''Psychopharmacologic Drugs Advisory Committee'' meeting.

Agenda: The committee will discuss new drug application (NDA) 20–717, S–019, PROVIGIL (100 milligrams (mg), 200 mg, 85 mg, 170 mg, 255 mg, 340 mg, and 425 mg) Tablets, Cephalon, Inc.; the proposed indication is for the treatment of attention deficit hyperactivity disorder (ADHD).

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 by March 15, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 15, 2006, 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.

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 Cicely Reese at least 7 days in advance of the meeting.

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

Dated: January 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1222 Filed 1–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held via teleconference on February 17, 2006, from 1 p.m. to 5:30 p.m.

Location: National Institutes of Health (NIH) campus, Food and Drug Administration, Bldg. 29B, conference rooms A and B, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend. A speakerphone will be provided at the specified location for public participation in this meeting. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the internet at *http://www.nih.gov/about/visitor/index.htm*. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Visitors must show two forms of identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the medical center metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–71), 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review and discuss the selection of strains to be included in the influenza virus vaccine for the 2006–2007 season.

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 by February 10, 2006. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 10, 2006, 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.

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 Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

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

Dated: January 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1224 Filed 1–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Leukocyte Antibodies Prevalence (LAP) Study

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 Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Leukocyte Antibodies Prevalence (LAP) Study. *Type of Information Collection Request: NEW. Need and Use of Information Collection:* The two current hypotheses for pathogenesis of transfusion-related acute lung injury (TRALI) include the development of acute pulmonary insufficiency from immune and non-immune causes. The immune mediated mechanism

postulates that passively transferred anti-leukocyte antibodies from blood donors are responsible for TRALI. The donor antibodies implicated in TRALI include antibodies directed towards HLA class I and class II antigens, and anti-neutrophil antibodies. The LAP Study is a cross-sectional multi-center study to measure the prevalence of HLA and neutrophil antibodies in blood donors with or without a history of blood transfusion or pregnancy, and the development of a repository of blood samples obtained from these donors. Specifically, 7,900 adult blood donors across six blood centers participating in the Retrovirus Epidemiology Donor Study II (REDS–II) will be enrolled in the study. Eligible donors will be asked to complete a short questionnaire on their transfusion history (ever, and date of last transfusion) and, for female donors, questions on pregnancy history (ever, number and outcome of pregnancies, last pregnancy). Each donor will also be asked to provide a sample of blood which will be tested for the presence of HLA class I and class II antibodies. This data will help us evaluate variations in HLA antibody prevalence based on blood transfusion and pregnancy history and time since the last immunizing event. Further, neutrophil specific antibodies will be measured in those blood donors who have HLA antibodies. Also, donors with neutrophil antibodies will be tested to determine their neutrophil phenotype using routine serologic and DNA methods, since individuals homozygous for certain neutrophil antigens are more prone to develop certain neutrophil antibodies. The results from testing HLA positive donors for neutrophil antibodies in this primary study could be used to develop an optimal testing strategy for large number of donors using the stored repository samples. These data will provide the basis for calculating donor loss in the event that a TRALI prevention strategy is implemented that includes deferring donors with a history of transfusion or pregnancy or those with HLA or neutrophil antibodies. The second major goal of this study is to develop a repository of blood samples from well characterized blood donors whose detailed transfusion and pregnancy histories are known. Repository samples will be stored indefinitely. Although future research on repository samples is yet to be determined, they may be tested for studies designed to help transfusion safety and transfusion biology. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is a follows: *Estimated Number of Respondents:* 7,900; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.17; and *Estimated Total Annual Burden Hours Requested:* 1343. The annualized cost to respondents is estimated at: $24,174 (based on $18 per hour). 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
Adult Blood Donors	7,900	1	0.17	1343

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0075, or e-mail your request to *nemog@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: January 20, 2006.

Charles M. Peterson,

Director, DBDR, National Institutes of Health.

[FR Doc. E6–1269 Filed 1–31–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: FDA Approvable Human DNA Diagnostic Test for Endometriosis

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in U.S. Patent Application Number 60/654,331 filed February 18, 2005, entitled ''Identification of Molecular Markers for Endometriosis in Blood Lymphocytes Using DNA Microarrays,'' to Ortho-Clinical Diagnostics, having a place of business in Raritan, NJ 08869. The contemplated exclusive license may be limited to an FDA approvable human DNA diagnostic test for endometriosis. The United States of America is the assignee of the patent rights in this invention.

DATES: Only written comments and/or application for a license which are received by the National Institutes of Health on or before April 3, 2006 will be considered.

ADDRESSES: Requests for a copy of the patent, inquires, comments, and other materials relating to the contemplated license should be directed to: Marlene Astor, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4426; Facsimile: 301–402–0220; e-mail: *ms482m@nih.gov.*

SUPPLEMENTARY INFORMATION: Endometriosis is a common, non-malignant gynecological disease that