

1. *Native American Bancorporation, Co.*, Denver, Colorado; to engage through Native American Community Development Corporation, Denver, Colorado, in community development activities, pursuant to 12 CFR 225.28(b)(12).

Board of Governors of the Federal Reserve System, February 22, 2001.

**Robert deV. Frierson**

*Associate Secretary of the Board.*

[FR Doc. 01-4808 Filed 2-27-01; 8:45 am]

BILLING CODE 6210-01-S

## GOVERNMENT PRINTING OFFICE

### Depository Library Council to the Public Printer; Meeting

The Depository Library Council to the Public Printer (DLC) will meet on Sunday, April 1, 2001, through Wednesday, April 4, 2001, in San Antonio, Texas. The sessions will take place from 7:30 p.m. until 10 p.m. on Sunday, 8:30 a.m. until 5 p.m. on Monday and Tuesday and from 8:30 a.m. until 3:30 p.m. on Wednesday. The meeting will be held at the Adam's Mark San Antonio Riverwalk Hotel, 111 Pecan Street East, San Antonio, Texas. The purpose of this meeting is to discuss the Federal Depository Library Program. All sessions are open to the public.

A limited number of hotel rooms have been reserved at the Adam's Mark San Antonio Riverwalk Hotel for anyone needing hotel accommodations. Telephone: 210-354-2800. Please specify the U.S. Government Printing Office when you contact the hotel. Room cost per night is \$91 (plus tax) per night single and \$115 (plus tax) per night double, triple or quad through March 5, 2001.

**Michael F. DiMario,**

*Public Printer.*

[FR Doc. 01-4855 Filed 2-27-01; 8:45 am]

BILLING CODE 1520-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee for Injury Prevention and Control: Family and Intimate Violence Prevention Subcommittee: Conference Call

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC)

announces the following subcommittee conference call.

*Name:* ACIPC Family and Intimate Violence Prevention Subcommittee.

*Times and Dates:* 1 p.m.-3 p.m., March 12, 2001.

*Place:* National Center for Injury Prevention and Control (NCIPC), Koger Center—Vanderbilt Building, Conference Room 2000, 2939 Flowers Road South, Atlanta, Georgia 30341.

*Status:* Open to the public, limited only by the space available.

*Purpose:* To provide and make recommendations to ACIPC and the Director, NCIPC, regarding feasible goals for prevention and control of family and intimate violence and sexual assault. The Subcommittee will make recommendations regarding policies, strategies, objectives and priorities.

*Matters To Be Discussed:* The Subcommittee will discuss the FY 2001 Violence Against Women activities, and NCIPC's Research Agenda.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Ileana Arias, Ph.D., Chief, Etiology and Surveillance Branch (Provisional), Division of Violence Prevention, NCIPC, CDC, 4770 Buford Highway, NE, M/S K60, Atlanta, Georgia 30341-3724, telephone 770/488-4410.

This notice is published less than 15 days prior to the meeting due to administrative delays.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 22, 2001.

**John Burckhardt,**

*Acting Director, Management Analysis and Services Office.*

[FR Doc. 01-4828 Filed 2-27-01; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0063]

#### 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 information collection requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation.

**DATES:** Submit written comments or electronic comments on the collection of information by April 30, 2001.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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: (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 (CGMP) Quality System (QS) Regulation—21 CFR Part 820 (OMB Control No. 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, 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 act.

The CGMP/QS regulation implementing the authority provided by this statutory provision is found in part 820 (21 CFR part 820) of the Code of Federal Regulations 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. Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review: The quality policy; the organizational structure; the quality plan; and the quality system procedures of the organization. Section 820.22 requires the conduct and documentation of quality system 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 the following respective order, the establishment, maintenance, and/or documentation of: Procedures to control design of class III and class II devices, and certain class I devices as listed therein; plans for design and development activities and updates;

procedures identifying, documenting, and approving design input requirements; procedures defining design output, including acceptance criteria, and documentation of approved records; procedures for formal review of design results and documentation of results in the design history file (DHF); procedures for verifying device design and documentation of results and approvals in the DHF; procedures for validating device design, including documentation of results in the DHF; procedures for translating device design into production specifications; procedures for documenting, verifying and validating approved design changes before implementation of changes; and the records and references constituting the DHF for each type of device.

Section 820.40 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 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), and (g) through (i) requires the establishment, maintenance, and/or documentation of: Process control procedures; procedures for verifying or validating changes to specification, method, process, or procedure; procedures to control environmental conditions and inspection result records; requirements for personnel hygiene; procedures for preventing contamination of equipment and products; equipment adjustment, cleaning and maintenance schedules; equipment inspection records; equipment tolerance postings; procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and validation protocols and validation records for computer software and software changes.

Sections 820.72 and 820.75(a), (b), (b)(2), and (c) require, respectively, the establishment, maintenance, and/or documentation of: Equipment calibration and inspection procedures; national, international or in-house calibration standards; records that

identify calibrated equipment and next calibration dates; validation procedures and validation results for processes not verifiable by inspections and tests; procedures for keeping validated processes within specified limits; records for monitoring and controlling validated processes; and records of the results of revalidation where necessitated by process changes or deviations.

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

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

Sections 820.120(b) and (d), 820.130, 820.140, 820.150, 820.160, and 820.170, respectively, require the establishment, maintenance, and/or documentation of: Procedures for controlling and recording the storage, examination, release and use of labeling; the filing of labels/labeling used in the DHR; procedures for controlling product storage areas and receipt/dispatch authorizations; procedures for controlling the release of products for distribution; distribution records that identify consignee, product, date and control numbers; and 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, 820.184, and 820.186 require, respectively, the maintenance of records: That are retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; that are contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; that are contained in DHR's, demonstrate the manufacture of each unit, lot or batch of product in conformance with DMR and regulatory requirements, and include manufacturing and distribution dates and quantities, acceptance documents, labels and labeling, and control numbers; and that are 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) and (d), respectively, require the establishment, maintenance and/or documentation of: Complaint files and procedures for receiving, reviewing, and evaluating complaints; complaint investigation records identifying the device, complainant, and relationship of the device to the incident; complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and 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, that are written and based on a 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 at part 820. It adds design and purchasing controls; modifies previous critical device requirements; revises previous validation and other requirements; and

harmonizes device CGMP requirements with quality system specifications in the international standard, ISO (International Organization for Standardization) 9001:1994 "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 burdens upon finished device manufacturer firms, which are subject to all recordkeeping requirements, and upon finished device contract manufacturer, specification developer, repacker and relabeler, and contract sterilizer firms, which are subject only to requirements applicable to their activities. Due to modifications to the guidance given for remanufacturers of hospital single use devices, reusers of hospital single-use devices 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 final 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.

If FDA did not impose these recordkeeping requirements, it anticipates that design-related device failures would continue to occur in the same numbers as before and continue to result in a significant number of device recalls and preventable deaths and serious injuries. Moreover, manufacturers would be unable to take advantage of substantial savings attributable to reduced recall costs,

improved manufacturing efficiency, and improved access to international markets through compliance with CGMP requirements that are harmonized with international quality system standards.

The CGMP/QS regulation applies to some 9,229 respondents. These recordkeepers consist of 7,229 original respondents and an estimated 2,000 hospitals that remanufacture or reuse single use medical devices. 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 single use medical devices (SUD's) are now defined to be manufacturers under guidelines issued by the Center for Devices and Radiological Health's (CDRH's) 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 single use medical devices. The estimates for burden are derived from those incremental tasks that were determined when the new CGMP/QS regulation became final (October 7, 1996, 61 FR 52602) as well as those carry-over requirements. The carry-over requirements are based on decisions made by the agency on July 16, 1992, under OMB Paperwork Reduction Act submission No. 0910-0073. This still provides valid baseline data.

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,167,670 hours (shown as 3,167,670 in table 1, of this document, of this justification statement due to rounding). This figure also consists of approximately 114,882 hours spent on a startup basis by 650 new firms. Table 1 below identifies burden estimates per sections of the regulation.

FDA estimates information collection burdens imposed as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours | Total Operating & Maintenance Costs |
|----------------|----------------------|------------------------------------|----------------------|------------------------|-------------|-------------------------------------|
| 820.20(a)      | 9,229                | 1                                  | 9,229                | 6.58                   | 60,727      |                                     |
| 820.20(b)      | 9,229                | 1                                  | 9,229                | 4.43                   | 40,884      |                                     |
| 820.20(c)      | 9,229                | 1                                  | 9,229                | 6.17                   | 56,943      |                                     |
| 820.20(d)      | 9,229                | 1                                  | 9,229                | 9.89                   | 91,275      |                                     |

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

| 21 CFR Section           | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours | Total Operating & Maintenance Costs |
|--------------------------|----------------------|------------------------------------|----------------------|------------------------|-------------|-------------------------------------|
| 820.20(e)                | 9,229                | 1                                  | 9,229                | 9.89                   | 91,275      | \$1,181,925                         |
| 820.22                   | 9,229                | 1                                  | 9,229                | 32.72                  | 301,973     |                                     |
| 820.25(b)                | 9,229                | 1                                  | 9,229                | 12.68                  | 117,024     |                                     |
| 820.30(a)(1)             | 9,229                | 1                                  | 9,229                | 1.75                   | 16,151      |                                     |
| 820.30(b)                | 9,229                | 1                                  | 9,229                | 5.95                   | 54,913      |                                     |
| 820.30(c)                | 9,229                | 1                                  | 9,229                | 1.75                   | 16,151      |                                     |
| 820.30(d)                | 9,229                | 1                                  | 9,229                | 1.75                   | 16,151      |                                     |
| 820.30(e)                | 9,229                | 1                                  | 9,229                | 23.39                  | 215,866     |                                     |
| 820.30(f)                | 9,229                | 1                                  | 9,229                | 37.42                  | 345,349     |                                     |
| 820.30(g)                | 9,229                | 1                                  | 9,229                | 37.42                  | 345,349     |                                     |
| 820.30(h)                | 9,229                | 1                                  | 9,229                | 3.34                   | 30,825      |                                     |
| 820.30(i)                | 9,229                | 1                                  | 9,229                | 17.26                  | 159,293     |                                     |
| 820.30(j)                | 9,229                | 1                                  | 9,229                | 2.64                   | 24,365      |                                     |
| 820.4                    | 9,229                | 1                                  | 9,229                | 8.91                   | 82,230      |                                     |
| 820.40(a) and (b)        | 9,229                | 1                                  | 9,229                | 2.04                   | 18,827      |                                     |
| 820.50(a)(1) to (a)(3)   | 9,229                | 1                                  | 9,229                | 21.9                   | 202,115     |                                     |
| 820.50(b)                | 9,229                | 1                                  | 9,229                | 6.02                   | 55,559      |                                     |
| 821                      | 9,229                | 1                                  | 9,229                | 0.32                   | 2,953       |                                     |
| 821                      | 9,229                | 1                                  | 9,229                | 0.67                   | 6,183       |                                     |
| 820.70(a)(1) to (a)(5)   | 9,229                | 1                                  | 9,229                | 1.85                   | 17,074      |                                     |
| 820.70(b) and (c)        | 9,229                | 1                                  | 9,229                | 1.85                   | 17,074      |                                     |
| 820.70(d)                | 9,229                | 1                                  | 9,229                | 2.87                   | 26,487      |                                     |
| 820.70(e)                | 9,229                | 1                                  | 9,229                | 1.85                   | 17,074      |                                     |
| 820.70(g)(1) to (g)(3)   | 9,229                | 1                                  | 9,229                | 1.43                   | 13,197      |                                     |
| 820.70(h)                | 9,229                | 1                                  | 9,229                | 1.85                   | 17,074      |                                     |
| 820.70(i)                | 9,229                | 1                                  | 9,229                | 7.5                    | 69,218      |                                     |
| 820.72(a)                | 9,229                | 1                                  | 9,229                | 4.92                   | 45,407      |                                     |
| 820.72(b)(1) to (b)(2)   | 9,229                | 1                                  | 9,229                | 1.43                   | 13,197      |                                     |
| 820.75(a)                | 9,229                | 1                                  | 9,229                | 2.69                   | 24,826      |                                     |
| 820.75(b)                | 9,229                | 1                                  | 9,229                | 1.02                   | 9,414       |                                     |
| 820.75(c)                | 9,229                | 1                                  | 9,229                | 1.11                   | 10,244      |                                     |
| 820.80(a) to (e)         | 9,229                | 1                                  | 9,229                | 4.8                    | 44,299      |                                     |
| 820.86                   | 9,229                | 1                                  | 9,229                | 0.79                   | 7,291       |                                     |
| 820.90(a)                | 9,229                | 1                                  | 9,229                | 4.95                   | 45,684      |                                     |
| 820.90(b)(1) and (b)(2)  | 9,229                | 1                                  | 9,229                | 4.95                   | 45,684      |                                     |
| 820.100 (a)(1) to (a)(7) | 9,229                | 1                                  | 9,229                | 12.48                  | 115,178     |                                     |
| 820.100(b)               | 9,229                | 1                                  | 9,229                | 1.28                   | 11,813      |                                     |
| 820                      | 9,229                | 1                                  | 9,229                | 0.45                   | 4,153       |                                     |
| 820.120(b)               | 9,229                | 1                                  | 9,229                | 0.45                   | 4,153       |                                     |
| 820.120(d)               | 9,229                | 1                                  | 9,229                | 0.45                   | 4,153       |                                     |
| 820.130                  | 9,229                | 1                                  | 9,229                | 0.45                   | 4,153       |                                     |
| 820.140                  | 9,229                | 1                                  | 9,229                | 6.34                   | 58,512      |                                     |
| 820.150(a) and (b)       | 9,229                | 1                                  | 9,229                | 5.67                   | 52,328      |                                     |
| 820.160(a) and (b)       | 9,229                | 1                                  | 9,229                | 0.67                   | 6,183       |                                     |
| 820.170(a) and (b)       | 9,229                | 1                                  | 9,229                | 1.5                    | 13,844      |                                     |
| 820.180(b) and (c)       | 9,229                | 1                                  | 9,229                | 1.5                    | 13,844      |                                     |
| 820.181(a) to (e)        | 9,229                | 1                                  | 9,229                | 1.21                   | 11,167      |                                     |
| 820.184(a) to (f)        | 9,229                | 1                                  | 9,229                | 1.41                   | 13,013      |                                     |
| 820.186                  | 9,229                | 1                                  | 9,229                | 0.4                    | 3,692       |                                     |
| 820.198(a) to (c)        | 9,229                | 1                                  | 9,229                | 4.94                   | 45,591      |                                     |
| 820.200(a) and (d)       | 9,229                | 1                                  | 9,229                | 2.61                   | 24,088      |                                     |
| 820.250                  | 9,229                | 1                                  | 9,229                | 0.67                   | 6,183       |                                     |
| Totals                   |                      |                                    |                      |                        | 3,167,673   | \$1,181,925                         |

<sup>1</sup> There are no capital costs associated with this collection of information.

Burden (labor) hour and cost estimates were developed under FDA contract by the Eastern Research Group, Inc. (ERG), in 1996 when the CGMP/QS regulation became final. These figures are still accurate. Additional factors

considered in deriving estimates included:

- Establishment type: Query has been made of CDRH's registration/listing data bank and has counted 7,229 domestic firms subject to CGMP's. They were

then grouped as: Manufacturers (5,463), contract manufacturers (204), specification developers (960), repackers/relabelers (574), remanufacturer (21) and contract sterilizers (7). In addition, hospitals that

reuse or remanufacture devices are now considered manufacturers under new FDA guidance. It is estimated that out of the 6,000 hospitals in the United States, one-third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. Thus, the number of manufacturers will increase from 5,463 to 7,463 making the total number of firms subject to CGMP's 9,229.

- 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 part 820 Subpart C—Design Controls. The type of firm subject to each requirement was identified by 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 submission No. 0910-0073. It was approved by OMB on July 16, 1992, and it 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 a 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 9,229 respondents), which compensates for differences in methodology.

FDA estimates that some 650 "new" establishments (marketing devices for the first time) will expend some 114,882 "development" hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent—to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent—to requirements dealing with components and acceptance activities; 25 percent—to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent—to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: February 22, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-4850 Filed 2-27-01; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0069]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Information From U.S. Processors That Export to the European Community

**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 the maintenance of lists of U.S. processors that export certain animal-derived foods (i.e., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the European Community (EC), temporary exemptions from certain food labeling requirements for the purpose of conducting authorized food labeling experiments, petitions for health claims, and petitions for nutrient content claims.

**DATES:** Submit written or electronic comments on the collection of information by April 30, 2001.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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:** Peggy Schlosburg, Office of Information

Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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: (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.

#### Request for Information From U.S. Processors That Export to the European Community (OMB Control Number 0910-0320)—Extension

EC is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed below in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors