DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0924]

Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry.'' This guidance is intended to provide recommendations for information that is to be included in premarket submissions—investigational device exemption (IDE), premarket approval application (PMA), and 510(k) submisions for medical devices that either contain or are exposed to animal-derived materials during manufacturing.

DATES: Written comments concerning this guidance must be received by February 4, 1999. Comments submitted after February 4, 1999, must be submitted to one of the contact persons.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry'' to the Division of Small Manufacturers 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. Written comments concerning this guidance must be submitted 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Karen F. Warburton, Office of Device Evaluation (HFZ–460), or Kiki B. Hellman, Office of Science and Technology (HFZ–113), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–7158.

SUPPLEMENTARY INFORMATION:

I. Background

FDA believes that an animal disease such as bovine spongiform encephalopathy (BSE) is a concern in the manufacture of FDA-regulated products intended for administration to humans. In 1993 and, more recently, on May 6, 1996, FDA issued letters to manufacturers to request that bovine-derived materials from cattle which have resided in or originated from countries where BSE has been diagnosed (as designated by the U.S. Department of Agriculture) not be used in the manufacture of FDA-regulated products. To identify medical devices which either contain or are exposed to animal-derived materials during manufacturing, CDRH developed the biomaterials database that contains an inventory of these devices, including type of material, animal species and county of origin, and target organ or tissue for each device. Originally proposed in response to the BSE issue, the database was expanded to include all animal-derived products (including human) in order to respond to other animal-based sourcing concerns that may arise in the future.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical devices containing materials derived from animal sources. 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. The agency is accepting public comments, but it is implementing this guidance immediately because of public health concerns related to the use of bovine-derived materials in medical devices and the agency's previous communication to manufacturers on this subject.

III. Electronic Access

In order to receive ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry'' via your fax machine, call the CDRH Facts–On–Demand 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 (2206) 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 Web. Updated on a regular basis, the CDRH home page includes ''Medical Devices Containing Materials Derived From Animal Sources (Except In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry,'' 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. ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry'' will be available at http://www.fda.gov/cdrh/ode/guid.html.

IV. Comments

Interested persons may, on or before February 4, 1999, submit to Dockets Management Branch (address above) written comments regarding this immediately in effect guidance. At any time after 90 days from the date of publication in the **Federal Register**, 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.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29750 Filed 11–5–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0896]

Guidances for the Medical Device Industry on PMA Shell Development and Modular Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review.'' This guidance describes a new program for the submission and review of premarket approval applications (PMA's) in a modular format, termed the ''PMA Shell.'' FDA is issuing this document as part of its commitment to improve the PMA development and review processes.

DATES: Written comments concerning this guidance must be received by February 4, 1999.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review'' (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 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 on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ashley A. Boulware or Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–460 or HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053 or 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Despite a marked improvement in device approval times, FDA's Center for Devices and Radiological health (CDRH) is committed to substantial improvement of the PMA development and review processes. Often FDA's involvement with the product has been greatest during review of the PMA, which is at the end of the process. This new program involves the development of a plan for modular submission, termed the ''PMA Shell,'' and the submission of sections of the PMA, termed modules, to increase early and effective interactions with applicants.

The essence of the modular concept for data development, submission, review, and closure is to break the contents of a PMA into well delineated components (modules) that can be submitted over time; this is expected to be particularly applicable to the preclinical information as the clinical data are being developed. The PMA Shell is a document that is proposed by the potential PMA applicant and agreed to by CDRH. The PMA Shell is used to identify the proposed modules and the proposed contents for each module. The PMA Shell allows CDRH to prospectively determine whether each proposed module will be appropriate as a document that can be reviewed separately from other information needed to evaluate the PMA. For example, the toxicology data may be appropriate as a module, whereas labeling may not be appropriate as a module independent of the clinical study data. Modules will be submitted to CDRH for review. Once they are complete and acceptable to FDA, modules will not generally be reevaluated unless a significant safety and effectiveness issue later develops that bears on the previously reviewed module.

Through increased interaction with applicants and earlier review of data and analyses, CDRH expects this program to increase the efficiency of PMA review by reviewing and bringing to closure modules nearer to when the data are developed and when the corporate staff who developed the data should most easily be able to respond to any need for clarification of the reports.

II. Significance of Guidance

This guidance document represents the agency's current thinking on improving the PMA process. 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 satisfied 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. Comments

Interested persons may, on or before February 4, 1999, submit to the Dockets Management Branch (address above) written comments regarding this guidance. After February 4, 1999, submit written comments regarding this guidance to the contact persons (address above). 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.

IV. Electronic Access

In order to receive ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review'' via your fax machine, call the CDRH Facts-On-Demand 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 (835) 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 Web. Updated on a regular basis, the CDRH home page includes ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review,'' 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.