*Agenda:* The meeting agenda will be posted at *http://www.bioethics.gov*.

*Public Comments:* The Council encourages public input, either in person or in writing. At this meeting, interested members of the public may address the Council, beginning at 10:45 a.m. on Friday, November 9. Comments are limited to no more than five minutes per speaker or organization. As a courtesy, please inform Ms. Diane M. Gianelli, Director of Communications, in advance of your intention to make a public statement, and give your name and affiliation. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of the addresses given below.

**FOR FURTHER INFORMATION CONTACT:** Ms. Diane M. Gianelli, Director of Communications, The President's Council on Bioethics, 1425 New York Avenue, NW., Suite C100, Washington, DC 20005. Telephone: 202/296–4669. E-mail: *info@bioethics.gov,* Web site: *http://www.bioethics.gov*.

Dated: October 10, 2007.

**F. Daniel Davis,**

*Executive Director, The President's Council on Bioethics.*

[FR Doc. 07–5145 Filed 10–17–07; 8:45 am]

**BILLING CODE 4154–06–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Health and Nutrition Examination Survey (NHANES) DNA Samples: Guidelines for Proposals To Use Samples and Cost Schedule

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The National Health and Nutrition Examination Survey (NHANES) is a program of periodic surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Examination surveys conducted since 1960 by NCHS have provided national estimates of the health and nutritional status of the U.S. civilian noninstitutionalized population. To add to the extensive amount of information collected for the purpose of describing the health of the population, DNA specimens were collected during two NHANES surveys. DNA is available in the form of crude lysates of cell lines derived from approximately 7,157 participants enrolled in Phase II of NHANES III (1991–1994). In addition, DNA purified from whole blood is also available from approximately 7,900 participants enrolled in the 1999–2002 NHANES survey years. All specimens (NHANES III and NHANES 1999–2002 were sent to the Division of Laboratory Sciences (DLS) at the National Center for Environmental Health (NCEH) for processing. DNA samples from these specimens are being made available to the research community for genetic analyses.

No funding is provided as part of this solicitation. NCHS will begin to accept proposals after the publication of this notice and will continue to accept proposals on an on-going basis.

Proposals received within 60 days of the notice will complete review approximately 180 days after the notice is published. After this initial review of proposals, all proposal categories will be reviewed twice a year beginning January 1 and July 1 of each year. Unforeseen circumstances could result in a change to this schedule. Proposals will be reviewed by a technical panel and by an internal Secondary Review Committee of senior CDC scientists. The Secondary Review Committee will perform a programmatic review based on the results of the technical review panel and consider the scientific and technical results from the first level of review, important programmatic considerations such as program priorities, program relevance, and other criteria germane to this announcement and to CDC. Projects approved by both reviews will be submitted to the NCHS Ethics Review Board for final approval.

Approved projects that do not obtain funding on their own will be canceled. A more complete description of this program follows.

**DATES:**

- *Submission of Proposals:* December 17, 2007, and thereafter on January 1 and July 1.
- *Scientific Review:* 30 days after proposal submission date.
- *Secondary Review:* Approximately 30 days after Scientific review is complete.
- *Ethics Review Board:* Approximately 30 days after Secondary review is complete.
- *Notification of approval:* Approximately 30 days after ERB approval.
- *Anticipated distribution of samples:* Approximately 60 days after all approvals are obtained.

**Note:** Timeframe may vary depending on the nature of the proposal and the results of each level of review. Unforeseen circumstances could result in a change to this schedule.

**ADDRESSES:** *To send comments and for information, contact:* Christopher Sanders, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4203, Hyattsville, MD 20782, *Phone:* 301–458–4840, *FAX:* 301–458–4028, *E-mail: NHANESgenetics@cdc.gov.*

**Authority:** Sections 301 and 306 of the Public Health Service Act (42 U.S.C. 241 and 242k).

**SUPPLEMENTARY INFORMATION:** The goals of NHANES are (1) to estimate the number and percentage of people in the U.S. population and designated subgroups with selected diseases and risk factors for those diseases; (2) to monitor trends in the prevalence, awareness, treatment and control of selected diseases; (3) to monitor trends in risk behaviors and environmental exposures; (4) to analyze risk factors for selected diseases; (5) to study the relation among diet, nutrition and health; (6) to explore emerging public health issues and new technologies; (7) to establish and maintain a national probability sample of baseline information on health and nutritional status.

The availability of the NHANES III DNA samples has been previously announced (Thursday, August 8, 2002 [67 FR 51585] and Friday, January 13, 2006 [71 FR 22248]). NHANES III DNA samples are in the form of crude cell lysates available from the cell lines derived from samples obtained from Phase II (1991–1994) participants. DNA concentrations are unknown and vary between samples (see NHANES III DNA Samples section for a description).

Beginning in 1999, NHANES became a continuous, annual survey rather than a periodic survey. For a variety of reasons, including disclosure and reliability issues, the survey data are released on public use data files every two years. In addition to the analysis of data from any two year cycle, it is possible to combine two cycles to increase sample size and analytic options. Blood samples for DNA purification were collected from participants age 20 or more years in survey years 1999–2002. Purified DNA samples are available from these survey years in a single set. DNA samples can be obtained and analyzed with survey data from the NHANES 1999–2000 or 2001–2002 or all four years combined (NHANES 1999–2002). The data release cycle for the NHANES during the period in which DNA specimens were collected is described as NHANES 1999–2000 and NHANES 2001–2002.

See: *http://www.cdc.gov/nchs/about/major/nhanes/nhanes99_00.htm* or *http://www.cdc.gov/nchs/about/major/nhanes/nhanes01–02.htm* for additional details.

Identifiable health information collected in the NHANES is kept in strictest confidence. During the informed consent process, survey participants are assured that data collected will be used only for stated purposes and will not be disclosed or released to others without the consent of the individual in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m). In NHANES 1999–2002, a separate consent form was signed by eligible participants who agreed to the storing of specimens for future genetic research. Only participants that consented specifically to future genetic research in 1999–2002 will be available for analyses. Genetic variation results will be linked to the requested information from the NHANES public use data file by the Division of Health and Nutrition Examination Surveys (DHANES) staff. All analyses must be done through an NCHS RDC approved mechanism to assure confidentiality.

*Research Proposals Categories:* Note that the following proposal categories differ from those used in previous announcements for use of NHANES III DNA samples (Thursday, August 8, 2002 [67 FR 51585] and Friday January 13, 2006 [71 FR 22248]).

*Category (A):* Studies involving the typing of the complete set of NHANES DNA samples (NHANES III, 7,157 samples; NHANES 1999–2002, approximately 7,900 samples) for selected genes and relating these findings to demographic data or demographic and phenotypic data available from NHANES. This category is open for proposals for use of NHANES III or NHANES 1999–2002 samples. A total of ten full sets of samples for each survey cycle will be available for any review cycle. The investigator will specify which DNA bank, NHANES III or NHANES 1999–2002, they are requesting as well as the genetic analyses to be conducted on the samples. The investigator will also include in the research protocol an analytic plan that includes a list of NHANES demographic and clinical variables that would be used for the data analyses. The researcher will conduct the genetic analyses of the approved variations on the samples that are labeled with a unique identification number that is not directly linkable to the public use file and therefore, anonymous to the researcher. To analyze these data with the NHANES public use data, the researcher will provide the genetic variation results with the identification numbers to the Division of Health and Nutrition Examination Surveys. The identification numbers will be matched to the requested variables from public use files data by DHANES staff for analyses that must be conducted through the NCHS Research Data Center (RDC) or its equivalent.

Proposals are limited to the testing of 3,000 genetic variations or less because CDC has proposals to perform whole genome analysis on these samples under review.

After the NCHS has completed the initial quality control assessment, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The timeframe allowed for this review will depend on the number and characteristics of the genetic tests submitted. At the completion of this review, an announcement will be made to the public announcing the availability of the genetic variation results and the opportunity to link these results to other NHANES data for secondary data analysis. The list of currently available SNPs is available at: *http://www.cdc.gov/nchs/about/major/nhanes/genetic.htm.*

All samples will be distributed in complete sets of samples of 96 well plates. NHANES III DNA is in the form of crude cell lysates. There will be a total of 7,157 NHANES III samples distributed in a total of 75 plates with an additional five plates of quality control samples. There are approximately 7,900 NHANES 1999–2002 purified DNA samples. These will be distributed into 83 plates with approximately five plates of quality control samples.

**Note:** If the investigator would like to propose a subsample of the full set, please contact the Program to discuss feasibility.

*Category (B): Additional research using samples already obtained from previous solicitations:* Researchers that have obtained NHANES DNA samples from previous solicitations and have sufficient DNA left may request to do additional tests on the remaining DNA. Proposals under this Category must be submitted and approved before the DNA samples were scheduled to be destroyed or returned. The investigator will specify the genetic analyses to be conducted on the samples. The investigator will also include in the research protocol an analytic plan that includes a list of demographic and clinical variables that would be used for the data analyses.

**NHANES III DNA Samples**

The laboratory will distribute aliquots of crude cell lysates. DNA concentrations vary and are estimated to range from 7.5–65 ng/μL with an average of approximately four micrograms in 100 ul. Each 96 well plate will be bar-coded and labeled with a readable identifier. Quality control samples (approximately 480 samples) will be sent at no charge, either inserted with the NHANES samples or in separate plates, as blind replicates and/or blanks. Description of these samples and cost has been previously published; see: (Friday, January 13, 2006 [71 FR 22248]).

**NHANES 1999–2002 DNA Samples**

The laboratory will distribute aliquots of purified DNA of normalized concentrations of 50 nanograms per microliter whenever possible. Some samples may fall below this threshold. Forty microliters of each specimen will be supplied. The amount of DNA in each aliquot may vary but will be on average approximately two micrograms. Each 96 well plate will be bar-coded and labeled with a readable identifier. Quality control samples (approximately 480 samples) will be sent at no charge, either inserted with the NHANES samples or in separate plates, as blind replicates and/or blanks.

Proposed Cost Schedule for Providing Nhanes Dna Samples. Costs are determined both for NCEH and NCHS and include the physical materials needed to process the samples at the NCEH laboratory, as well as the materials to process the requests for samples at NCHS. These costs include salaries of the staff needed to conduct these activities at each Center. The fee is estimated to cover the costs of processing, handling, and preparing the samples. Technical panel travel and expenses are based on the panel meeting twice a year. The space estimate is based on acquiring storage and sample aliquoting space in the laboratory.

The cost per samples for NHANES III samples is the same as published in 2006 (Friday, January 13, 2006 [71 FR 22248]). The additional cost for the NHANES 1999–2002 samples is due to the increased costs associated with DNA purification and normalization of this collection.

| Total costs | Cost per sample full set, 99–02 | Cost per sample partial set, 99–02 (special request) | Cost per sample full set, NHANES III | Cost per sample partial set, NHANES III (special request) |
|---|---|---|---|---|
| Materials | $0.89 | $2.19 | $0.85 | $1.90 |
| Labor | 4.60 | 25.30 | 3.30 | 22.00 |
| Application review and other administrative expenses | 0.54 | 3.09 | 0.35 | 2.69 |
| Space | 0.17 | 1.12 | 0.13 | 0.97 |
| Subtotal | 6.20 | 31.70 | 4.63 | 27.56 |
| NCHS overhead (18 percent) | 1.12 | 5.71 | 0.83 | 4.97 |
| Subtotal | 7.32 | 37.41 | 5.46 | 32.52 |
| CDC/FMO overhead (0.9 percent) | 0.66 | 3.37 | 0.49 | 2.93 |
| Total sample cost per sample | 7.98 | 40.78 | 5.95 | 35.45 |
| TOTAL COST PER PROPOSAL | $63,024.00 | NA | $42,596.36 | NA |
| Total cost per category B proposal: for Data handling. | 6,302 | 10 percent of original cost of samples | 4,260 | 10 percent of original cost of samples |

*Procedures for Proposals:* The investigator should follow these instructions for preparation of proposals. Both proposal categories need a full research proposal for review. The cover page of the research proposal should contain the title of the research project, the name, address phone number and E-mail address of the lead investigator along with the name of the institution where the DNA analysis will be done, and the category of proposal (A or B) submitted. OHRP assurance numbers for the institutions engaged in the research project should be included. CDC investigators need to include their Scientific Ethics Verification Number. E-mail submission of the proposal is encouraged.

The proposals should be a maximum of 20 single-spaced typed pages, excluding figures and tables, using ten cpi type density. Please use appendices sparingly. If a proposal is approved, the title, specific aims, name, and phone number of the author will be maintained by NCHS and released if requested by the public. Unapproved proposals will be returned to the investigator and will not be maintained by NCHS.

Since the number of sets of DNA is limited, proposals will be reviewed by the technical panel and then will be reviewed by a secondary review panel composed of CDC officials. The technical panel will determine if the proposal is technically sound and if so, the technical panel will rank the proposal on a scale of 0–100. Proposals that are rejected will not be scored. The technical panel will evaluate the whole proposal but will focus on proposal elements 1, 3, and 4.

Applications will also be reviewed by an internal Secondary Review Committee which will perform a programmatic review based on the results of the peer review for technical merit. The Secondary Review Committee considers the scientific and technical merit results from the first level of review, important programmatic considerations such as program priorities, program relevance, and other criteria germane to this announcement and to CDC. The secondary review panel will be comprised of senior CDC scientists.

*Proposals should include the following information:*

*(1) Specific Aims:* List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested.

*(2) Background and Public Health Significance:* Describe the public health significance, scientific merit, and practical utility of the proposed research. Scientific merit will be judged on the basis of the scientific, technical, or medical significance of the research; the appropriateness and adequacy of the experimental approach; and the methodology proposed to reach the research goals. Convey how the results will be used and the relationship of the results to the data already collected in NHANES 1999–2002. Analyses should be consistent with the NHANES mission to assess the health of the nation. Because NHANES is a complex, multistage probability sample of the national population, the appropriateness of using the NHANES sample to address the goals of the proposal will be an important aspect of determining scientific merit. The Panel will ensure that the proposed project does not go beyond either the general purpose for collecting the samples in the survey, i.e., to determine allele frequencies in subgroups of the population, or, the specific stated goals of the proposal.

*(3) Research Design and Methods:* Include power calculations and a list of variables requested. For all proposal categories, include a detailed description of the laboratory methods. The characteristics of the laboratory assay, such as reliability, validity, should be included with appropriate references. The potential difficulties and limitations of the proposed procedures should also be discussed. Category A proposals will be provided with approximately 480 quality control samples at no additional cost. Approved projects must run these quality control samples and submit the results from the NHANES DNA samples. Category B proposals will be required to use residual quality control samples. The proposal should contain a discussion of additional quality control procedures the laboratory will use to assure the validity of the test results. Address adequate methods planned for handling and storage of samples.

*(4) Discussion Regarding the Race/Ethnicity Variables:* If the research is limited to specific race or ethnic groups (only applicable for a subsample request) or if information about the race or ethnicity of the subjects is requested, indicate the reason for analyzing race/ethnicity and how the results will be interpreted. Discuss the potential for group harm.

*(5) Clinical Relevance of Research Findings:* The samples under this Plan are available for genetic research, not genetic testing. Therefore, it is the intent of the program to approve only those proposals that would yield meaningful research, but not clinically relevant information for the participants.

Researchers should justify that the test results should not be reported to the subjects.

*(6) Qualifications:* Provide a brief description of the requestor's expertise in the proposed area, including publications in this area within the last three years.

*(7) Period of Performance:* Specify the project period. The period may be up to three years. At the end of the project period, any unused samples must be returned to the NHANES DNA Specimen Bank in accordance with instructions from the Division of Environmental Laboratory Science. Extensions to the period of performance may be requested.

*(8) Funding:* Include the source and status of the funding to perform the requested laboratory analysis. Investigators will be responsible for the cost of processing and shipping the samples. Currently the cost per DNA specimen is $7.98 for NHANES 1999–2002 proposals that use the full set of approximately 7,900 samples. Costs for partial sets are $40.78 per specimen. Reimbursement for the samples will be collected before the samples are released. NHANES III samples which are DNA crude lysates, not purified DNA, are $5.95 per sample for the 7,157 total set of samples. If a subsample of NHANES III is requested and approved the cost schedule published in (Friday, January 13, 2006 [71 FR 22248]) will be utilized ($35.45 per sample).

**Public Availability of Data**

Genetic test results from all studies using NHANES DNA samples will be made available to the public for secondary data analyses. After the NCHS quality control review is completed, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The final quality control review timeframe will be negotiated between the researcher and the NCHS Project Officer and will depend on the number and characteristics of the genetic tests submitted. This time for final review is provided before the announcement is made to the public that the test results are available for submission of proposals for secondary data analyses. The list of currently available genotypes will be outlined on: *http://www.cdc.gov/nchs/about/major/nhanes/genetic.htm.* Proposals for secondary data analyses linking NHANES public use data with genetic variation data are accepted in May and October of each year.

Proposals reviewed by a Genetics Technical Panel and the Secondary Review Panel will be reviewed by the CDC/NCHS Ethics Review Board (ERB) to ensure appropriate for human subjects protections are provided, in compliance with 45 CFR part 46. The ERB review will be conducted, even though investigators' proposals may have received review by their home institution. The Director of NCHS will verify that projects have received appropriate reviews.

*Requirements for the Inclusion of Women and Racial and Ethnic Minorities in Research:* In NHANES III and NHANES 1999–2002, race/ethnicity was derived by combining responses to questions on race and Hispanic origin. These categories are defined as non-Hispanic white, non-Hispanic black, or Mexican American. Individuals who did not self-select into these categories were classified as ''other''. If proposal requests a subsample and excludes one or more race/ethnic groups or a gender, this exclusion must be justified.

CDC is also sensitive to the stigmatization of racial/ethnic specific populations through inappropriate reporting and interpretation of findings. For all proposals that request information on race/ethnicity for the samples selected, the investigator should indicate the reason for analyzing race/ethnicity and how the results will be interpreted.

*Submission of Proposals:* Proposals can be submitted immediately. The review process will begin approximately 60 days from the publication of the notice and will include all proposals submitted as of that date, electronic submission of proposals is encouraged. *Please submit proposals to:* Christopher Sanders, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4203, Hyattsville, MD 20782, *Phone:* 301–458–4840, *FAX:* 301–458–4028, *E-mail: NHANESgenetics@cdc.gov.*

*Approved Proposals:* The genetic results will be sent back to NCHS so they can be linked to the requested NHANES III or NHANES 1999–2002 public use data. Analysis will be done in the Research Data Center.

*Agency Agreement:* A formal signed agreement in the form of a Materials Transfer Agreement (MTA) with individuals who have projects approved will be completed before the release of the samples. This agreement will contain the conditions for use of the DNA as stated in this document and as agreed upon by the investigators and CDC. A key component of this agreement is that no attempt will be made to link the results of the proposed research to any other data, including, but not limited to, the NHANES public use data sets outside the Research Data Center. Also, the investigator agrees that the samples cannot be used for commercial purposes. A list of genes generated from the testing of the NHANES samples will be made available to the public for potential solicitation of proposals for secondary data analysis after the quality control process has been completed (approximately six months after NCHS receives the genetic variation results). These secondary data analysis proposals must also be reviewed by the ERB.

*Progress Reports:* A progress report will be submitted annually. CDC/NCHS ERB continuation reports are also required annually. An ERB continuation form will be sent to the researcher each year for project update.

*Disposition of Results and Samples:* No DNA samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Genetics Technical Panel, the Secondary Review Committee and the NHANES ERB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be returned upon completion of the approved project. These results, once returned to NCHS and quality controlled, will be part of the public domain. Genetic test results from all studies using NHANES DNA samples will be made available to the public for secondary data analyses. After the NCHS quality control review is completed, researchers will be given up to six months to conduct a more comprehensive quality assurance review. The final quality control review timeframe will be negotiated between the researcher and the NCHS Project Officer and will depend on the number and characteristics of the genetic tests submitted. Data analyses will be conducted at the NCHS' Research Data Center or similar environment provided by NCHS. Proposals for secondary data analyses are accepted in May and October of each year (*http://www.cdc.gov/nchs/about/major/nhanes/genetic.htm*).

*Send Requests for Information:* Christopher Sanders, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4203, Hyattsville, MD 20782, *Phone:* 301–458–4840. *FAX:* 301–458–4028. *E-mail: NHANESgenetics@cdc.gov.*

Dated: October 11, 2007.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

[FR Doc. E7–20592 Filed 10–17–07; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2000D–0084] (formerly 00D–0084)**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Special Protocol Assessment

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Special Protocol Assessment'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 22, 2007 (72 FR 34470), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0470. The approval expires on October 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 12, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–20549 Filed 10–17–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Cardiovascular and Renal Drugs 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*: Cardiovascular and Renal Drugs 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 on December 11 and 12, 2007, from 8 a.m. to 5 p.m.

*Location*: Sheraton College Park Hotel, 4095 Powder Mill Rd., Beltsville, MD, 301–937–4422.

*Contact Person*: Cathy A. Miller, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Cathy.Miller1@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. 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*: On December 11, 2007, the committee will discuss new drug application (NDA) 22–034, vernakalant hydrochloride injection, 20 milligrams (mg) per milliliter (ml), Astellas Pharma U.S., Inc., for the proposed indication of use for conversion of atrial fibrillation to normal sinus rhythm. On December 12, 2007, the committee will discuss NDA 22–123, PULZIUM (tedisamil sesquifumarate) IV solution 2 mg per ml, Solvay Pharmaceuticals, Inc., for the proposed indication of use for conversion of atrial fibrillation or atrial flutter to normal sinus rhythm.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and 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 November 27, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days for the corresponding agenda. Those desiring to make 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 November 16, 2007. 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 November 20, 2007.

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 John Lauttman 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/oc/advisory/default.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).