

**Date and Time:** The meeting will be held on January 6, 2012, from 9 a.m. to 4 p.m.

**Location:** FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at <https://collaboration.fda.gov/scienceboard/>. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**Contact Person:** Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 32, rm. 4286, Silver Spring MD 20993-0002, (301) 796-4627, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompt to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The Science Board will hear about and provide input regarding the two Centers for Excellence in Regulatory Science and Innovation. The Science Board will also hear updates regarding the Scientific Computing/JANUS program, and FDA's Scientific Integrity Policy. FDA's Modernizing Toxicology Working Group will present an overview to the Science Board for input and discussion. The Center for Drug Evaluation and Research (CDER) will provide their response to the May 2011 Subcommittee Report regarding the Review of the FDA/CDER Pharmacovigilance Program.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the

location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 23, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ms. Martha Monser, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 18, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-30416 Filed 11-25-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

### Request for Nominations for Voting Members on Public Advisory Committee, Science Board to the Food and Drug Administration

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Science Board to the FDA (the Science Board).

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

**DATES:** Nominations received on or before December 28, 2011, will be given first consideration for membership on the Science Board. Nominations received after December 28, 2011, will be considered for nomination to the Science Board should nominees still be needed.

**ADDRESSES:** All nominations for membership should be sent electronically to [CV@FDA.HHS.GOV](mailto:CV@FDA.HHS.GOV), or by mail to Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

**FOR FURTHER INFORMATION CONTACT:** Regarding all nomination questions for membership, the primary contact is: Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4286, Silver Spring, MD 20993-0002, (301) 796-4627, email: [martha.monser@fda.hhs.gov](mailto:martha.monser@fda.hhs.gov).

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/oc/advisory/default.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members on the Science Board.

### I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner of Food and Drugs (the Commissioner) and other appropriate officials on both general and specific scientific and technical issues as well as emerging issues within the scientific community. Additionally, the Science Board will

provide advice to the Agency on keeping pace with technical and scientific advances in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency strategic science plan and its implementation as well as of related intramural and extramural scientific research and training.

## II. Criteria for Voting Members

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food safety, nutrition, chemistry, pharmacology, toxicology, clinical research, and other scientific disciplines. Members shall represent academia and industry. The Science Board may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is either recommended by either a consortium of consumer oriented organizations or other interested persons. The Science Board may also include technically qualified federal members. FDA is currently specifically seeking persons knowledgeable in the fields of pharmacology, translational and clinical medicine, toxicology, clinical research and related biostatistics, public health and epidemiology, international public health and regulation, product safety, product manufacturing sciences and quality or other scientific areas relevant to FDA regulated products such as systems biology, advanced scientific informatics, nanotechnology, food sciences, medical devices and combination products.

## III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Science Board. Self nominations are also accepted. Nominations shall include the name of the committee, complete curriculum vitae of each nominee, and their current business address and telephone number and email address if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: November 21, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-30415 Filed 11-25-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0828]

#### **Wyeth Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for MYLOTARG**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for MYLOTARG (gemtuzumab ozogamicin) for Injection, held by Wyeth Pharmaceuticals, Inc. (Wyeth), 500 Arcola Rd., Collegeville, PA 19426. Wyeth, now a part of Pfizer, Inc., has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

**DATES:** Effective November 28, 2011.

#### **FOR FURTHER INFORMATION CONTACT:**

David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993-0002, (301) 796-3601.

**SUPPLEMENTARY INFORMATION:** FDA approved MYLOTARG (gemtuzumab ozogamicin) for Injection on May 17, 2000, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. MYLOTARG was indicated for the treatment of patients with CD33-positive acute myeloid leukemia in first relapse who were 60 years of age or older and who were not considered candidates for other cytotoxic chemotherapy. On May 21, 2010, FDA requested that Wyeth voluntarily withdraw MYLOTARG from the market, after results of a required postapproval clinical trial failed to verify clinical benefit to patients and raised new concerns about the drug's safety. In a letter dated October 25, 2010, Wyeth requested that FDA withdraw approval of NDA 21-174, MYLOTARG (gemtuzumab ozogamicin) for Injection, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Wyeth also waived its

opportunity for a hearing, provided under 21 CFR 314.150 and 314.530. In FDA's acknowledgment letter of November 2, 2010, the Agency stated that a large prospective trial that tested the addition of MYLOTARG to first-line chemotherapy for patients with newly diagnosed acute myelogenous leukemia failed to verify clinical benefit of MYLOTARG and raised safety concerns. FDA also acknowledged that Wyeth waived its opportunity for a hearing.

Therefore, under sections 505(e) and 506(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e) and 356(b)(3)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21-174, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d))).

Dated: November 22, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-30473 Filed 11-25-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request: "Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey"**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Department of Bioethics, the Clinical Center, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This survey is intended to collect information about the ethical dilemmas that surgeons have faced in their practices over the past year, and assess their experiences, if any, with their hospital consultation services. Specifically, the information gathered in this study will be valuable