3. Defining Gulf War Illness—New—National Center for Environmental Health (NCEH)—This study will characterize and compare alternative classifications for symptoms and functional disability which remain medically unexplained in Gulf War veterans. This will be accomplished in three phases. Phase I will assess persistence and stability of symptoms over time, as well as compare the performance of data-driven case definitions derived from two samples: (1) The New Jersey Center for Environmental Hazards Research sample of Gulf War veterans participating in the Department of Veterans Affairs Gulf War Registry; and (2) a cohort of Air Force members from a previous CDC study of Gulf War veterans and Gulf War-era controls from Pennsylvania and Florida. In addition to assessing data-driven case definitions for illness among Gulf War veterans, existing definitions for medically unexplained symptoms, such as chronic fatigue syndrome, multiple chemical sensitivity, and fibromyalgia will be evaluated. Phase II will attempt to assess the generalizability of both derived and existing case definitions in a random sample of deployed and non-deployed Gulf War era veterans. Phase III will consist of a standardized telephone interview for the assessment of psychiatric conditions. This will be administered to a sample of Phase I and Phase II participants who are identified through their responses to paper-and-pencil questionnaires as having high levels of psychologic distress. The total annual burden hours are 4,761.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Initial Address Confirmation	50	1	.0333
Introductory Script	7,000	1	.05
Main Questionnaire	5,361	1	.75
Mail Survey	387	1	.05
Refusal Conversion	150	1	.0333
Address Confirmation	200	1	.0333
Third-Party Contact	25	1	.0333
Recontact Script	25	1	.0333
Follow-up Letter	500	1	.083
Follow-up Care	804	1	.10
Request for Medical Records (letter)	1,340	1	.05
Request for Medical Records Follow-up Call	750	1	.0333
Medical Care Providers:			
Request for Medical Records (letter)	140	1	1
Request for Medical Records Follow-up Call	42	1	0.0333

Dated: May 24, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–13739 Filed 5–28–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99115]

Cooperative Agreement for Strategies to Prevent Genital Herpes Infections: Building a National Prevention Program; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year 1999 funds for the Strategies to Prevent Genital Herpes Infections: Building a National Prevention Program was published in the **Federal Register** on May 18, 1999, (Vol. 64 FR No. 95). The notice is amended as follows:

On page 26983, second column, paragraph G., sub-paragraph titled ''Application,'' replace second sentence:

On or before July 26, 1999, submit application to: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99115, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341.

Dated: May 25, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–13741 Filed 5–28–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey III (NHANES) DNA Specimens: Guidelines for Proposals To Use Anonymized Samples and Proposed Cost Schedule

ACTION: Notice and request for comments.

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 health and nutritional status of the United States civilian non-institutionalized population. To add to the large amount of information collected for the purpose of describing the health of the population in the most recent survey, white cells were collected in NHANES III in anticipation of advances in genetic research.

The cells have been stored and maintained at the Division of Environmental Health Laboratory Sciences (DEHLS) at the National Center for Environmental Health (NCEH), CDC. The collection of white cells was begun because of the significant advances in the rapidly evolving field of molecular biology that were occurring during the planning phase of this survey.

Technical advances now make it possible to use these samples for genetic analysis. NCHS and NCEH, CDC are making anonymized DNA samples from these specimens available to the research community for such analyses. No cell lines will be made available.

The purpose of this notice is to request comments on this program and cost schedule. After consideration of comments submitted, CDC plans to

finalize the cost schedule and solicit letters of intent and proposals for use of the NHANES III anonymized DNA samples. Please contact Ms. Burwell or go to www.cdc.gov/nchswww/about/major/nhanes/nhanes.htm for final proposal guidelines and request for letters of intent.

All interested researchers are encouraged to submit letters of intent. No funding is provided as part of this solicitation. DNA samples will not be provided to those projects requiring funding until the project has received funds. Approved projects that do not obtain funding will be canceled. A more complete description of this program follows.

DATES:

- Comment Receipt Date: June 30, 1999
- Invitation to submit Letters of Intent: July 14, 1999
- Letter of Intent Receipt Date: September 1, 1999
- Invitation to Submit Proposals: September 22, 1999
- Application Receipt Date: November 3, 1999.
- Scientific Review Date: December 1999.
- Institutional Review Date: January 1999.
- Notification of approval: January 1999.
- Anticipated distribution of samples: February–March 2000.

TO SEND COMMENTS AND FOR INFORMATION: Audrey L. Burwell, MS, Health Research Administrator, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1100, Hyattsville, MD 20782, Phone: 301–436–7062, 127, FAX: 301–436–4233, E-Mail: azb2@cdc.gov, Internet: www.cdc.gov/nchswww/about/major/nhanes/nhanes.htm.

SUPPLEMENTARY INFORMATION: The goals of NHANES are: To estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors; to monitor trends in the prevalence, awareness, treatment and control of selected diseases; to monitor trends in risk behaviors and environmental exposures; to analyze risk factors for selected diseases; to study the relationship between diet, nutrition and health; to explore emerging public health issues and new technologies; and, to establish and maintain a national probability sample of baseline information on health and nutrition status.

The third National Health and Nutrition Examination Survey (NHANES III) began in the Fall of 1988 and ended in the Fall of 1994. The survey data were collected, and can be analyzed, in two phases: Phase I was conducted from October 1988 to October 1991, and Phase II was conducted from October 1991 to October 1994. Both phases are nationally representative samples. For details of the sampling design see the Plan and Operation of NHANES III (1). This information can be obtained by contacting the Data Dissemination Branch, NCHS at 301–436–8500 or from the Internet at www.cdc.gov/nchswww/products/catalogs/subjects/nhanes3/nhanes3.htm.

Blood specimens were collected from participants as a part of NHANES III. Lymphocytes were isolated from the blood collected from participants aged 12 years and older and stored frozen in liquid nitrogen or as cell cultures immortalized with Epstein-Barr virus and frozen at the Molecular Biology Branch of DEHLS, NCEH at the CDC, Atlanta GA. DNA is available primarily from cell lines of Phase II participants.

Health information collected in the NHANES III 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 or the establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m). Although the consent form was signed by participants in the survey and participants consented to storing specimens of their blood for future research, specific mention of genetic research was not included. Given the scientific importance of this resource, the NHANES Institutional Review Board (IRB) approved making anonymized samples of DNA available to the research community for genetic research. For this purpose, an anonymized sample is defined as a sample for which no one, including CDC staff, are able to link the results of the genetic tests back to the survey participant (2). NCHS and NCEH will anonymize the samples for each request.

All proposals for testing of anonymized NHANES III DNA samples will be evaluated by a Genetics Technical Panel (composed of 8–10 scientists; 40 percent from CDC; 30 percent from other Federal agencies and 30 percent non-government scientists) for scientific merit and by the NHANES IRB to assure that anonymity will be maintained, as well as for other human subjects concerns. The NHANES IRB review will be conducted, even though the investigator may have received review by their home institution. The NHANES IRB must review all projects because determination of anonymity required by this proposal review process can only be accomplished by the NHANES staff who have access to confidential records. Projects recommended for approval by the Genetics Technical Panel and the IRB will be submitted to the Director of NCHS for verification that all appropriate reviews have been conducted.

The Genetics Technical Panel will evaluate the public health significance and scientific merit of the proposed research. Scientific merit will be judged as to 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. See Criteria for Technical Evaluation of Proposals below. The proposer should outline how the results from the DNA analysis will be used. Because NHANES is a complex, multistage probability sample of the national population, the appropriateness of the NHANES sample to address the goals of the proposal will be an important aspect of scientific merit. The Genetics Technical Panel will assure 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 of the specific stated goals of the proposal. The Panel will also review an evaluation by the NCHS staff as to whether anonymity can be assured for the proposed project.

Investigators are encouraged to obtain the NHANES III Reference Manuals and Reports and NHANES III Public Use Data (on CD–ROM) These can be obtained by contacting the Data Dissemination Branch, NCHS at 301–436–8500 or from the Internet at www.cdc.gov/nchswww/products/catalogs/subject/nhanes3/nhanes3.htm.

Because of the complex nature of this Survey, sampling weights are used to make national estimates of frequencies. The use of weights, sampling frame and methods of assessment of variables included in the data tape are likely to affect the proposed research. The Genetics Technical Panel will review the analysis plan and evaluate whether the proposal is an appropriate use of the NHANES III population.

Due to the design of NHANES III, the DNA samples are not suitable for family studies. On average, NHANES III sampled 2 individuals from each household in Phase II. The relationship

between individuals is not available on the data file. If the investigator requires strict assurance that only one subject per household is included among the samples, the investigator should request only one subject per household, and estimate statistical cell sizes by dividing the results from cross tabulations by 2 (see Special Studies procedures below). In this instance, the NCHS staff can use the confidential household code (not available on public use tapes) to select one subject per household for approved projects.

The provided samples will consist of DNA suitable for use in the polymerase chain reaction or other justifiable genetic assessments. No cell lines will be made available. Unique, randomized IDs will be assigned to each set of DNA samples.

Two types of proposals will be evaluated: (a) Those that aim to describe allele frequencies which require only basic demographic information (age, race, and gender) linked to the samples or (b) those where additional co-variates from the NHANES data base are required (special studies).

Age-Race-Gender Studies

To facilitate proposal preparation of allele frequency research, NCHS will make available the following data with the DNA sample: age in 10-year age groups, race-ethnicity (white, black, Mexican-American), gender, mean sample weights for each demographic group and the average design effect. These proposals, therefore, do not need to provide an analysis of NHANES III data to support the anonymization scheme proposed. These data have sufficient sample sizes in each category (the smallest age, race/ethnicity, gender statistical cell contains 62 persons) to preserve anonymity. To further preserve anonymity, only 80 percent of the subjects in each statistical cell will be used.

Proposals submitted for this review will be limited to those requesting samples from within these domains for the identification of the frequency of the genes in the population. These proposals must address all criteria except for the verification that anonymization can be achieved. Because of the limited data associated with the genetic result, a shortened (2–3 pages) proposal is acceptable as long as each of the criteria below are addressed.

Special Studies (Requests for Additional Variables)

Include a list of demographic and clinical variables and specify recoding schemes, if appropriate, that the principal investigator would like to have linked to the DNA samples to meet the objectives of the study. The combined information on all variables provided to the investigator by CDC must not constitute a unique set of values that could link the DNA samples with participant data on the NHANES III public use data set. Investigators should obtain the NHANES III Public Use Data and should verify prior to submission that anonymity is achievable with the requested set of variables. To obtain the NHANES III Public Use Data contact the Data Dissemination Branch, NCHS at 301–436–8500 or from the Internet at www.cdc.gov/nchswww/products/catalogs/subject/nhanes3/nhanes3.htm.

Recoding is required for continuous variables and may be required for integral variables to assure anonymity. A cross tabulation of all requested variables must be provided, with demonstration that there are at least five individuals in each statistical cell of that cross tabulation. Because the DNA specimens are primarily available on phase II subjects, these analyses should be run using phase II subjects only (SDPPHASE=2). (Household codes are confidential data. Therefore, if only 1 individual per household is to be included in the protocol, the investigator can estimate the sample size per statistical cell by halving the cross tabulation results. For instance, if only 1 individual per household is requested, the minimum statistical cell size of the cross tabulation should be 10 subjects.) From each statistical cell, either 2 subjects or 20 percent of the subjects of the cell, whichever is larger, will be deleted from the pool of samples sent to the investigator. The DNA samples which are sent to the investigator will be selected by the NCHS staff at random from the domain.

All protocols, either for the age-race-gender studies or the special studies, will be reviewed by NCHS staff for anonymity and must be approved by the Genetics Technical Panel and the NHANES IRB. The anonymity of all sample requests, when linked with demographic and clinical data, will be verified prior to release to the investigator.

Applicants may request a project period of up to 3 years. At the end of the project period, any unused samples must be returned to the Bank in accordance with instructions that will be provided. Extensions to the period of performance may be requested.

Procedures for Letter of Intent

After consideration of comments on the program and the cost schedule, NCHS plans to make requests for letters of intent. This request will be announced on the NHANES web site by July 14, 1999: Internet: www.cdc.gov/nchswww/about/major/nhanes/nhanes.htm. The letter of intent is required to enable CDC to plan the review more efficiently, evaluate the number and magnitude of the requests, and to assess the capacity of the DNA Bank to fulfill requests.

Investigators from both the extramural and the CDC intramural research communities must submit letters of intent. The letter should be no more than two pages and include: a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, a list of key investigators and their institution(s), one paragraph on the background for the proposal, the genetic assessments proposed, a list of proposed variables, and an estimate of the number of samples that would be requested. The background should state concisely the importance of the research in terms of the broad, long-term objectives and public health relevance.

If the total number of proposals and samples requested from all the letters of intent exceed the handling capacity of the DNA Specimen Bank, a determination of priorities will be made by the Genetics Technical Panel using the letters of intent. Priority will be based on the public health importance of the proposed research and the prevalence of the health outcome(s) targeted by the research.

All investigators will be notified as to whether they should submit a full proposal based on review of the letters of intent.

Letters of intent should be submitted by September 1, 1999, to: Audrey L. Burwell, MS, Health Research Administrator, National Center for Health, Statistics, Centers for Disease Control and Prevention 6525 Belcrest Road, Room 1100, Hyattsville, MD 20782, Phone: 301–436–7062, 127, FAX: 301–436–4233, E–Mail: azb2@cdc.gov.

Procedures for Proposals

After notification by NCHS that a proposal for use of samples and data from the NHANES III DNA-Bank can be submitted, the investigator should use the following format: Proposals are limited to a maximum of 5 single-spaced typed pages, excluding figures and tables, using 10 cpi type density. 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. Unapproved proposals will be returned to the investigator and will not be maintained

by NCHS. The cover of the proposal should include the name, address, and phone number and E-mail address, if available, of the principal investigator (PI) and the name of the institution where the DNA analysis will be done. The cover page should be signed by the responsible institution representative.

The Criteria for Technical Evaluation of Proposals section at the end of this announcement and the following information should be used to develop the proposal content.

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*—Briefly describe in 1–2 pages the background of the proposal, identifying gaps in knowledge that the project is intended to fill. State concisely the importance of the research in terms of the broad, long-term objectives and public health relevance including a discussion of how the results will affect health policy or further scientific knowledge. The proposal should include a discussion of the potential clinical significance of the results and whether there is definitive evidence that results of the genetic test would provide grounds for medical intervention.

3. *Research Design and Methods*—Describe the research design and the procedures to be used. A detailed description of laboratory methods must be included with references. If non-standard methods will be used, discuss how the method is more appropriate than current methods or that there are no standard methods to accomplish the task. Laboratory quality control should be described. Include a justification for determination of sample size or a power calculation. A detailed description and justification of any sample design whether a random subsample or case control design, must be given. The program will evaluate the endpoints assessed in these projects to determine whether the projects are consistent with the mission of the NHANES program. Further, the program and IRB are concerned with the possible breach of anonymity due to the determination of a large number of genetic analyses in individual research studies. The specific concern is that, when large numbers of genetic findings are available that are potentially correlated with other NHANES III data, the investigator or program staff might be able to inadvertently identify specific subjects. Therefore, if several genetic analyses are proposed, the investigator must discuss the potential for linking the findings with NHANES III data on public use tapes that was not requested as part of the proposal. A list of variables requested should be included. A crosstabulation demonstrating the recoding and resulting statistical cell sizes should be included for special studies.

4. *Qualification of Investigators*—A brief description of the Principal Investigator's expertise in the proposed area should be provided, including publications in this area within the last three years. A representative sample of earlier publications may be listed as long as this section does not exceed two pages.

5. *Funding*—The source and status of the funding to perform the requested laboratory analysis should be included. Investigators will be responsible for the cost of processing and shipping the samples. At this time the cost per DNA specimen is $38.00. The basis for the cost structure is in the last section of this document. Reimbursement for the samples will be collected before the samples are released.

Requirements for the Inclusion of Women and Racial and Ethnic Minorities in Research

In NHANES III, race/ethnicity was defined by self-report as non-Hispanic white, non-Hispanic black, or Mexican American. Individuals who did not self-select into these categories were classified as ''other'' . If the proposal excludes one or more race/ethnic groups or a gender, this exclusion must be justified.

The 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

Investigators who are invited to submit proposals should send the original written proposal and 20 copies to: Audrey L. Burwell, MS, Health Research Administrator, National Center for Health Statistics, 6525 Belcrest Rd., Rm 1100, Hyattsville, MD 20782, Phone: (301) 436–7062, 127, FAX: (301) 436–4233, E-Mail: azb2@cdc.gov, Attention: NHANES III Genetic Testing Program.

Criteria for Technical Evaluation of Proposals

The following criteria will be used for technical evaluation of proposals.

1. *Background and Public Health Significance:* The public health significance, scientific merit and practical utility of the assay. The proposer has conveyed how the results will be used and the relationship of the results to the data already collected in NHANES III. Proposer addresses how they will use results of the DNA analyses. The analyses are consistent with the NHANES mission and the health status variables will be evaluated appropriately given the methods of data collection in NHANES III.

2. *Research Design and Methods:* The sampling scheme must be described and address its relationship to the NHANES III design. Power calculations for a subsample must be included. A list of variables requested with the recoding schemes are included. A cross-tabulation is provided if the investigator requests a special set of variables. A detailed description of the laboratory methods is included. If a non-standard laboratory method is to be used, its advantage over existing methodology is adequately discussed. The characteristics of the laboratory assay, such as reliability, validity, and ''state-of-the-art'', must be included with appropriate references. The potential difficulties and limitations of the proposed procedures are discussed. The volume of DNA and the number of samples required are specified. Adequate methods for handling and storage of samples must be addressed. The laboratory has demonstrated the capability for handling the workload requested in the proposal.

3. *Discussion regarding the race/ethnicity and gender variables:* If either race/ethnicity or gender are used to restrict the sample, the proposal gives a clear and compelling rationale for this restriction. On the other hand, if the race/ethnicity variable is requested, the proposer indicates the reason for analyzing race/ethnicity and how the results will be interpreted.

4. *Qualifications:* A brief description of the requestor's expertise in the proposed area is provided including publications in this area within the last three years. A representative sample of earlier publications may be listed as long as this section does not exceed two pages.

5. *Anonymity:* NCHS determination of anonymity has been reviewed and found to be adequate.

6. *Period of performance*—The project period should be specified. 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 DEHLS.

Extensions to the period of performance may be requested.

Approved Proposals

NCHS/NCEH will provide a data file with the requested recoded variables and a randomly assigned unique identification number that is linked to the DNA specimen. No record connecting the new number with the original identification number will be kept after the samples have been sent. These samples can not be traced to any files maintained by NCHS.

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 III public use data set. Also, the investigator agrees that the samples can not be used for commercial purposes.

Progress Reports

A progress report will be submitted annually. NHANES IRB continuation reports are also required annually.

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 Genetic Technical Panel and the NHANES IRB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be returned to the Bank upon completion of the approved project. Researchers requesting DNA samples for age-race-gender studies and special studies will be required to provide NCHS with the results of all DNA tests performed for each anonymized sample. These results, once returned to NCHS, will be part of the public domain. Therefore, ample time will be given to the investigator to publish results prior to reporting the results to NCHS.

Proposed Cost Schedule For Providing NHANES III DNA Specimen Bank

A nominal processing fee of $38.00 is proposed for each sample received from the NHANES III DNA Specimen Bank. The 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 are inclusive of the staff needed for these activities at each Center. The fee is estimated to cover the costs of processing, handling and preparing the samples in accordance with the detailed requirements of the investigators. These costs were based on an assumption that NCEH and NCHS will receive and process 15 proposals in a year each requesting 1000 samples as shown in the table below.

The materials listed are for the recurring laboratory costs to dispense and prepare the samples for shipping; the computer software needed for the Web page and advertisements in scientific journals. Labor costs are based on the need for microbiologists, a proposal administrator and computer programmers for NCHS and NCEH to maintain the data bases and verify anonymity. Technical panel travel and expenses are based on the panel meeting twice a year. The space estimate is based on acquiring storage and aliquoting space.

Total Costs Per Sample if 15 Requests for 1,000 Samples

Materials	$1.90
Labor	22.00
Panel Travel/Expenses	2.69
Space	0.97
Subtotal	27.56
NCHS overhead (15%)	4.12
Subtotal	31.68
CDC/FMO overhead (20%)	6.32
Total	*38.00

*Shipping costs are not included in the $38.00 processing fee. These costs must also be paid by the investigator.

Comments are solicited on the proposed cost schedule. Comments are due by June 30, 1999.

Send Comments and for Information

Audrey L. Burwell, MS, Health Research Administrator, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1100, Hyattsville, MD 20782, Phone: 301–436–7062, 127, FAX: 301–436–4233, E-Mail: azb2@cdc.gov

References

1. Plan and Operation of the Third National Health and Nutrition Examination Survey, 1988–94. National Center for Health Statistics. Vital Health Stat (32) 1994.

2. Clayton EW, Steinberg KK, Khoury MJ, et al. Informed consent for genetic research on stored tissue samples. JAMA 1995;274:1786–1792.

Dated: May 25, 1999.

Joseph R. Carter,

Acting Associate Director for Management And Operation, Centers for Disease Control and Prevention.

[FR Doc. 99–13740 Filed 5–28–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of May 20, 1999 (64 FR 27581). The meeting will be open to the public. This amendment is being made to change the meeting starting time and the procedures paragraph and to cancel the closed session.

FOR FURTHER INFORMATION CONTACT: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 20, 1999 (64 FR 27581), FDA announced that a meeting of Oncologic Drugs Advisory Committee would be held on June 7 and 8, 1999. On page 27581, in the third column, the ''Date and Time'' and ''Procedure'' portions are amended and on page 27582, in the first column, the ''Closed Committee Deliberations'' portion is removed to read as follows:

Date and Time: The meeting will be held on June 7, 1999, 9:30 a.m. to 5:30 p.m. and June 8, 1999, 8 a.m. to 5:30 p.m.

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 May 28, 1999. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. and 1:45 p.m. and 2 p.m. on June 7, 1999, and between approximately 8:15 a.m. and 8:45 a.m.