availability of a guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance.'' This guidance document provides examples of the agency's criteria and approaches for determining which products may be subject to postmarket surveillance (PS) under the Food and Drug Administration Modernization Act of 1997 (FDAMA). In developing this guidance document, the agency considered comments received from consumer, clinical, and industry representatives at a public meeting on changes in medical device tracking and PS authority on January 15, 1998, in Gaithersburg, MD. To facilitate conformance with the requirements under FDAMA, this guidance document is immediately in effect.

DATES: Written comments concerning the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' must be received by February 1, 1999. After February 1, 1999, you may submit written comments on the guidance document to the contact person listed below.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' on a 3.5'' diskette to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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 for information on electronic access to the guidance document.

Submit written comments regarding this guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Anita M. Rayner, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0639.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 amended the Federal Food, Drug, and Cosmetic Act (the act), among other things, to add section 522 (21 U.S.C. 360l) to require PS for certain medical devices. Section 522 of the act was further amended by FDAMA (Pub. L. 105–115). As amended, section 522 of the act revises the criteria for determining which devices are subject to PS and revises the procedures for implementing PS. The revised provisions of section 522 of the act became effective on February 19, 1998. FDA is making this guidance document available at this time in order to facilitate the initial implementation of the revised PS provisions.

This guidance document represents the agency's current thinking on criteria and approaches for PS. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's. This document is for immediate implementation to facilitate conformance with PS changes in section 522 of the act under FDAMA.

II. Electronic Access

In order to receive the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (009) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance on Criteria and Approaches for Postmarket Surveillance,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

III. Comments

Interested persons may, on or before February 1, 1999, submit to Dockets Management Branch (address above) written comments regarding the guidance document. After February 1, 1999, submit to the contact person (address above) written comments regarding the guidance document. Such comments will be considered when determining whether to amend the current guidance document. Two copies of any comments are to be submitted, 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29390 Filed 11–2–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0108]

SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols.'' This guidance is for industry and FDA staff. This document indicates the agency's intent to terminate or continue postmarket surveillance (PS) orders for existing products and describes the criteria used to reach these determinations.

DATES: Written comments may be submitted at anytime.

ADDRESSES: Submit written comments on ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols'' to the contact person. Submit written

requests for single copies on a 3.5'' diskette of the guidance document entitled ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, 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 for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Laura A. Alonge, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0648.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Safe Medical Devices Act (the SMDA) of 1990, FDA had implemented required PS (RPS) for 17 category ''A'' devices (permanent implants the failure of which could result in death or serious injury) and one category ''C'' device (plasma sprayed porous coated hips). In addition, the discretionary PS (DPS) authority under the SMDA had been used to order studies of a number of devices. The FDA Modernization Act (FDAMA) of 1997 (Pub. L. 105–115) has significantly modified the requirements for PS under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l). Under FDAMA, PS may be ordered only for those devices that are Class II or Class III the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be: (1) Implanted in the human body for more than 1 year, or (2) [is] life sustaining or life supporting and used outside a device user facility. The draft of this guidance was made available for comment on February 25, 1998. FDA received comments from three sources. General comments were supportive of the criteria used to make the determinations contained in the guidance and urged that manufacturers of devices for which PS orders would be rescinded be notified as quickly as possible. FDA agrees with these comments as well as comments related to three specific devices: Replacement heart valve, implantable cardioverter-defibrillator (ICD), and plasma-sprayed porous coated hip. The guidance for replacement heart valves and ICD's has been revised accordingly. The comments on the plasma-sprayed porous coated hip did not affect the guidance, but will be considered in the evaluation of each existing protocol for continuation or termination of PS requirements.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the disposition of existing PS protocols. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 318 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols'' will be available at ''http://www.fda.gov/cdrh/modact/modguide.html''.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29389 Filed 11–2–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0928]

Semiannual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the first semiannual guidance document agenda. FDA committed to publishing, on a semiannual basis, possible guidance topics or documents for development or revision during the next year, and seeking public comment on additional ideas for new or revisions of existing guidance documents. This commitment was made in FDA's February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidances.

DATES: Comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: