## 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 The draft guidance entitled ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' provides FDA's recommendations on the use of Bayesian statistical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 Submit written or electronic comments on the draft guidance by August 21, 2006.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 The draft guidance entitled ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' describes FDA's current thinking on statistical aspects of the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.*

[FR Doc. 06–5804 Filed 6–26–06; 12:30 pm]

**BILLING CODE 4160–01–S**

## 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

a number of health professions. HEAL forms collect information that is required for responsible program management. The HEAL Repayment Schedule, Fixed and Variable, provides the borrower with the cost of a HEAL loan, the number and amount of payments, and the Truth-in-Lending disclosures. The Lender's Report on HEAL Student Loans Outstanding (Call Report) provides information on the status of loans outstanding by the number of borrowers and total number of loans whose loan payments are in various stages of the loan cycle, such as student education and repayment, and the corresponding dollar amounts. These forms are needed to provide borrowers with information on the cost of their loan(s) and to determine which lenders may have excessive delinquencies and defaulted loans.

The estimate of burden for the forms is as follows:

| Form | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Repayment Schedule HRSA 502 | 8 | 666 | 5,328 | .5 | 2,664 |
| Call Report HRSA–512 | 20 | 4 | 80 | .75 | 60 |
| Total | 28 | | 5,408 | | 2,724 |

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 22, 2006.

**Cheryl R. Dammons,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E6–10236 Filed 6–28–06; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### ''Low Income Levels'' Used for Various Health Professions and Nursing Programs Included in Titles III, VII and VIII of the Public Health Service Act

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is updating income levels used to identify a ''low income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training for individuals from disadvantaged backgrounds. These various programs are included in Titles III, VII and VIII of the Public Health Service (PHS) Act.

The Department periodically publishes in the **Federal Register** low income levels used to determine eligibility for grants and cooperative agreements to institutions providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from ''low income families.''

**SUPPLEMENTARY INFORMATION:** The various health professions and nursing grant and cooperative agreement programs that use the low-income levels to determine whether an individual is from an economically disadvantaged background in making eligibility and funding determinations generally make awards to: Accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health podiatric medicine, nursing, chiropractic, public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

**Low-Income Levels**

The Secretary defines a ''low income family'' for programs included in Titles III, VII and VIII of the PHS Act as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together or an individual who is not living with any relatives. Most HRSA programs use the income of the student's parents to compute low income status, while a few programs, depending upon the legislative intent of the program, programmatic purpose of the low income level, as well as the age and circumstances of the average participant, will use the student's family as long as he or she is not listed as a dependent upon the parents' tax form. Each program will announce the rationale and choice of methodology for determining low income levels in their program guidance. The Department's poverty guidelines are based on poverty thresholds published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index.

The Secretary annually adjusts the low income levels based on the Department's poverty guidelines and makes them available to persons responsible for administering the applicable programs. The income figures below have been updated to reflect increases in the Consumer Price Index through December 31, 2005.

| Size of parents' family * | Income Level ** |
|---|---|
| 1 | $19,600 |
| 2 | 26,400 |
| 3 | 33,200 |
| 4 | 40,000 |
| 5 | 46,800 |
| 6 | 53,600 |
| 7 | 60,400 |
| 8 | 67,200 |

* Includes only dependents listed on Federal income tax forms. Some programs will use the student's family rather than his or her parents' family.

** Adjusted gross income for calendar year 2005.

Dated: June 21, 2006.

**Elizabeth M. Duke,**

*Administrator.*

[FR Doc. E6–10238 Filed 6–28–06; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HOMELAND SECURITY

### Agency Information Collection Activities: New Information Collection, Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review: CIS Ombudsman Case Problem Submission, Form G–1107. OMB Control No. 1615–NEW.