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

study involving a potential new patient population for an ICD with an approved functional indication.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on functional indications for ICDs. 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 statute and regulations.

III. Electronic Access

To receive ''Functional Indications for Implantable Cardioverter Defibrillators '' by fax, 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 1304 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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 Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing IDEs (21 CFR part 812, OMB control number 0910–0078) and PMAs (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before January 4, 2006. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20092 Filed 10–5–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

[DHS–2005–0066]

Office of Inspector General; Privacy Act of 1974; Systems of Records

AGENCY: Office of Investigations, Office of Inspector General, Department of Homeland Security.

ACTION: Notice of revised Privacy Act systems of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security Office of Inspector General is giving notice of a revised and updated system of records titled, ''Investigations Data Management System (IDMS).''

DATES: Comments must be received on or before November 7, 2005.

ADDRESSES: You may submit comments, identified by Docket Number DHS–2005–0066, by *one* of the following methods:

EPA Federal Partner EDOCKET Web site: *http://www.epa.gov/feddocket.* Follow instructions for submitting comments on the Web site. DHS has joined the Environmental Protection Agency (EPA) online public docket and comment system on its Partner Electronic Docket System (Partner EDOCKET).

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Fax: (202) 254–4285 (This is not a toll-free number).

Mail: Richard N. Reback, DHS, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528.

Hand Delivery/Courier: Richard N. Reback, DHS, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to *http://www.epa.gov/feddocket,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket.* You may also access the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Richard N. Reback, Department of Homeland Security, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528 by telephone (202) 254–4100 or facsimile (202) 254–4285; Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, 601 S. 12th Street, Arlington, VA 22202–4202 by telephone (571) 227–3813 or facsimile (571) 227–4171.

SUPPLEMENTARY INFORMATION:

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which personally identifiable information is put, and to assist the individual in finding such files within the agency.

The Department of Homeland Security (DHS), Office of Inspector