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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