

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.

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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.

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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