to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections (listed below) are required to include UDI data elements for the device that is the subject of such information collection. Addition of the UDI data elements is included in this burden estimate for the conforming amendments in the following 21 CFR parts:

Part 803—Medical Device Reporting (OMB control number 0910–0437),

Part 806—Medical Devices; Reports of Corrections and Removals (OMB control number 0910–0359),

Part 814—Premarket Approval of Medical Devices (OMB control number 0910–0231),

Part 820—Quality System Regulation (OMB control number 0910–0073),

Part 821—Medical Device Tracking Requirements (OMB control number 0910–0442), and

Part 822—Postmarket Surveillance (OMB control number 0910–0449).

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

TABLE 1—ESTIMATED ANNUAL BURDEN

	Number of respondents [1]	Number of responses per respondent [2]	Total annual responses [3]	Average burden per response [4]	Total hours [5]	Total capital costs and operating and maintenance costs
Reporting	6,199	51	316,149	0.023 (1 minute)	7,289	$425,000
Recordkeeping	5,987	51	305,337	0.989 (59 minutes)	302,121	14,733,333
Third-Party Disclosure	5,987	51	305,337	0.885 (53 minutes)	270,143	13,033,333

[1] Maximum number of respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[2] Maximum number of responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[3] Maximum total annual responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[4] Rounded to three decimals. Total hours reflects a more precise, non-rounded average burden per response. An approximate (non-rounded) conversion to minutes is shown in parentheses.

[5] Total hours is based on a more precise burden per response than the rounded value show in this table.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16269 Filed 7–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 30, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for

information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2544 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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 (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 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) 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 (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 (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 (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 (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, examination/release for storage and use, and to 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 the 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, and 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 (g) 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) re-packer, re-labelers, and contract sterilizer firms, which are subject only to requirements applicable to their activities. In addition, remanufacturers of hospital single-use devices are now 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 27,074 respondents. This estimate is based on a query of the Agency's registration and listing database. Respondents to this information 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 27,074 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)	27,074	1	27,074	7	189,518
Organization—820.20(b)	27,074	1	27,074	4	108,296
Management review—820.20(c)	27,074	1	27,074	6	162,444
Quality planning—820.20(d)	27,074	1	27,074	10	270,740
Quality system procedures—820.20(e)	27,074	1	27,074	10	270,740
Quality audit—820.22	27,074	1	27,074	33	893,442
Training—820.25(b)	27,074	1	27,074	13	351,962
Design procedures—820.30(a)(1)	27,074	1	27,074	2	54,148
Design and development planning—820.30(b)	27,074	1	27,074	6	162,444
Design input—820.30(c)	27,074	1	27,074	2	54,148
Design output—820.30(d)	27,074	1	27,074	2	54,148
Design review—820.30(e)	27,074	1	27,074	23	622,702
Design verification—820.30(f)	27,074	1	27,074	37	1,001,738
Design validation—820.30(g)	27,074	1	27,074	37	1,001,738
Design transfer—820.30(h)	27,074	1	27,074	3	81,222
Design changes—820.30(i)	27,074	1	27,074	17	460,258
Design history file—820.30(j)	27,074	1	27,074	3	81,222
Document controls—820.40	27,074	1	27,074	9	243,666
Documentation approval and distribution and document changes—820.40(a) and (b)	27,074	1	27,074	2	54,148
Purchasing controls—820.50(a)	27,074	1	27,074	22	595,628
Purchasing data—820.50(b)	27,074	1	27,074	6	162,444
Identification—820.60	27,074	1	27,074	1	27,074
Traceability—820.65	27,074	1	27,074	1	27,074
Production and process controls—820.70(a)	27,074	1	27,074	2	54,148
Production and process changes and environmental control—820.70(b) and (c)	27,074	1	27,074	2	54,148
Personnel—820.70(d)	27,074	1	27,074	3	81,222
Contamination control—820.70(e)	27,074	1	27,074	2	54,148
Equipment maintenance schedule, inspection, and adjustment—820.70(g)(1)–(3)	27,074	1	27,074	1	27,074
Manufacturing material—820.70(h)	27,074	1	27,074	2	54,148
Automated processes—820.70(i)	27,074	1	27,074	8	216,592
Control of inspection, measuring, and test equipment—820.72(a)	27,074	1	27,074	5	135,370
Calibration procedures, standards, and records—820.72(b)(1)–(2)	27,074	1	27,074	1	27,074
Process validation—820.75(a)	27,074	1	27,074	3	81,222

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
Validated process parameters, monitoring, control methods, and data—820.75(b)	27,074	1	27,074	1	27,074
Revalidation—820.75(c)	27,074	1	27,074	1	27,074
Acceptance activities—820.80(a)–(e)	27,074	1	27,074	5	135,370
Acceptance status—820.86	27,074	1	27,074	1	27,074
Control of nonconforming product—820.90(a)	27,074	1	27,074	5	135,370
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1)–(2)	27,074	1	27,074	5	135,370
Procedures for corrective/preventive actions—820.100(a)(1)–(7)	27,074	1	27,074	12	324,888
Corrective/preventive activities—820.100(b)	27,074	1	27,074	1	27,074
Labeling procedures—820.120(b)	27,074	1	27,074	1	27,074
Labeling documentation—820.120(d)	27,074	1	27,074	1	27,074
Device packaging—820.130	27,074	1	27,074	1	27,074
Handling—820.140	27,074	1	27,074	6	162,444
Storage—820.150(a) and (b)	27,074	1	27,074	6	162,444
Distribution procedures and records—820.160(a) and (b)	27,074	1	27,074	1	27,074
Installation—820.170	27,074	1	27,074	2	54,148
Record retention period—820.180(b) and (c)	27,074	1	27,074	2	54,148
Device master record—820.181	27,074	1	27,074	1	27,074
Device history record—820.184	27,074	1	27,074	1	27,074
Quality system record—820.186	27,074	1	27,074	1	27,074
Complaint files—820.198(a)–(g)	27,074	1	27,074	5	135,370
Servicing procedures and reports—820.200(a) and (d)	27,074	1	27,074	3	81,222
Statistical techniques procedures and sampling plans—820.250	27,074	1	27,074	1	27,074
Total					9,421,752

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

Our estimated burden for the information collection reflects an overall increase of 812,928 hours. We attribute this adjustment to an increase in the number of respondents.

Dated: July 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16260 Filed 7–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0579]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 the information collection requirements relating to the reporting of biological product deviations and human cells, tissues, and cellular and tissue-based product (HCT/P) deviations in manufacturing, and Forms FDA 3486 and 3486A.July 31, 2019

DATES: Submit electronic or written comments on the collection of information by September 30, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 30, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').