

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0559]

Draft Guidance for Industry and Food and Drug Administration Staff; Heart Valves — Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled “Heart Valves — Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications.” This draft guidance document describes FDA’s recommendations about investigational device exemption and premarket approval applications for heart valves. This draft guidance document is not final, nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 20, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Heart Valves — Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, Room 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. 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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carolyn D. Vaughan, Center for Devices

and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1230, Silver Spring, MD 20993, 301-796-6338.

SUPPLEMENTARY INFORMATION:

I. Background

On October 14, 1994, FDA issued a guidance document on replacement heart valves (“the 1994 draft”), before the implementation of FDA’s good guidance practices regulation. FDA withdrew the 1994 draft on January 5, 2005 (70 FR 824) and is now issuing this new draft guidance document for public comment. This draft guidance document describes FDA’s recommendations about manufacturing, preclinical in vitro bench testing, preclinical in vivo studies, clinical investigations, and labeling that are different from or in addition to the recommendations of the International Organization For Standardization (ISO), ISO 5840:2005, “Cardiovascular Implants — Cardiac Valve Prostheses” (ISO 5840). Although the draft guidance document provides complementary information to ISO 5840:2005, the draft guidance document can also be used with other methods equivalent to ISO 5840:2005.

II. Significance of Guidance

This draft guidance document is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance document, when finalized, will represent the agency’s current thinking on “Heart Valves — Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications.” 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

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive “Heart Valves — Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications,” you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document, or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1607).

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. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/default.htm>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520) (the PRA). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0338; and the collections of information in parts 50 and 56 have been approved under OMB control number 0910-0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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: January 9, 2010.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

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