July of 2003 to July of 2004 as published by the Bureau of Labor Statistics, Department of Labor. The CPI level was at 297.6 in July of 2003 and rose to 311 in July of 2004. This change accounted for the 4.5 percent increase. The increase in the AIC threshold for ALJ hearing requests would have changed to $104.50 based on the 4.5 percent increase. Section 940 of the MMA requires, however, that the increase be rounded to the nearest $10 if the increase is not a multiple of $10. Therefore, after rounding, the 2005 AIC threshold amount for ALJ hearings remained at $100. The AIC threshold amount for judicial review changed to $1,045 based on the 4.5 percent increase. This amount was rounded to the nearest multiple of $10, resulting in a 2005 AIC threshold amount of $1,050.

The 2005 AIC threshold amounts were published in the preamble to the Interim Final Rule, 70 FR 11423 (March 8, 2005), regarding ''Changes to the Medicare Claims Appeal Procedures.'' In addition, this information was previously made available to the public through a change to the Medicare Claims Processing Manual. CMS Change Request 3127, Revisions and Corrections to Chapter 29 of the IOM, Claims Processing Manual—Appeals § 30.8 (Nov. 26, 2004).

B. Calendar Year 2006

The AIC threshold amount for ALJ hearing requests has risen to $110 and the AIC threshold amount for judicial review has risen to $1,090 for the 2006 calendar year. These new amounts are based on the 8.9 percent increase in the medical care component of the CPI from July of 2003 to July of 2005. The CPI level was at 297.6 in July of 2003 and rose to 324.1 in July of 2005. This change accounted for the 8.9 percent increase. The increase in the AIC threshold amount for ALJ hearing requests changes to $108.90 based on the 8.9 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of $10. Therefore, the 2006 AIC threshold amount for ALJ hearings is $110. The AIC threshold amount for judicial review changes to $1,089 based on the 8.9 percent increase. This amount was rounded to the nearest multiple of $10, resulting in a 2006 AIC threshold amount of $1,090.

C. Summary Table of Adjustments in the AIC Threshold Amounts

TABLE 1.—AMOUNT-IN-CONTROVERSY THRESHOLD AMOUNTS

	CY 2004	CY 2005	CY 2006
ALJ Hearing	$100	$100	$110
Judicial Review	1000	1050	1090

* CY—Calendar Year.

Dated: January 9, 2006.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 06–346 Filed 1–10–06; 2:43 pm]

BILLING CODE 4150–24–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 Samples and Cost Schedule

AGENCY: Centers for Disease Control and Prevention (CDC), 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 non-institutionalized population. To add to the large amount of information collected for the purpose of describing the health of the population, blood lymphocytes were collected in NHANES III in anticipation of advances in genetic research.

The lymphocytes have been stored and maintained at the Division of Laboratory Sciences (DLS) at the National Center for Environmental Health (NCEH), CDC. The collection of lymphocytes was begun in the second phase of the survey (1991–1994) because of the significant advances in the rapidly evolving field of molecular biology that were occurring during the planning phase of this survey. CDC is making DNA samples from these specimens available to the research community for genetic analyses. Specimens are available from approximately 7,159 participants in the second phase of NHANES III. No cell lines will be made available.

This program has been previously announced (Tuesday, June 1, 1999 [64 FR 29321]; Thursday, August 8, 2002 [67 FR 51585]). The purpose of this notice is to announce a fourth category for proposals for use of these specimens, add an additional secondary review of approved applications and provide a new proposal schedule. For final proposal guidelines and requests or letters of intent, please contact Ms. Oraegbu or go to *http://www.cdc.gov/nchs/about/major/nhanes/dnafnlgm2.htm.*

All interested researchers are encouraged to submit letters of intent. No funding is provided as part of this solicitation. Proposals will be reviewed by a technical panel and approved applications will 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 primary purpose of the Secondary Review Committee is to factor in 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. The secondary review panel will be comprised of senior CDC scientists, who will advise the Director, NCHS, on the approved applications. 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:

- Letter of Intent Receipt: February 13, 2006.
- Submission of Proposals: March 14, 2006.
- Scientific Review: April 13, 2006.
- Secondary Review: May 15, 2006.
- Ethics Review Board: July 12, 2006.
- Notification of approval: August 1, 2006.
- Anticipated distribution of samples: December 11, 2006.

ADDRESSES: To send comments and for information, contact:

Ms. Kika Oraegbu, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4207, Hyattsville, MD 20782, Phone: 301–458–4367, Fax: 301–458–4028, *E-mail: KDO1@cdc.gov*. Internet: *http://www.cdc.gov/nchs/about/major/nhanes/dnafnlgm2.htm*.

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 Third National Health and Nutrition Examination Survey (NHANES III) began in the Fall of 1988 and ended in the Fall of 1994. Survey data were collected and can be analyzed from 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 301–458–4636 or from the Internet at *http://www.cdc.gov/nchs/about/major/nhanes/nh3data.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 DLS, NCEH, CDC, Atlanta, GA. DNA in the form of crude cell lysates is available from the cell lines derived from samples obtained from Phase II (1991–1994) participants. DNA concentrations are unknown and vary between samples.

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. Nevertheless, given the scientific importance of this resource, the CDC/NCHS Ethics Review Board (ERB) approved making anonymized samples of DNA available to the genetic research community.

The anonymization requirements proved to be restrictive and difficult to implement, therefore, in August, 2001, the CDC/NCHS ERB approved a revised plan for using these specimens based on the guidelines in the August, 1999, National Bioethics Advisory Commission (NBAC) report on the use of stored biological materials for research. This revised plan includes a process that gives researchers the ability to obtain more information associated with specimens for protocols that are determined by the ERB to have minimal risk for harm to the participant. For those protocols that cannot be conducted under unlinked (or anonymous) conditions, but have been determined to involve minimal risk, the revised plan allows for linking the genetic laboratory results to the NHANES data through the NCHS Research Data Center. This process would ensure that confidentiality of the subjects' identity is maintained and would reduce the possibility that linking genetic information to the NHANES III data files might identify an individual or cause group harm.

Potential Research Proposals

Category (A): Special studies using the NCHS Research Data Center: Complete set of samples in 96-well plates (a total of 7,159 samples distributed into 75 plates with additional five plates of quality control samples). Studies which request DNA samples linked to previously collected NHANES III public use data without the restriction of anonymization. Data analyses must be done within the NHANES Research Data Center.

Category (B): Age-race-sex studies using anonymized samples: A limited number of subsets may be distributed in 50μL cryovials. Subsets based on the selection criteria proposed by investigators. Studies of allele frequencies which require only basic demographic information (age, race/ethnicity, and sex) to be linked to the samples.

Category (C): Special anonymized studies: A limited number of subsets may be distributed in 50μL cryovials. Subsets based on the selection criteria proposed by investigators. Studies in which additional co-variates from the NHANES III public use database are required, but the re-coding maintains anonymization (minimum of five individuals in each statistical cell) of the samples.

Category (D): Additional research using specimens already obtained from previous solicitations: Researchers that have obtained NHANES III DNA samples from previous solicitations and have sufficient DNA left that they can now do additional genotyping, may request doing these additional tests on the remaining DNA. Proposals under this Category must be submitted and approved before the DNA would have had to be destroyed or returned. The proposals will be reviewed by the NHANES Genetic Technical Panel, the CDC Secondary Review panel and the ERB and if accepted, the researcher can begin the additional analysis with only the administrative cost for data handling.

These research designs A–C do not differ from the previous Plan for distributing NHANES III DNA samples to researchers.

Category (A): Special studies using the NCHS Research Data Center— Distribution of the complete set of 96 well plates (a total of 7,159 samples distributed into 75 plates with five additional plates with quality control samples). The investigator will specify the genetic analyses to be conducted on the samples. The investigator will also include in the research protocol application a list of demographic and clinical variables that would be used for the data analyses. Data analyses that combine the genetic analyses with NHANES III public use data must be conducted through the NCHS Research Data Center (RDC) or its equivalent in the Division of Health and Nutrition Examination Surveys. The researcher will conduct the genetic laboratory analyses 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 perform the data analyses, the researcher will provide the results of the genetic laboratory tests with the identification numbers to the Division of Health and Nutrition Examination Surveys (DHANES). The identification numbers will be matched to the NHANES III public use file data

by DHANES staff. The resulting data file will be used for these analyses. Data analyses will be conducted at NCHS under the direction of the researcher. Individual data sets will not be generated but the researcher can obtain the output from these analyses.

Category (B) Age-race-gender Studies: A limited number of subsets may be distributed in 50μL cryovials. Subsets based on the selection criteria proposed by investigators. To facilitate the research proposal preparation of allele frequency, NCHS will make the following data available with the DNA sample: age in ten year age groups, race-ethnicity (white, black, Mexican-American), gender, mean sample weights for each demographic group and the average design effect. Thus, investigators wishing to submit proposals under this research design type do not need to provide an analysis of NHANES III data to support the unlinked (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. NCHS will provide a data file with the demographic variables and the sample weights linked to 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 cannot be traced to any files maintained by NCHS.

Proposals submitted for this category of review are limited to those requesting samples from within this ages, gender, race/ethnicity cells for identifying the frequency of the alleles in the population. These proposals must address all criteria except for the verification that anonymization can be achieved.

Category (C): Special Anonymized Studies (Requests for Additional Variables)—A limited number of subsets may be distributed in 50μL aliquots in cryovials. Subsets are based on the selection criteria proposed by the investigator(s). The investigator will 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 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 samples with participant data on the NHANES III public use data set. Investigators should obtain the NHANES III Public Use Data and should verify that anonymity can be achieved before submitting the proposal with the requested set of variables.

A cross tabulation of all requested variables must be provided and must demonstrate that there are at least five individuals in each statistical cell of that cross tabulation. Recoding is required for continuous variables and may be required for integral variables to ensure anonymity. Because the samples are primarily available from phase II subjects, these analyses should be run using phase II subjects only (SDPPHASE=2). (Household codes are confidential data. Therefore, if only one 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 one individual per household is requested, the minimum statistical cell size of the cross tabulation should be ten subjects.) From each statistical cell, either two observations or 20 percent of the subjects of the cell, whichever is larger, will be deleted from the pool of samples sent to the investigator. In all this proposal design, the investigators will receive samples that are coded with a random identifier that is unique to that proposal and not linkable to any other data or data file once the crosswalk is deleted. NCHS 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 cannot be traced to any files maintained by NCHS.

Category (D): Additional research using specimens already obtained from previous solicitations: Researchers that have obtained NHANES III DNA samples from previous solicitations and have sufficient DNA left that they can now do additional genotyping, may request doing these additional tests on the remaining DNA. The guidelines for the proposals are the same as Category A proposals and will be reviewed by the NHANES Genetic Technical Panel, the CDC Secondary Review Panel and the ERB. If the additional research proposal is accepted, the researcher can begin the additional analysis with only the administrative cost for data handling (ten percent of the cost of a full set of samples). Proposals under this Category must be submitted and approved before the DNA would have had to be destroyed or returned.

DNA Samples

For proposals falling into category A, the laboratory will distribute 100 μl aliquots of crude cell lysate. The amount of DNA in each aliquot will be approximately 180–1,500 nanograms (ng). Aliquots will be dispensed into 96-well plates for distribution to investigators. Each plate will be bar-coded and labeled with a readable identifier. Quality control samples (approximately 480 samples) will be sent, either inserted with the NHANES samples or in separate plates, as blind duplicate and/or blanks. Approximately ten sample sets of specimens from 7,159 participants will be available for proposals. An investigator must purchase the samples in full sets. For proposals falling into category B or C, specimens will be distributed in 50 μL aliquots in cryovials rather than 96-well plates. The amount of DNA in each aliquot will be approximately 90 to 750 nanograms. Only a limited number of smaller specialized sets for category B or C are available. There are only two complete sets of cryovials, so the number of projects that can be filled with these samples depends on the types of projects proposed.

Proposed Cost Schedule for Providing Nhanes III DNA Specimens

A nominal processing fee of $6.39 is charged for each sample received from the NHANES III DNA Specimen Bank if the full sets of specimens (category A) are requested. If more limited sets of cryovials are requested, a cost of $38.00/vial is assessed to cover the manual selection of these samples. For proposals submitted under category D, where the researcher already is in possession of the NHANES DNA and administrative cost of ten percent of the processing fee will be charged to cover the data base processing and handling at NCHS. 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 in accordance with the detailed requirements of the investigators.

The materials listed are for the recurring laboratory costs to dispense and prepare the samples for shipping. Labor costs are based on the need for genetic analysts, 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 once a year. The space estimate is based on acquiring storage and sample aliquoting space in the laboratory.

Total costs	Per sample for 7,159 samples in 96-well plates	Per sample for individual cryovials
Materials	$0.85	$1.90
Labor	3.30	22.00
Application review and other administrative expenses	0.35	2.69
Space	0.13	0.97
Subtotal	4.63	27.56
NCHS overhead (15 percent)	0.69	4.12
Subtotal	5.32	31.68
CDC/FMO overhead (20 percent)	1.06	6.32
Total cost per sample	6.39	38.00
Total cost per proposal	45,746	NA
Total cost per Category D proposal: for Data handling	4,662	[1]

[1] 10 Percent of original cost of specimens.

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

Procedures for Letter of Intent

NCHS will post information about letters of intent on the NHANES Web site *www.cdc.gov/nchs/about/major/nhanes/nhanes.htm*, by January 13, 2006. The letter of intent is required to enable CDC to plan the review more efficiently, evaluate the number of requests, and to assess the capacity of the DNA Bank to fulfill requests. All letters of intent will be reviewed by the Division of Health and Nutrition Examination Surveys staff for potential major problems related to the feasibility of the project. If a problem is identified, the Division staff will inform the investigator so it can be addressed in the proposal.

All potential investigators must submit letters of intent. The letter should be no more than two pages and include (1) A descriptive title of the overall proposed research; (2) the name, address and telephone number of the Principal Investigator (PI); (3) a list of key investigators and their institution(s); (4) one paragraph on the background for the proposal and a paragraph briefly addressing each criterion for technical evaluation of letters of intent and proposals; (5) the genetic assessments proposed; (6) a list of proposed variables; and (7) an estimate of the number of samples that would be requested. The background paragraph should state concisely the importance of the research in terms of the broad, long-term objectives and public health relevance and consistency of NCHS' mission to monitor the nation's health.

Letters of intent should be submitted by February 13, 2006. E-mail submission is encouraged.

Ms. Kika Oraegbu, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4207, Hyattsville, MD 20782, Phone: 301–458–4367, FAX: 301–458–4028, E-mail: *KDO1@cdc.gov*.

Procedures for Proposals

The investigator should follow these instructions for preparation of proposals. All 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, B, C, D) submitted. Office for Human Research Protections (OHRP) assurance number for the institutions included 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 for this round of proposals, 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, 5, 6, and 7.

Approved applications will 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 primary purpose of the Secondary Review Committee is to factor in 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, who will advise the Director, NCHS, on the approved applications.

The proposal title page should include the title of the research proposal; a list of the investigators and institutions; OHRP assurance number for the institutions included in the research project; address, phone number and E-mail address of lead investigator. CDC investigators need to include their Scientific Ethics Verification Number. The proposal should contain, and will be evaluated according to, the following elements:

(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. Category D proposals where the

researcher already has the set of DNA samples and Category A proposals which request using the full set of specimens will receive priority consideration. Category B and C proposals will be evaluated together since they will be competing for the limited set of cryovials.

(2) *Background and Public Health Significance:* Describe the public health significance, scientific merit, and practical utility of the assay. 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 relation of the results to the data already collected in NHANES III. 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:* Describe the sampling scheme and number of samples requested if submitting a category C proposal. Include power calculations for the sub-sample and a list of variables requested; provide a cross-tabulation of requested variables for category C proposals. For all proposal categories, include a detailed description of the laboratory methods. The use of standard genotyping reactions vs. multiplex reactions should be discussed with reference to any anticipated problems and proposed solutions with the use of the cell lysate provided. 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. Approximately 480 quality control samples will be provided at no additional cost but the approved projects must run these samples and submit the results with the NHANES DNA samples. The proposal should contain a discussion of additional quality control procedures the laboratory used to assure the validity of the test results. Address adequate methods for handling and storage of samples. NCHS will verify the anonymity for category B and C proposals.

(4) *Discussion regarding the race/ethnicity variables:* If the sample request is limited to specific race or ethnic groups 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 specimens 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 address whether or not findings from the proposed research merit disclosure.

(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) *Anonymity:* Final approval is based upon NCHS confirmation that anonymity can be maintained by the categorization of variables for category C proposals (proposals requiring anonymity).

(8) *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 unless a new Category (D) proposal has been approved. Extensions to the period of performance may be requested.

(9) *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 $6.39 for proposals that use the full set of samples (7,159) and $38.00 per sample for subsets. Reimbursement for the samples will be collected before the samples are released.

Proposals approved by a Genetics Technical Panel and the Secondary Review Panel will also be reviewed by the CDC/NCHS ERB for human subject concerns. The ERB review will be conducted, even though investigator's proposals may have received review by their home institution. The Panel will also review an NCHS evaluation of whether anonymity can be assured for the proposed project for proposals in categories B and C. The samples that are sent to the investigator will be selected randomly from the domains by NCHS staff. 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, 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.

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 should be submitted by March 14, 2006. All investigators who submitted letters of intent may submit proposals.

Electronic submission of proposals is encouraged. Please submit proposals to: Ms. Kika Oraegbu, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Rd., Room 4207, Hyattsville, MD 20782, Phone: (301) 458–4367, Fax: (301) 458–4028, E-mail: *KDO1@cdc.gov.*

Approved Proposals

NCHS will provide a data file with the requested recoded variables (for category B and C proposals) 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 cannot be traced to any files maintained by NCHS. For proposals in category A and D, the genetic results will be sent back to NCHS so they can be linked to the NHANES III public use data in the Research Data Center for analysis.

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 cannot be used for commercial purposes. A list of genes generated from the testing of the NHANES III samples will be made available to the public for potential solicitation of proposal for secondary data analysis, six months after the data is sent to the RDC. These secondary data analysis proposals must also be reviewed by the NHANES Genetics Technical Panel and the ERB.

Progress Reports

A progress report will be submitted annually. CDC/NCHS ERB 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 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 destroyed upon completion of the approved project, unless a request is submitted and approved under Category D. 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.

Send Requests for Information

Ms. Kika Oraegbu, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4207, Hyattsville, MD 20782, Phone: 301–458–4367, Fax: 301–458–4028, E-mail: *KDO1@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: December 21, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. E5–8104 Filed 1–12–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

University of Arkansas/Food and Drug Administration Food Labeling; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 4, 2006 (71 FR 349). The document announced a public workshop entitled ''UA/FDA Food Labeling Workshop.'' The document was published with a typographical error in the **SUPPLEMENTARY INFORMATION** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–243–4970.

SUPPLEMENTARY INFORMATION: In FR Doc. E5–8225, appearing on page 349, in the **Federal Register** of Wednesday, January 4, 2006, the following correction is made:

1. On page 349, in the third column, the second sentence under **SUPPLEMENTARY INFORMATION** is corrected to read: ''This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by the FDA Dallas District Office.''

Dated: January 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–268 Filed 1–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Synthesis and High-Throughput Screening of In Vivo Cancer Molecular Imaging Agents.

Date: February 24, 2006.

Time: 12 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Executive Plaza North, 6130 Executive Boulevard, Room C, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Kenneth L Bielat, PhD, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892. (301) 496–7576. *bielatk@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 5, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–303 Filed 1–12–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as