advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss FDA's draft guidance on tablet scoring. This topic will include an overview of FDA's proposed plan to move forward and the United States Pharmacopoeia's perspective on the topic. During the afternoon session, the committee will discuss: (1) The Center for Drug Evaluation and Research (CDER) Nanotechnology Risk Management Working Group activities; (2) nanotechnology-related research conducted and published by CDER, to include examples related to sunscreens; and (3) the overview and preliminary analysis of nanotechnology-related information collected from drug application submissions.

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 July 26, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. for the morning session, and 3:15 p.m. to 3:45 p.m. for the afternoon session. 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 July 18, 2012. 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 July 19, 2012.

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 Yvette Waples 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: July 10, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–17193 Filed 7–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

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 National Cancer Institute (NCI), 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: Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) (NCI). *Type of Information Collection Request:* Revision (OMB #: 0925–0407, current expiration date 9/30/2014). *Need and Use of Information Collection:* This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 255,700 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since. The main change to this submission is that the Supplemental Questionnaire is being replaced with the Medication Use Questionnaire. As PLCO participants now range from 74–94 years of age, the focus is now on collecting additional information regarding medications that are particularly common among older adults. Additionally, the contracts for 8 of the 10 Screening Centers (SCs) ended in 2011 and the remaining two sites will close in 2012 and 2014. NCI has awarded a contract for continuation of participant follow-up activities to one data collection site named the PLCO Central Data Collection Center (CDCC). In 2011, participants were re-consented for at least an additional five years of follow-up. The current number of respondents is limited to the approximately 94,000 participants being actively followed up. The reports on cancer screening and prostate, lung, colorectal, and ovarian cancer mortality based on this trial have been published in peer review medical journals. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer screening in high versus low risk individuals. *Frequency of Response:* Annually. *Affected Public:* Individuals. *Type of Respondents:* Adult men and women. The annual reporting burden is provided for each study component as shown in Table 1 below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Male and female participants.	ASU	94,000	1.00	5/60	7,833

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
	Script for ASU Non-response.	3,760	1.00	5/60	313
	HSQ	2,000	1.00	5/60	167
	MUQ	94,000	1.00	15/60	23,500
Total					31,813

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) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3100, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301–496–8544 or email your request, including your address to: *bergc@mail.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: July 10, 2012.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2012–17237 Filed 7–13–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: The Development of Human Anti-CD22 Monoclonal Antibodies for the Treatment of Human Cancers and Autoimmune Disease

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in U.S. Patent Application 61/042,239 entitled ''Human Monoclonal Antibodies Specific for CD22'' [HHS Ref. E–080–2008/0–US–01], PCT Application PCT/US2009/124109 entitled ''Human and Improved Murine Monoclonal Antibodies Against CD22'' [HHS Ref. E–080–2008/0–PCT–02], US patent application 12/934,214 entitled ''Human Monoclonal Antibodies Specific for CD22'' [HHS Ref. E–080–2008/0–US–03], and all related continuing and foreign patents/patent applications for the technology family, to Customized Therapeutics. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective co-exclusive licensed territory may be worldwide, and the field of use may be limited to:

The use of the m971 and m972 (SMB–002) monoclonal antibodies as therapies for the treatment of B cell cancers and autoimmune disease. The Licensed Field of Use includes the use of the antibodies in the form of an immunoconjugate, including immunotoxins.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 31, 2012 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; E-mail: *lambertsond@od.nih.gov*.

SUPPLEMENTARY INFORMATION: This invention concerns monoclonal antibodies against CD22 and methods of using the antibodies for the treatment of CD22-expressing cancers, including hematological malignancies such as hairy cell leukemia, chronic lymphocytic leukemia and pediatric acute lymphoblastic leukemia, and autoimmune disease such as lupus and Sjogren's syndrome. The specific antibodies covered by this technology are designated m971 and m972 (SMB–002; applicant designation).

CD22 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, and is involved in the modulation of the immune system. The m971 and m972 antibodies can selectively bind to diseased cells and induce cell death while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective co-exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated co-exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the