POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

Information collected will be retrieved by the name or other identifying information of the participating provider, and may also be retrievable by HICN at the individual beneficiary record level.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E–Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. Office of Management and Budget Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain identifiable information maintained in the MCMP system of records for a period of 6 years. Data residing with the designated claims payment contractor shall be returned to CMS at the end of the project, with all data then being the responsibility of CMS for adequate storage and security. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Medicare Demonstration Program Group, Office of Research Development and Information, CMS, 7500 Security Boulevard, Mail stop C4–17–27, Baltimore, Maryland, 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name, provider identification number, and the patient's medical record number.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Information maintained in this system will be collected from physicians volunteering to participate in the MCMP Demonstration. Additional data will be collected from Medicare claims payment records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–19907 Filed 10–5–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Essentials of Food and Drug Administration Device Regulations: A Primer for Manufacturers and Suppliers; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Philadelphia District, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a public workshop on FDA device regulations. This 1 1/2-day public workshop for start up and small device manufacturers and their suppliers will include both industry and FDA perspectives and a question and answer period.

Date and Time: The public workshop will be held on Tuesday, October 11, 2005, from 8:30 a.m. to 5:30 p.m. and Wednesday, October 12, 2005, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at The Wyndham Philadelphia at Franklin Plaza, 17th and Race St., Philadelphia, PA 19103, 215–448–2000. For further hotel information and driving directions, go to *http://www.wyndham.com/hotels/PHLFP*. (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**.)

Contact:

For FDA: Judy Summers-Gates, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–717–3008, FAX: 215–597–4660, e-mail: *judith.summers-gates@fda.gov*.

For AdvaMed: Krystine McGrath, 202–434–7237, FAX: 202–783–8750, *kmcgrath@advamed.org*; or Dia Black, 202–434–7231, FAX: 202–783–8750, e-mail: *dblack@avamed.org*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of $350 per person to the AdvaMed contacts (see *Contact*). The registration fee for FDA employees is waived. To register via the Internet go to *http://www.advamed.org/philadelphia*. (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**.)

Payment forms accepted are major credit card (MasterCard, Visa, or American Express) or company check. If you wish to pay by check contact Krystine McGrath (see *Contact*). For more information on the meeting, or for questions on registration, contact Krystine McGrath or Dia Black (see *Contact*). Attendees are responsible for their own accommodations.

The registration fee will be used to offset the expenses of hosting the workshop, including meals (breakfasts and a lunch), refreshments, meeting rooms, and training materials. It also includes a networking reception on Tuesday, October 11, 2005. Space is limited, therefore interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Judy Summers-Gates at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''Essentials of FDA Device Regulations: A Primer for Manufacturers and Suppliers'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- The quality system regulations and inspections;
- Complaints, medical device reporting, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—where do you go for assistance?;
- General question and answer session;
- Manufacturers and suppliers—the chain of regulatory responsibility;
- Reimbursement and medical rechnology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

Dated: September 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20093 Filed 10–5–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0391]

Draft Guidance for Industry and Food and Drug Administration Staff; Functional Indications for Implantable Cardioverter Defibrillators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Functional Indications for Implantable Cardioverter Defibrillators.'' Many implantable cardioverter defibrillators (ICDs) currently have a functional indication. This draft guidance is designed to describe ICD functional indications and the types of devices appropriate for the indication; to provide guidance regarding labeling, advertising, and promotion of ICDs with an approved functional indication and cardiac resynchronization therapy defibrillators (CRT/ICDs) with an approved indication that describes the function of the ICD component; and to discuss when to submit an application for an investigational device exemption (IDE) for a study involving a potential new patient population for an ICD with an approved functional indication.

DATES: Submit written or electronic comments on this draft guidance by January 4, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Functional Indications for Implantable Cardioverter Defibrillators'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (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 in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For premarket issues: Owen Faris or Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

For promotion and advertising issues: Deborah Wolf, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4589.

SUPPLEMENTARY INFORMATION:

I. Background

Prior to June 2000, the indication statement for ICDs included language to describe the types of patients who would benefit from an ICD. If a manufacturer demonstrated in a clinical trial that a new patient population benefited from its ICD, that manufacturer could submit a premarket approval application (PMA) supplement to update its indication statement to include that new patient population. That manufacturer could then promote its ICD as indicated for the new population. On June 20, 2000, FDA held a public meeting of the Circulatory Systems Devices Panel to introduce the concept of a functional indication. The functional indication describes what the device does and does not explicitly specify as an indicated patient population or expected outcome. FDA presented the functional indication as a least burdensome method of allowing the clinical community to identify the patient populations that would benefit from an ICD. The panel endorsed the functional indication concept for ICDs and, since that time, FDA has approved a functional indication for most manufacturers' ICDs. This guidance document is intended to discuss the intended patient population for ICDs with an approved functional indication and CRT/ICDs with an approved indication that describes the function of the ICD component, labeling, advertising, and promotion of those ICDs and CRT/ICDs, and when to submit an application for an IDE for a