indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 10, 1998.

A. Federal Reserve Bank of Richmond (A. Linwood Gill III, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. First Region Bancshares, Inc., Richlands, Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of First Sentinel Bank, Richlands, Virginia.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Mercantile Bancorporation Inc., St. Louis, Missouri, and its wholly owned subsidiary, Ameribanc, Inc., St. Louis, Missouri; to acquire and thereby merge with Financial Services Corporation of the Midwest, Rock Island, Illinois, and thereby indirectly acquire The Rock Island Bank, N.A., Bettendorf, Iowa.

C. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Financial Bancshares, Inc., Holton, Kansas; to acquire 18.18 percent of the voting shares of Arizona Bancshares, Inc., Flagstaff, Arizona, and thereby indirectly acquire First State Bank, Flagstaff, Arizona, a *de novo* bank. Comments regarding this application must be received not later than July 6, 1998.

2. Gold Banc Corporation, Inc., Leawood, Kansas; to acquire 100 percent of the voting shares of Northwest Bancshares, Inc., Colby, Kansas, and thereby indirectly acquire Peoples State Bank, Colby, Kansas.

Board of Governors of the Federal Reserve System, June 10, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–15841 Filed 6–12–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 30, 1998.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. The Peoples Bancshares, Inc., Sardis, Tennessee; to engage in the leasing of personal or real property, pursuant to § 225.28(b)(3) of Regulation Y.

Board of Governors of the Federal Reserve System, June 10, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–15842 Filed 6–12–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 98088]

Notice of Availability of Funds for Fiscal Year 1998; Resource Center for Unintentional Injury Prevention Among Older Americans

Introduction

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement to establish a Resource Center for Unintentional Injury Prevention Among Older Americans.

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Unintentional Injuries. (For ordering copies of ''Healthy People 2000'' and ''Major Causes of Unintentional Injuries Among Older Persons'' [1996], see the Section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under sections 301, 317, and 391–394 [42 U.S.C. 241, 247b, and 280b–280b–3] of the Public Health Service Act as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations are eligible to apply.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described

in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately $194,000 is available in FY 1998 to fund one award. It is expected that the award will begin on or about September 30, 1998, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change.

A continuation award within the project period will be made on the basis of satisfactory progress and the availability of funds.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Public Law 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress itself or any State legislature. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Prohibition on Use of CDC Funds for Certain Gun Control Activities

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, specifies that: ''None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control.''

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the language in the CDC's 1998 Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

Background

The elderly population is increasing more rapidly than other age groups, and its share of the total U.S. population is rising rapidly. Among people 65 years and older, unintentional injuries are the seventh leading cause of death; there were over 29,000 deaths from unintentional injuries in 1995. The death rate from injuries increases exponentially with age. Among people aged 65 years and older; the death rate is higher among men than among women, and higher among whites than among other races. The major causes of unintentional injury mortality are falls, motor vehicle crashes, drowning, fires and burns, and poisonings.

Falls are the second leading cause of injury deaths among people 65–84 and the leading cause for people aged 85 years and older. In 1995, almost 7,900 people over age 65 years died as a result of falls. Falls are the most common cause of injuries and hospital admissions for trauma among the elderly. Falls account for 87 percent of all fractures among people aged 65 years or older and are the second leading cause of spinal cord and brain injury. The most serious fall-related injury is hip fracture. Approximately 240,000 hip fractures occur each year in the United States; 75 percent to 80 percent of all hip fractures are sustained by women. The impact of these injuries on the quality of life is enormous. Half of all elderly adults hospitalized for hip fracture cannot return home or live independently after the fracture. The annual cost for treating these injuries was over 3 billion dollars in 1986.

Since most fractures are the result of falls, understanding factors which contribute to falling is essential in order to design effective intervention strategies. For people aged 65 years or older, 60 percent of fatal falls occur in the home, 30 percent occur in public places, and 10 percent occur in health care institutions. Factors that contribute to falls include dementia, visual impairment, neurologic and musculoskeletal disabilities, psychoactive medications, and difficulties in gait and balance. Environmental hazards such as slippery surfaces, uneven floors, poor lighting, loose rugs, unstable furniture, and objects on floors may also play a role.

People 65 years and older represent 13 percent of the population and about 17 percent of all motor vehicle-related deaths. In 1995, 6,991 people 65 years and older died in crashes—79 percent as passenger vehicle occupants, and 18 percent as pedestrians. This represents a 25 percent increase from 1985. Per mile driven, elderly drivers have higher fatal crash rates than drivers in all other age groups except teenagers. One reason elderly people have higher death rates than younger people from motor vehicle crashes is that they are more susceptible to medical complications following injuries. This means they are more likely to die from their injuries.

Purpose

The purpose of this announcement is to establish a Resource Center for the Prevention of Unintentional Injuries Among Older Americans (people ages 65 and older) and to disseminate this information. The Resource Center will provide this information to health care professionals, caretakers, and other individuals concerned about reducing injuries among Older Americans.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities listed under B. (CDC Activities).

A. Recipient Activities

In Year one:

1. Establish links and/or collaborative relationships with organizations which have demonstrated resources, information, and/or programs related to injuries among older adults.

2. Identify the target audiences which will benefit from access to injury prevention program materials. For example, these may include public or private organizations, health care professionals, caretakers, and others concerned about reducing injuries among seniors.

3. Conduct a needs assessment to determine the types and forms of information needed by the various target audiences. This assessment should guide the decisions about what types and in what forms data are to be made available.

4. Compile unintentional injury prevention program information and resource materials related to people 65 years and older from these collaborating organizations and establish a repository for these materials.

5. Develop and test a system that incorporates a variety of methods by which the identified target audiences can access/obtain this data.

6. Develop training materials and distribution plan that will ensure participation of the target audiences.

7. Conduct process and outcome evaluation of year 01 activities.

In Years two and three: (Continue work on 1–7).

8. Implement the dissemination/ distribution plan developed during Year 01.

9. Conduct process and outcome evaluation of Year 02 and 03 activities.

B. CDC Activities

1. Provide technical advise and consultation on all aspects of recipient activities.

2. Provide technical assistance regarding up-to-date scientific resources regarding injuries and injury prevention among people 65 years and older.

Technical Reporting Requirements

An original and two copies of a semi-annual progress report must be submitted 30 days after the end of each six month period. The progress reports must include the following for each function or activity involved: (1) a comparison of actual accomplishments to the objectives established for the period; (2) the reasons for slippage if established objectives are not met; and (3) other pertinent information including, when appropriate, analysis and explanation of unexpectedly high costs for performance. An original and two copies of a Financial Status Report (FSR) is required no later than 90 days after the end of the budget period. A final progress report and FSR are due no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, CDC.

Application Content

Each application should be limited to 30 pages, excluding the budget/budget justification page(s) and attachments (i.e., letters of commitment, data collection forms, resumes, etc.). All material must be typewritten, double-spaced, with type no smaller than 10 characters per inch (CPI) or 12 point type Times Roman or Courier 10 point, on 8.5″ x 11″ paper, with at least a 1″ margin. Number each page clearly and provide a complete index.

A. The application must include:

1. *Abstract:* A one page abstract and summary of the proposed effort.

2. *Background and Need:* Provide background and documentation of the need for and benefits of maintaining a national repository and actively disseminating information on injury prevention among older Americans, and keeping the subject in the public's attention.

3. *Goals and Objectives:* Overall goal(s) which indicate where the applicant desires to be at the end of the project period and specific time-framed, measurable and achievable program objectives for each goal(s).

4. *Description of Activities:* A detailed description (i.e., who, what, how, and when) of specific activities to be undertaken to achieve each of the program objectives during the project period. A time-frame should be included which indicates when each activity will occur and who will be responsible for each activity. Include an organizational chart identifying placement of the program within its relevant organizational system (e.g., the university system).

5. *Methodology:* A detailed description of the process and outcome methods used to evaluate the effectiveness of each activity proposed, including what will be evaluated, the data to be used, who will perform the evaluation and the time-frame for the evaluation. The evaluation should include progress in meeting the objectives and conducting activities during the project period.

6. *Collaboration:* A description of any proposed collaboration with other entities, including academic institutions, Federal, State or local agencies, institutes, associations, laboratories, or experts. Applicant should provide a letter from each outside entity describing their willingness and capacity to fulfill their specific responsibilities.

7. *Staff and Resources:* A description of the roles and responsibilities of the project director and all other staff members and collaborators. Descriptions should include the position titles, education and experience, and the percentage of time each will devote to the program. Curriculum vitae for each critical staff member and collaborator should be included. Include a description of current activities and previous experience in injury prevention. Include relevant experience and capability to implement and maintain a database and actively disseminate information.

8. *Budget:* A detailed budget with accompanying narrative justifying all individual budget items which make up the total amount of funds requested. The budget should be consistent with the stated objectives and planned activities.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (10 Percent)

The extent to which the applicant presents the magnitude of the need for this project, demonstrates experience in this area, and describes the likely impact of their activities on the this need.

2. Goals and Objectives (25 Percent)

The extent to which the goal(s) and objectives are relevant to the purpose of the proposal, feasible for accomplishment during the project period, measurable, and specific in terms of what is to be done and the time involved. The extent to which the objectives address all activities necessary to accomplish the purpose of the proposal.

3. Methods (20 Percent)

The extent to which the applicant provides a detailed description of all proposed activities needed to achieve each objective and the overall program goal(s). The extent to which the applicant provides a reasonable and complete schedule for implementing all activities. The extent to which position descriptions, lines of command, and collaborations are appropriate to accomplishing the program goal(s) and objectives.

4. Evaluation (20 Percent)

The extent to which the proposed evaluation plan is detailed and capable of documenting program process and outcome measures (e.g., establishing a

tracking system to record number of calls received, type and number of materials distributed). The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

5. Facilities, Staff, and Resources (25 Percent)

The extent to which the applicant can provide adequate facilities, staff and/or collaborators, and resources to accomplish the proposed goal(s) and objectives during the project period. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

6. Budget and Justification (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

Executive Order 12372

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372, which sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, ATTN: Joanne Wojcik, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, no later than 45 days after the application deadline. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, ATTN: Joanne Wojcik, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, no later than 45 days after the application deadline. The granting agency does not guarantee to ''accommodate or explain'' for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF 424).

B. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not to exceed one page, and include the following:

1. A description of the population to be served;

2. A summary of the services to be provided; and

3. A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.136.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Control Number 0937–0189) must be submitted to Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, on or before August 10, 1998.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the independent review committee. For proof of timely mailing, applicant must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

2. *Late Applications:* Applications that do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

The program announcement and application forms may be downloaded from the Internet: www.cdc.gov (look under funding). You may also receive a complete application kit by calling 1–888–GRANTS4. You will be asked to identify the program announcement number and provide a name and mailing address. A complete announcement kit will be mailed to you.

If you have questions after reviewing the forms, for business management technical assistance contact Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6535, Internet Address: jcw6@cdc.gov.

Programmatic assistance may be obtained from Judy Stevens, Ph.D., National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K63, Atlanta, GA 30341–3724, telephone (770) 488–4652, Internet Address: jas2@cdc.gov.

Please refer to Announcement Number 98088 when requesting

information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''INTRODUCTION'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

A copy of American Society for Testing and Materials (ASTM) Number 1292 may be obtained from ASTM, Customer Services, 1916 Race Street, Philadelphia, PA 19103–1187, telephone (215) 299–5585.

Dated: June 9, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–15805 Filed 6–12–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0378]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 19, 1998 (63 FR 27581). The document announced an opportunity for public comment on the proposed collection of certain information by the agency. The document published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

In FR Doc. No. 98–13228, appearing on page 27581 in the **Federal Register** of Tuesday, May 19, 1998, the following correction is made:

1. On page 27581, in the first column, ''[Docket No. 98N–0194]'' is corrected to read ''[Docket No. 98N–0378]''.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15770 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0357]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 15, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS) (21 CFR Part 820)—(OMB Control Number 0910–0073—Reinstatement)

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 (the Secretary) has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing the authority provided by this statutory provision is found in part 820 of the Code of Federal Regulations (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. 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 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