7	1	7	48	336

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

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate of 48 hours is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910-0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of

food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at <http://www.cfsan.fda.gov>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: June 16, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-15302 Filed 6-23-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0273]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit either electronic or written comments on the collection of information by August 23, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20857, 301-796-5156 email: Daniel.Gittleston@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

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 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, pre-production 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 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/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 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 reaudits.

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 the remanufacture 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.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	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
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	1,300,805	196,328
820.50(b)	8,924	1	8,924	6		53,544

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
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
Total					1,300,805	3,105,552

¹ There are no capital costs associated with this collection of information.

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 data bank 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 FY 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.

Dated: June 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-15338 Filed 6-23-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adoption of the Food and Drug Administration Food Code by Local, State, and Tribal Governments

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 July 26, 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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0448. 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, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed