

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

in understanding the ethical dilemmas that surgeons face, the utility of institution ethics consultations services for surgeons, and to identify what barriers, if any, discourage surgeons from utilizing these services. The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, they will provide a better understanding of the ethical dilemmas that surgeons face in their practices. Second, they will provide understanding of factors that

determine the current utilization of hospital consultation services by surgeons. Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to ethical dilemmas in their practices and how ethics consultation services could better support surgeons when faced with these dilemmas. *Frequency of Response:* One occasion. *Affected Public:* Individuals. *Type of Respondents:* Surgeons

practicing in the US. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,156; *Estimated Number of Responses per Respondent:* 29 items per questionnaire; *Average Burden Hours Per Response:* 0.00862; and *Estimated Total Annual Burden Hours Requested:* 789. The annualized cost to respondents is estimated at: \$0. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---------------------|---------------------------------|----------------------------------------------|-----------------------------------|-----------------------------------------------|
| Surgeons .....      | 3156                            | 29                                           | 0.00862                           | 789                                           |
| Total .....         | .....                           | .....                                        | .....                             | 789                                           |

### Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Marion Danis at Department of Clinical Bioethics, National Institutes of Health, Building 10, Room 1C118, Bethesda, MD 20892-1156, Telephone: (301) 435-8727, Facsimile: (301) 496-0760, or email your request, including your address to: [mdanis@cc.nih.gov](mailto:mdanis@cc.nih.gov).

### Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 6, 2011.

**Laura M. Lee,**

*Special Assistant to the DDCC—Patient Safety and Clinical Quality Project Clearance Liaison, CC, National Institutes of Health.*

[FR Doc. 2011-30548 Filed 11-25-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI)

**Summary:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 21, 2011 (76 FR 58520) and allowed 60 days for public comment. One public comment was received in which the individual suggested asking the respondents to report the number of procedures performed per month rather than per week because of the infrequency of some procedures. The program staff will assess this during the pre-test. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented

on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection: Title:** Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI). **Type of Information Collection Request:** Reinstatement with change of a previously approved collection (OMB No. 0925-0405, expiration 02/28/2011). **Need and Use of Information Collection:** By conducting a fourth cohort follow-up survey in an ongoing cohort study of U.S. Radiologic Technologists (USRT), updated information will be collected on cancer and other medical outcomes, personal medical radiation procedures, and other risk factors from all participants, plus detailed employment data from subgroups of participants who performed or assisted with fluoroscopically-guided or radioisotope procedures. Researchers at the National Cancer Institute and The University of Minnesota have followed a nationwide cohort of 146,000 radiologic technologists since 1982, of whom 110,000 completed at least one of three prior questionnaire surveys and 23,454 are deceased. This cohort is unique because estimates of cumulative radiation dose to specific organs (e.g. breast) are available and the cohort is largely female, offering a rare opportunity to study effects of low-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women. The fourth survey will be administered by mail to approximately 93,000 living and located cohort members who completed at least one of the three previous surveys to collect information on new cancers and other disease outcomes, detailed work