withdraw the accelerated approval of Avastin for [the MBC indication], subject to Genentech's conduct of a new confirmatory study of Avastin with paclitaxel" (Letter from Michael Labson to the Presiding Officer, April 8, 2011, page 1). CDER has stated the issue, "Whether CDER has appropriately exercised its authority by proposing to withdraw approval of the MBC indication, rather than allowing the indication to remain on the label while the sponsor designs and conducts additional studies intended to verify the drug's clinical benefit" (CDER's Statement of Questions Presented, page 3). Ultimately, while stated differently, the parties seem to agree that there is an issue of the propriety of CDER's proposed withdrawal of this indication now as opposed to the alternative of continuing the approval of the breast cancer indication while Genentech performs new clinical studies of Avastin with paclitaxel to verify the clinical benefit of the MBC indication. This statement of the issue raises the question of why, to confirm an indication for combination use with paclitaxel, Genentech proposed, and CDER agreed, that Genentech could rely on studies of Avastin in combination with chemotherapeutic agents other than paclitaxel. It appears that the explanation is that these studies were already ongoing at the time of the initial approval and both CDER and Genentech believed, at that time, that the results of these studies could provide evidence to verify the claim that Avastin, combined with paclitaxel, would have the effect indicated in the approved labeling.

FDA is addressing the issue of whether to maintain the accelerated approval while additional studies are conducted as the third issue for this hearing as follows:

Issue 3. If the Commissioner agrees with the grounds for withdrawal set out in issue 1, issue 2.A, or issue 2.B, should FDA nevertheless continue the approval of the breast cancer indication while the sponsor designs and conducts additional studies intended to verify the drug's clinical benefit?

While the parties would state the issues differently, the three issues stated in this notice will be those upon which the Commissioner expects to decide this matter. If Genentech prevails on issues 1, 2.A, and 2.B, the approval will be continued. If CDER prevails on issue 1, 2.A, or 2.B, the question of withdrawal will depend on issue 3.

In addition to the issues 1, 2.A, 2.B, and 3, Genentech has proposed to raise issues concerning the consistency of CDER's position here with CDER's decisions with respect to other products for the treatment of MBC or of other products approved under the accelerated approval program. Issues with respect to FDA action on other products are not relevant to this proceeding. Each decision to withdraw or not to withdraw the approval of a product must be made on its own merits. If the decision with respect to another product is in error, that would not justify continuing that error with respect to the MBC indication for Avastin. Moreover, as a practical matter, it would not be possible to evaluate the different circumstances associated with decisions with respect to other products in the context of this or any hearing. FDA has consistently rejected attempts to bring evidence with respect to decisions on other products into hearings on approval or withdrawal of approval of products and will not deviate from that position here.

B. Process

As further specified previously in this document, the hearing will be held in the Agency's White Oak Conference Center on June 28 and 29, 2011. Although no statute or regulation requires that separation of functions be applied to this proceeding, the Agency is observing separation of functions as a matter of policy in this matter. As the Center responsible for the proposed action, CDER, like Genentech, will be a party to the hearing and will be responsible for presenting its position at the hearing in accordance with § 601.43 and part 15.

In accordance with § 601.43(e)(2), no person other than the Presiding Officer, the three designated representatives for each party, and the members of the advisory committee may question witnesses present at the hearing.

Because this is a public hearing, it is subject to our regulations concerning the policy and procedures for electronic media coverage of public agency administrative proceedings (§§ 10.200 through 10.206 (21 CFR 10.200 through 10.206)). These procedures are primarily intended to expedite media access to our public proceedings. Representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record our public administrative proceedings, including the testimony of witnesses in the proceedings. Accordingly, the parties and nonparty participants to this hearing, and all other interested persons, are directed to §§ 10.200 through 10.206, for a more complete explanation of those regulations' effect on this hearing.

III. Transcripts

Please be advised that, as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Registration and Requests to Make Oral Presentation*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857.

Dated: May 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11539 Filed 5–6–11; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Proposed Adoption and Implementation of the Eighth Edition of the Guide for the Care and Use of Laboratory Animals

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of Additional Extension of Comment Period.

SUMMARY: NIH is further extending the period for public comments on (1) NIH's adoption of the eighth edition of the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for evaluation of institutional programs receiving or proposing to receive Public Health Service (PHS) support for activities involving animals; and (2) if NIH decides to adopt the eighth edition of the *Guide,* NIH's proposed implementation plan, which would require that institutions complete at least one semiannual program and facility evaluation using the eighth edition of the *Guide* as the basis for evaluation by March 31, 2012. NIH will consider comments on (1) The adoption of the *Guide* and (2) the implementation plan. The notice on the proposed adoption and implementation plan for the eighth edition of the *Guide* was published in the **Federal Register** on February 24, 2011 (76 FR 10379). The comment period is extended by an additional 30 days and thus will end on May 24, 2011. Additionally, character limits on the comment form fields have been removed.

DATES: Written comments on the adoption and implementation of the eighth edition of the Guide must be received by NIH on or before May 24, 2011, in order to be considered.

ADDRESSES: Public comments may be entered at: *http://grants.nih.gov/grants/olaw/2011guidecomments/add.htm.* Character limits on the comment form fields have been removed. If the character limit previously in place prevented you from submitting your entire comment, please resubmit by the deadline in order to be considered. Comments will be made publicly available. Personally identifiable information (except organizational affiliations) will be removed prior to making comments publicly available.

FOR FURTHER INFORMATION CONTACT: Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health, RKL1, Suite 360, 6705 Rockledge Drive, Bethesda, MD 20892–7982; telephone 301–496–7163.

SUPPLEMENTARY INFORMATION:

I. Background

The *Guide,* first published in 1963, is a widely accepted primary reference on animal care and use. Recommendations in the *Guide* are based on published data, scientific principles, expert opinion, and experience with methods and practices that are determined to be consistent with high quality, humane animal care and use. The eighth edition of the *Guide* was published in January 2011 following a study by the Institute for Laboratory Animal Research of the National Academy of Sciences (NAS). The NAS study process began in 2008 and followed the requirements of Section 15 of the Federal Advisory Committee Act. The NAS study process is described at the NAS Web site: *http://www.nationalacademies.org/studyprocess/index.html.*

Since 1985, the PHS Policy on Humane Care and Use of Laboratory Animals, authorized by Public Law 99–158, 42 U.S.C. 289d, and incorporated by reference at 42 CFR 52.8 and 42 CFR 52a.8, has required that institutions receiving PHS support for animal activities base their animal care and use programs on the current edition of the *Guide* and comply, as applicable, with the Animal Welfare Act and other Federal statutes and regulations relating to animal activities. The PHS Policy is applicable to all PHS-conducted or -supported activities (including research, research training, experimentation, biological testing, or related purposes) involving live vertebrate animals.

The eighth edition of the *Guide* contains substantive changes and additions from the previous edition. To gain insight from institutions on the impact of changes to the *Guide* on their animal care and use programs, NIH seeks comments on whether it should adopt the eighth edition of the *Guide.* NIH simultaneously proposes an implementation plan for the eighth edition of the *Guide* and seeks comments on the proposed plan.

The implementation plan proposed by NIH would require institutions to complete at least one semiannual program and facility evaluation, using the eighth edition of the Guide as the basis for evaluation, by March 31, 2012. For such an evaluation to be considered complete by NIH, it would need to include reasonable and specific plans and schedules for corrections of deficiencies where appropriate.

II. Electronic Access

The eighth edition of the *Guide* is available on the NIH Office of Laboratory Animal Welfare Web site at *http://olaw.nih.gov*.

Dated: May 4, 2011.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2011–11490 Filed 5–10–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: June 14–15, 2011.

Closed: June 14, 2011, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: June 14, 2011, 8:30 a.m. to 12 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed June 14, 2011, 12 p.m. to 1:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: June 14, 2011, 1:15 p.m. to 3:15 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Agenda: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: June 14, 2011, 3:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: June 14, 2011, 3:30 p.m. to 4:15 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: June 14, 2011, 4:15 p.m. to 5:50 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: June 15, 2011, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: June 15, 2011, 8:30 p.m. to 11:15 a.m.

Agenda: Committee discussion, individual presentations, laboratory overview.