Dated: April 7, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0117]

Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the criteria it will use to accredit persons for the purpose of conducting inspections of eligible device manufacturers under section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which established an ''inspection by accredited persons'' program. The new law requires FDA to publish in the **Federal Register** the criteria it will use to accredit persons to conduct inspections of eligible device establishments. These criteria are set out in this document and will become effective immediately after approval by the Office of Management and Budget (OMB) of the collection of information proposed by FDA in connection with this program. At that time, FDA will begin accepting applications for this program. In this document, FDA is also announcing the availability of a guidance document that will provide information for those interested in participating in this newly-created program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff and Third Parties.'' In accordance with the agency's good guidance practices (GGPs), the guidance remains subject to comment at any time. FDA is taking these actions to implement provisions of MDUFMA.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section VI for information on electronic access to the guidance. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: http://www.fda.gov/dockets/ecomments. Identify comments with the docket number found in brackets within the heading of this document.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Director, Division of Small Manufacturers, International and Consumers Assistance, Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–6597 ext. 124.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to perform inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. The new law requires FDA within 180 days from the date MDUFMA was signed into law to ''publish in the **Federal Register** criteria to accredit or deny accreditation to persons who request to perform'' these inspections (section 704(g)(2) of the act). Under section 704(g)(2) of the act, through publication of this **Federal Register** document, the criteria set out in section II of this document will be binding on those persons who apply to become APs under this program. The criteria will be in effect immediately following approval by the OMB of the collection of information proposed by FDA in connection with this program. At that time, FDA will begin accepting applications for accreditation.

FDA is also issuing a guidance document that repeats the criteria it will use for accrediting APs. The guidance also addresses other aspects of this program such as the appropriate format and content for accreditation applications. The guidance is discussed further in section III of this document. Although it was not feasible to obtain comments before issuing the guidance due to tight statutory deadlines, in accordance with this agency's GGP procedures, FDA will accept comments on the guidance at any time.

The new law requires that no more than 15 firms receive accreditation during the 12 months following publication of this **Federal Register** document. In addition, on or before October 26, 2003, FDA must make available on its Web site a list of accredited firms that may conduct inspections and the specific information about the scope of their accreditation. Therefore, in order to comply with this statutory timeframe, FDA will not accept any applications for 2003 after August 25, 2003. The list of APs will be updated periodically but no later than 30 days after a new person is accredited. This update will show any withdrawal of accreditation or any change in activities for which an AP is accredited.

II. Accreditation Criteria

This section describes the criteria FDA will apply when making decisions about whether to accredit persons who request to conduct inspections of eligible class II and class III device manufacturers in lieu of FDA inspection. The guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties,'' repeats these criteria and provides suggestions on how applicants can address them in their application.

A. Minimum Requirements

Section 704(g)(3) of the act describes the minimum requirements that an AP must meet in order to be accredited by FDA. These requirements are that an AP:

1. May not be a Federal Government employee;

2. Shall be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of

articles regulated under the act and have no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor;

3. Shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

4. Shall not engage in the design, manufacture, promotion, or sale of articles regulated under the act;

5. Shall operate in accordance with generally accepted professional and ethical business practices and agree in writing that, at a minimum, it will:

(a) Certify that the reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with the act, and recommendations made during an inspection or at an inspection's closing meeting;

(b) Limit work to that for which competence and capacity are available;

(c) Treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the FDA;

(d) Respond promptly and attempt to resolve complaints regarding its activities for which it is accredited;

Protect against the use of any officer or employee of the AP to conduct inspections who has a financial conflict of interest regarding any product regulated under the act, and annually make available to the public disclosures of the extent to which the AP, and the officers and employees of the person, have maintained compliance with requirements relating to financial conflicts of interest.

B. Additional Criteria

In addition to the minimum requirements specified at section 704(g)(3) of the act for becoming an AP, this notice also establishes the following additional criteria:

1. Personnel Qualifications

FDA expects AP to have sufficient personnel, with the necessary education, training, skills and experience to review records and perform inspections. FDA will consider several factors when accrediting applicants. These include:

(a) Whether personnel have demonstrated knowledge of:

• The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*);

• The Public Health Service Act (42 U.S.C. 201 *et seq.*);

• Regulations implementing these statutes, particularly 21 CFR part 11 and parts 800–1271, with special emphasis on Parts 11, 801, 803, 806, 807, 809, 814, 820 and 821;

• FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers;

• Guide to Inspection of Quality Systems: Quality System Inspection Technique (QSIT); and

• FDA Investigations Operations Manual, Chapter 5–Establishment Inspection.

(b) Whether the applicant:

• Has established, documented, and executed policies and procedures to ensure that inspections are performed by qualified personnel, and will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the performance of inspections;

• Has available to its personnel clear, written instructions for duties and responsibilities with respect to inspections;

• Has identified personnel who, as a whole, are qualified in all of the quality system disciplines for the inspections under the AP scope of work; and

• Has identified at least one individual who is responsible for providing supervision over inspections and who has sufficient authority and competence to assess the quality and acceptability of inspection reports.

2. Infrastructure

APs need the capability to interface with FDA's electronic data systems, including the FDA Internet Web sites, and the CDRH Facts-On-Demand system. At a minimum, this would entail a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties. APs must also have physical security and safeguards for protecting trade secret and confidential commercial or financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

3. Prevention of Conflicts of Interest (COI)

An AP must be impartial and free from any commercial, financial, and other pressures that might present a COI or an appearance of a COI. To that end, when deciding whether to accredit a person, we will consider whether they have established, documented, and executed policies and procedures to prevent any individual or organizational COI, including conflicts that their contractors or individual contract employees may have.

Although it is not feasible to identify all of the circumstances that would raise concerns about COI in this document, the most common conditions that indicate an actual or a potential COI are:

a. The AP is owned, operated, or controlled by a manufacturer, supplier or vendor of any article regulated under the act. Please see http://www.fda.gov/ohrms/dockets/yellow/yellotoc.htm for examples of firms that are regulated by FDA and, therefore, would create a conflict. This includes manufacturers of radiation-emitting electronic products such as televisions, microwave ovens, compact disk players, laser printers, industrial lasers, as well as foods, drugs, biologics, cosmetics, veterinary products, and medical devices.

b. The AP has any ownership or financial interest in any product, manufacturer, supplier or vendor regulated under the act (see section II.B.3.a of this document);

c. Any personnel of the AP involved in inspections or their spouse or minor children have an ownership or other financial interest regarding any product regulated under the act (see link at section II.B.3.a of this document);

d. The AP or any of its personnel involved in inspections participates in the design, manufacture, promotion or sale of any product regulated under the act;

e. The AP or any of its personnel involved in inspections provides consultative services to any manufacturer, supplier or vendor of products regulated under the act (see link at section II.B.3.a of this document);

f. Any personnel of the AP involved in the inspection process participates in an inspection of a firm in which they had performed contract work (e.g. conformity assessment body audit, laboratory testing, or AP inspection) within the last 12 months;

g. Any personnel of the AP involved in the inspection process participates in an inspection of a firm they were employed by within the last 12 months;

h. The fees charged or accepted are contingent or based upon the recommendation in the report made by the AP.

When the AP uses the services of a contractor in connection with an inspection, it is responsible for the work of the contractor and its personnel. It will be the AP's responsibility to assure that the contractor meets the same criteria for freedom from COI as the AP and its personnel.

In addition to conducting inspections as an AP, an AP may also conduct other activities, such as objective laboratory testing of products regulated under the act or assessment of conformance to

standards, if those other activities do not affect the impartiality of inspections. Examples of conflicted laboratory testing, i.e., activities an AP may not perform, are routine quality production tests, validation/verification studies, and quality assurance-related testing.

Information on the COI standards FDA applies to its own personnel is included in appendix 1 of the guidance entitled ''Standards for Ethical Conduct for Employees of the Executive Branch.'' An AP may adopt these standards, utilize the model COI policy FDA has provided as another appendix to the guidance, or demonstrate how alternative equivalent procedures will safeguard against COI.

4. Training

An AP will not be eligible to conduct independent inspections until they have successfully completed the classroom training required by FDA and conducted a satisfactory performance inspection under FDA observation. Firms identified on the FDA's list of APs to perform inspections will designate employees to participate in the classroom training and joint qualifying inspections. FDA will train no more than three employees per AP during the training sessions to be held by FDA in January 2004. FDA strongly encourages each AP to send at least two employees to the training, in recognition of employee attrition. APs with multiple sites engaged in FDA inspectional activities should request permission from the agency to send one representative from each site, not to exceed a total of five representatives from each AP.

Training for APs will be ''modeled'' after training of European Union Conformity Assessment Bodies (EU CABs) under the Mutual Recognition Agreement (MRA) Implementation Plan. (See http://www.fda.gov/cdrh/mra/guidance/mraprocedure.html.) EU CABs that have been accredited as APs and whose personnel have successfully completed the required training and/or joint inspections under the MRA program should state this in their application. If confirmed by FDA, the AP will not be required to have a representative repeat the classroom training or joint qualifying inspections. However, FDA does recommend that the AP send a representative to the FDA Investigator Training module as an update. Personnel trained by FDA under the MRA program who do not attend the current training will need to review a videotaped FDA presentation on evidence development.

The FDA training will consist of a two tiered program.

Tier one will include formal classroom training for AP inspectional staffers (trainees). At a minimum this will include:

a. The Association for the Advancement of Medical Instrumentation (AAMI) GMP/ Quality System: Requirements and Industry Practice (or equivalent). AAMI will be conducting this training throughout the United States and in Frankfurt, Germany in 2003; see AAMI web site at http://www.aami.org/meetings/courses/gmp.html[1] for specific dates and locations. Please note that you must register separately for the training session and the examination. The AAMI training schedule for 2004 will not be posted until late 2003.

b. FDA's Quality System Inspection Technique (QSIT) training module.

c. FDA Investigator Training, which will include training on:

- Food and drug law,
- Advanced QSIT,
- FDA inspectional procedures,
- FDA policies and device regulations and
- Evidence development.

FDA plans to conduct its training sessions from January 12 through 16, 2004, in the Washington, DC metropolitan area. FDA will make a final decision on applications in early October 2003, and plans to advise applicants and post the list of APs on the Internet in mid-October. Each applicant to this program should make tentative plans to send appropriate representatives to the FDA Investigator Training. However, only those applicants that are confirmed as APs in October will be eligible to attend the training. Applicants should advise FDA in their AP application of the names of the employee(s) that have either successfully completed this training or those who will be nominated to participate in this training. AP trainees will not qualify to enter the second tier, unless they successfully pass a test at the end of each tier one training session.

The second tier will involve the completion of three joint inspections, during which FDA and the AP will address the relevant parts of Compliance Program 7382.845—Inspection of Medical Device Manufacturers and the QSIT guidance—Guide to Inspection of Quality Systems. The three joint inspections will include:

(a) Collaborative Inspection—The FDA investigator will be the lead inspector and the AP trainee will act primarily as an observer. The FDA investigator will prepare a list of any nonconformities and an inspection report. The trainee will prepare a ''practice'' list of nonconformities and an inspection report.

(b) Modified Performance Inspection—Using established criteria, the FDA investigator will observe and evaluate the trainee performance of an inspection and may provide assistance. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report.

(c) Full Performance Inspection—The AP trainee will perform an independent inspection and will be observed and evaluated by the FDA investigator using established criteria. The FDA investigator may not provide assistance to the trainee. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report. The FDA investigator's evaluation of the trainee and recommendation will be presented to the FDA Office of Regulatory Affairs (ORA) certifier in the FDA Division of Human Resource Development who will determine if the trainee is qualified to perform independent inspections.

The criteria FDA will use to evaluate the joint inspections will be addressed at the FDA training sessions to be held in January 2004.

5. Evaluation of the AP Application

(a) The Third Party Recognition Board (TPRB) Chairman will e-mail the applicant's contact person, within 24 hours of receipt of the AP application, acknowledging receipt.

(b) Members of the TPRB will perform an initial review to determine if the request for accreditation addresses the information set forth below in section II.B.6 of this document, Contents of an AP Application, and is adequate for review by the full TPRB.

(c) The TPRB Chairman will advise the contact individual, via e-mail, within 60 days after the receipt of such request for accreditation, whether the request is adequate for review by the TPRB or whether additional information is needed.

[1] FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

(d) If the application is deficient, FDA will identify its shortcomings and advise the applicant so it may submit additional information within the designated time period. FDA may deem the application incomplete and deny the request for accreditation if the applicant fails to respond to a request for additional information in a timely manner. All information submitted to FDA in response to any requests for additional information should be received no later than September 25, 2003.

(e) If the application is adequate, FDA will file it for full review, rating and ranking by the TPRB. A rating criteria checklist will be used to assess the relevant qualifications and competence of persons applying to become APs. The agency has assigned a weight (5, 15 or 20) to each of eight elements. The eight elements are addressed in section II.B.6 of this document, Contents of an AP Application. The weight of the element is based on how essential the information is in determining if the applicant is suitable to perform Quality System / Good Manufacturing Practices (QS/GMP) inspections on behalf of FDA. Each member of the TPRB will assess each of the eight elements and will vote a ''quality level'' score from 0 to 4 (0 = Unsatisfactory, 2 = Satisfactory, 4 = Exceeds) for each element. The final Quality Level Score will be determined by a majority vote of the TPRB. Quality Level Score x Weight = Element Score. The eight element scores will be totaled to yield an ''Application Rating'' (maximum rating attainable is 400). The TPRB will then rank the applications (highest application rating first).

(f) If more than 15 applicants seeking accreditation satisfy the minimum requirements, FDA will accredit the 15 applicants that have the highest scores. If fewer than 15 persons are initially accredited, additional applications will be considered during the 12 months that follow the publication of this guidance. Persons seeking accreditation that are not among the 15 highest ranking applications can reapply 12 months after the publication of this guidance and persons who did not previously apply may also apply 12 months after publication of this guidance.

(g) FDA may deny the request for accreditation if we determine that the application does not meet the criteria established for APs or scores lower than the 15 highest rated applications received by August 25, 2003.

(h) FDA will stop accepting applications on August 25, 2003. FDA plans to publish on its Web site the List of Persons Accredited for Inspections on or before October 26, 2003.

6. Contents of an AP Application

Applicants should include the information described as follows:

(a) Administrative Information

- Application in English;
- Name and address of the organization seeking accreditation;
- Telephone number and e-mail address of the contact person. The contact person should be the individual to whom questions about the content of the application may be addressed and to whom a letter of determination and general correspondence will be directed;
- Name and title of the most responsible individual at the AP. Foreign applicants may wish to identify an authorized representative located within the United States who will serve as the AP's contact with FDA;
- Name and title of the most responsible individual at the parent organization, if applicable;
- Brief description of the applicant, including: type of organization (e.g., not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); organizational charts showing the relationship of the organization involved in the AP inspection program and its relationship with parent or affiliate companies; number of years in operation; nature of work (e.g., conformity assessment testing or certification laboratory); and sufficient information regarding ownership, operation, and control of the organization to assess its degree of independence from manufacturers and distributors of products regulated under the act. Please include your annual report or, if it is available electronically on the Internet, please include the appropriate Web site address. If the applicant's organization has offices in numerous locations, please be specific and name all locations that you plan to participate in the AP inspection process for your firm. Applicants may include all locations under one application if they will operate under the same processes and procedures for AP inspections. Include curriculum vitae (CVs) for all supervisory personnel and explain where supervisory oversight will be located;
- List countries that have certified, accredited or recognized the applicant for quality system or GMP inspections/auditing and the date of such certification, accreditation, or recognition;
- Specify any accreditation for assessment of quality systems that you may have, such as accreditation to ISO/IEC Guide 62. If you are accredited to standards other then Guide 62, please provide copies of the standards in English.
- Activities for which the AP seeks accreditation. This includes a list identifying the devices the applicant seeks to inspect. Applicants may simply state ''all devices'' or identify the devices they wish removed from their scope of work by classification panel or by classification name (e.g., except cardiovascular devices under 21 CFR part 870 or except 21 CFR 870.3620, 870.3630, 870.3640, and 870.3670).

(b) Prevention of Conflict of Interest

The applicant should submit a copy of the written policies, procedures and sample certification/compliance statements established to prevent conflicts of interest. MDUFMA requires that the AP and its employees (including contract employees) involved in the performance of inspections and the preparation and approval of reports be free from conflicts of interest and the appearance of conflicts of interest that might affect the inspection process. No personnel of an AP involved in inspections, nor their spouses or minor children, may have ownership of or other financial interest in any product regulated under the act. In accordance with section 704(g)(3)(E) of the act, APs will annually make available to the public the extent to which the AP complies with conflict of interest requirements.

(c) Technical Competence

FDA will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent inspections. The applicant should document these factors in its application and include:

- The written policies and procedures established to ensure that manufacturers are inspected by qualified personnel;
- The written instructions for the duties and responsibilities of personnel, including inspectors, with respect to the inspection of device manufacturing facilities;
- The written personnel qualification standards established to ensure that inspectors and other designated personnel are qualified in all of the regulatory and technical disciplines needed to effectively inspect for compliance with FDA's regulatory requirements for medical devices;
- The documentation (e.g., CVs) to establish that the inspectors and other involved non-supervisory personnel meet the established criteria for qualified personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including specialized education and experience needed for

the inspection of manufacturers' facilities;

• The documentation (e.g., CVs) to establish that the supervisor(s) of inspectors have sufficient authority and meet the established criteria for qualified supervisory personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including any specialized education and experience needed to supervise the inspection and review records prepared by inspectors;

• A description of the applicant's management structure and that of any contractor used for inspection work. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of the inspectors and other personnel involved in the inspection process. (If the applicant plans to utilize contractors, please address the additional information described at section II.B.6.f of the document, Contractors);

• A description of the inspection team. This includes documentation for any members of the team who may already have training and experience relevant to the assessment of compliance with FDA's regulatory requirements for medical devices (e.g., compliance programs, the QS regulation, and general auditing principles). The description should include documentation of the ability of the team to recognize, collect and identify evidence of noncompliance and adequately communicate with the manufacturer regarding the inspection;

• Documentation that personnel involved in inspections have broad quality systems knowledge and are qualified in accordance with generally accepted quality assurance standards, (e.g., ISO 10011–2 or 21 CFR part 820) and capable of functioning in accordance with the relevant parts of these standards;

• Documentation of training plan to assure technical competence;

• Documentation of records that demonstrate the appropriate experience and training of each inspector.

(d) Resources

The applicant should identify what reference materials are available to inspectors and other personnel involved in inspections, (e.g., the act, regulations, manuals, standards). Also, the application should identify equipment and resources available that will enable the inspector to perform technical and administrative tasks. At a minimum, this should include a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties.

APs should have physical security and safeguards in place for protecting trade secret and confidential commercial and financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

(e) Confidentiality

The applicant should include established procedures to ensure confidentiality of reports and all information obtained during an inspection. These should address aspects of authorized disclosure and the procedures by which the applicant maintains confidentiality between itself and the manufacturer. In addition, the applicant should describe the procedures through which the applicant's personnel and any contractors are made aware of confidentiality requirements.

(f) Contractors

FDA will consider several factors to determine whether the applicant ensures that contractors are properly qualified, utilized, and monitored. Special emphasis will be placed on personnel qualifications and preparedness to conduct technically competent inspections, and on conflict of interest controls. The applicant should document these factors in the application and include:

• The written policies and procedures established to ensure that contractors conform to the same requirements (e.g., education, training, and experience) that would apply to the applicant if it were performing the inspection or aspects of the inspection contracted. These policies and procedures should ensure that the contractor conducts inspections in accordance with the same procedures under which the applicant operates. The applicant should include assurances that it will maintain documentary evidence that the contractor has the necessary technical competence and resources to carry out contracted activities;

• Written policies and procedures documenting that the applicant will not contract the overall responsibility for reviewing the results of the inspections;

• Documentation of an agreement delineating the duties, responsibilities, and accountability of the contractor; and

• The written policies and procedures for establishing a register of qualified contractors.

(g) AP Quality System

FDA will consider the following factors to determine whether the applicant has established an adequate quality system to ensure compliance with FDA policies and procedures relevant to inspections:

• The applicant should establish a documented quality system to ensure that there are processes and procedures in place to demonstrate compliance with section 704(g) of the act;

• The policies and procedures the applicant follows are adequate to maintain control of all quality system documentation and to ensure that a current version is available at all locations; and

• The policies and procedures for internal auditing to ensure the quality system is implemented effectively and that resources are available for conducting such audits.

(h) Certification Agreement Statement

The applicant should provide a copy of a documented statement, which will be signed by the most responsible individual, certifying that:

• The AP has appropriate policies and procedures to meet FDA's conflict of interest provisions, has the appropriate staff and procedures in place to ensure technical competence for conducting inspections under section 704(g) of the act, and has the quality system in place to ensure acceptable and consistent inspections;

• Where the AP uses the services of a contractor for Quality System (QS)/GMP inspections, the AP should also certify that its contractor(s) meets the APs established criteria for freedom from conflicts of interest and technical competence;

• The AP consents to FDA inspection and copying of all records, correspondence, and other materials relating to any inspections conducted by the AP under this program, including records on personnel, education, training, skills, and experience and all documentation on prevention of conflicts of interest, including certification/compliance statements; and

• The AP will protect trade secret and confidential commercial or financial Information, and will treat as private information about specific patient identifiers in records such as adverse event reports, except that such information may be made available to FDA.

III. The Guidance

We are also issuing a guidance entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties,''

which repeats the AP criteria set out in section II of this document. In addition, the guidance provides other useful information such as suggestions about the format and content of the accreditation applications.

The guidance represents the agency's current thinking on the ''Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties.'' The issuance of this guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This document and the guidance entitled ''Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties'' contain a proposed collection of information that requires clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995. In a document found elsewhere in this issue of the **Federal Register**, FDA is announcing that this proposed collection of information has been submitted to OMB for emergency processing. The document also solicits comments concerning the proposed collection of information.

FDA will publish a separate document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions contained in this document and the guidance. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

Interested persons may submit their written or electronic comments regarding the guidance at any time to Dockets Management Branch (see **ADDRESSES**). Submit either a single copy of the electronic comments to: http://www.fda.gov/dockets/ecomments or send two paper copies of any mailed comments (individuals may submit only one copy). Identify comments with the docket number found in brackets in the heading of this document. Comments received will be made available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

To receive ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Guidance for Industry, FDA Staff, and Third Parties'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1200) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10415 Filed 4–23–03; 5:03 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act: CARE Act Data Report (CADR) Form: Extension (OMB No. 0915–0253)

The CARE Act Data Report (CADR) form, created in 1999 by the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA), is designed to collect information from grantees, as well as their subcontracted service providers, funded under titles I, II, III and IV of the Ryan White (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under title XXVI of the Public Health Services Act). All titles of the CARE Act specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records of the providers receiving CARE Act funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

CARE Act grantees are required to report aggregate data to HRSA annually. The CADR form is used by grantees and their subcontracted service providers to report data on six different areas: service provider information, client information, services provided/clients served, demographic information, AIDS