how many providers and suppliers will submit applications for enrollment during the moratoria, although it anticipates that most providers and suppliers will not submit applications during the moratoria period. Therefore, this notice does not reach the economic threshold and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $35.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This notice will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35; Sec. 1103 of the Social Security Act (42 U.S.C. 1302).

Dated: July 25, 2013

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–18394 Filed 7–26–13; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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: On February 25, 2013, the Agency submitted a proposed collection of information entitled ''Environmental Impact Considerations'' 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 0910–0322. The approval expires on May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18410 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0853]

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

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 September 30, 2013.

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 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: 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 Regulation—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 CGMP, as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the FD&C 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 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) 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) 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, 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 added design and purchasing controls, modified previous critical device requirements, revised previous validation and other requirements, and harmonized 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, or 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) are now to be considered to have the same requirements as manufacturers in regard to the regulation. The establishment, maintenance and/or documentation of procedures, records, and data required by the regulation assists 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 25,986 respondents. A query of the Agency's registration and listing database shows that approximately 15,113 domestic and 10,873 foreign establishments are respondents to this information collection.[1] These recordkeepers consist of 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 guidance issued by FDA's Center for

[1] Based on fiscal year 2012 data.

Devices and Radiological Health, 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. 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 PRA burden placed on the 25,986 establishments is an average burden.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality policy—820.20(a)	25,986	1	25,986	7	181,902
Organization—820.20(b)	25,986	1	25,986	4	103,944
Management review—820.20(c)	25,986	1	25,986	6	155,916
Quality planning—820.20(d)	25,986	1	25,986	10	259,860
Quality system procedures—820.20(e)	25,986	1	25,986	10	259,860
Quality audit—820.22	25,986	1	25,986	33	857,538
Training—820.25(b)	25,986	1	25,986	13	337,818
Design procedures—820.30(a)(1)	25,986	1	25,986	2	51,972
Design and development planning—820.30(b)	25,986	1	25,986	6	155,916
Design input—820.30(c)	25,986	1	25,986	2	51,972
Design output—820.30(d)	25,986	1	25,986	2	51,972
Design review—820.30(e)	25,986	1	25,986	23	597,678
Design verification—820.30(f)	25,986	1	25,986	37	961,482
Design validation—820.30(g)	25,986	1	25,986	37	961,482
Design transfer—820.30(h)	25,986	1	25,986	3	77,958
Design changes—820.30(i)	25,986	1	25,986	17	441,762
Design history file—820.30(j)	25,986	1	25,986	3	77,958
Document controls—820.40	25,986	1	25,986	9	233,874
Documentation approval and distribution and document changes—820.40(a) and (b)	25,986	1	25,986	2	51,972
Purchasing controls—820.50(a)	25,986	1	25,986	22	571,692
Purchasing data—820.50(b)	25,986	1	25,986	6	155,916
Identification—820.60	25,986	1	25,986	1	25,986
Traceability—820.65	25,986	1	25,986	1	25,986
Production and process controls—820.70(a)	25,986	1	25,986	2	51,972
Production and process changes and environmental control—820.70(b) and (c)	25,986	1	25,986	2	51,972
Personnel—820.70(d)	25,986	1	25,986	3	77,958
Contamination control—820.70(e)	25,986	1	25,986	2	51,972
Equipment maintenance schedule, inspection, and adjustment—820.70(g)(1) to (g)(3)	25,986	1	25,986	1	25,986
Manufacturing material—820.70(h)	25,986	1	25,986	2	51,972
Automated processes—820.70(i)	25,986	1	25,986	8	207,888
Control of inspection, measuring, and test equipment—820.72(a)	25,986	1	25,986	5	129,930
Calibration procedures, standards, and records—820.72(b)(1) to (b)(2)	25,986	1	25,986	1	25,986
Process validation—820.75(a)	25,986	1	25,986	3	77,958
Validated process parameters, monitoring, control methods, and data—820.75(b)	25,986	1	25,986	1	25,986

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

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Revalidation—820.75(c)	25,986	1	25,986	1	25,986
Acceptance activities—820.80(a) to (e)	25,986	1	25,986	5	129,930
Acceptance status—820.86	25,986	1	25,986	1	25,986
Control of nonconforming product—820.90(a)	25,986	1	25,986	5	129,930
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1) to (b)(2)	25,986	1	25,986	5	129,930
Procedures for corrective/preventive actions—820.100(a)(1) to (a)(7)	25,986	1	25,986	12	311,832
Corrective/preventive activities—820.100(b)	25,986	1	25,986	1	25,986
Labeling procedures—820.120(b)	25,986	1	25,986	1	25,986
Labeling documentation—820.120(d)	25,986	1	25,986	1	25,986
Device packaging—820.130	25,986	1	25,986	1	25,986
Handling—820.140	25,986	1	25,986	6	155,916
Storage—820.150(a) and (b)	25,986	1	25,986	6	155,916
Distribution procedures and records—820.160(a) and (b)	25,986	1	25,986	1	25,986
Installation—820.170	25,986	1	25,986	2	51,972
Record retention period—820.180(b) and (c)	25,986	1	25,986	2	51,972
Device master record—820.181	25,986	1	25,986	1	25,986
Device history record—820.184	25,986	1	25,986	1	25,986
Quality system record—820.186	25,986	1	25,986	1	25,986
Complaint files—820.198(a), (c), and (g)	25,986	1	25,986	5	129,930
Servicing procedures and reports—820.200(a) and (d)	25,986	1	25,986	3	77,958
Statistical techniques procedures and sampling plans—820.250	25,986	1	25,986	1	25,986
Total					9,043,128

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

Dated: July 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18351 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Steatohepatitis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research in cosponsorship with the American Association for the Study of Liver Diseases (AASLD) is announcing a 2-day public workshop entitled ''Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic fatty liver disease (NAFLD).'' There are no approved treatments for NAFLD and its complications of nonalcoholic steatohepatitis (NASH) and liver fibrosis and cirrhosis. This workshop will provide a forum to discuss trial design, including endpoints for clinical trials in NAFLD, to promote efficient drug development in this area and thus improved treatments for patients.

Date and Time: The public workshop will be held on September 5 and 6, 2013, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, in the Great Room (room 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*