DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0191]

The Use of Bayesian Statistics in Medical Device Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: The Use of Bayesian Statistics in Medical Device Clinical Trials. The draft guidance entitled ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' provides FDA's recommendations on the use of Bayesian statistical methods in the design and analysis of medical device clinical trials.

DATES: The public meeting will be held on July 27, 2006, from 8:30 a.m. to 5 p.m. Registration for this meeting is required (see the Registration section of this document for details). Submit written or electronic comments on the draft guidance by August 21, 2006.

ADDRESSES: The public meeting will be held at The Universities at Shady Grove, 9630 Gudelsky Dr., Rockville, MD. Additional information about and directions to the facility are available on the Internet at *http://www.fda.gov/cdrh/meetings/072706-bayesian.html*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3150, ext. 121, FAX: 240–276–3151, e-mail: *Cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Bayesian statistics is a theory and approach to data analysis that provides a coherent method for learning from evidence as evidence accumulates. In situations where good information on clinical use of a device already exists, the Bayesian approach may enable FDA to reach the same decision on a device with a smaller-sized or shorter-duration pivotal trial. In other instances, a Bayesian approach can provide flexible methods for handling interim analyses and other modifications to trials. The draft guidance entitled ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' describes FDA's current thinking on statistical aspects of the design and analysis of medical device clinical trials that use Bayesian statistical methods. FDA announced the availability of the draft guidance on May 23, 2006 (71 FR 29651). The draft guidance is available at *http://www.fda.gov/cdrh/osb/guidance/1601.html*.

II. Agenda

FDA will provide presentations on the draft guidance entitled ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' in the morning. In the afternoon, panels will discuss the draft guidance. There will be opportunities for public participation throughout the day.

III. Registration

Online registration for the meeting is required. Acceptance will be on a first-registered, first-served basis. There are no assurances of onsite registration. Please register online at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfsud/bayesian_meeting.cfm*.

FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfsud/bayesian_meeting.cfm* by July 21, 2006.

Persons without Internet access may call 240–276–3150, ext. 121, by July 21, 2006, to register for onsite meeting attendance or to register to listen to the meeting by phone. If you need special accommodations due to a disability, please contact Cindy Garris (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

IV. Request for Input and Materials

FDA is interested in receiving input from stakeholders on the draft guidance. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**). FDA will place an additional copy of any material it receives on the docket (Docket No. 2006D–0191). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: June 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms (OMB No. 0915–0043)—Extension

The Health Education Assistance Loan (HEAL) program continues to administer and monitor outstanding loans which were provided to eligible students to pay for educational costs in