Isolated from Humans, U.S. Patent Application 09/367,213 dated 12/08/1999. CDC Reference No. I–012–97/2; New Retrovirus Isolated from Humans, U.S. Patent Application PCT/US01/51411 dated 10.19.2001. CDC Reference No. I–023–00/0 Spumavirus Isolated from Humans, U.S. Patent Application PCT/US99/25171 dated 10/27/99. CDC Reference No. I–034–97/0; Spumavirus Isolated from Humans, U.S. Patent Application Serial No. 09/830,616 filed 9/05/01. CDC Reference No. I–034–97/1;

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

These inventions cover unique spumavirus isolates and clones from infected humans, and an infectious spumavirus vector. Licensee will further development this technology to assess this vector's suitability for gene therapy applications, attenuated vaccines, and use as a stable replicating viral vector.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770) 488–8600; facsimile: (770) 488–8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: August 2, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–20039 Filed 8–7–02; 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 Samples and Proposed Cost Schedule

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 such analyses. Specimens are available from approximately 7,300 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)). The purpose of this notice is to announce a third category for proposals for use of these specimens and a new cost schedule. For final proposal guidelines and request for 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. Approximately twenty proposals for a full set of specimens (~7,300 samples) and a limited number of proposals (less than five, depending on the number of specimens requested) for smaller sets of samples can be awarded in this solicitation. No funding is provided as part of this solicitation. Proposals will be reviewed by a technical panel. 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: September 9, 2002
- Submission of Proposals: October 7, 2002
- Application Receipt: November 18, 2002
- Scientific Review: January, 2003
- Institutional Review: February, 2003
- Notification of approval: March 2003
- Anticipated distribution of samples: July-August 2003

ADDRESSES: To send comments and for information, contact:

Ms. Kika Oraegbu, Division of Health Examination Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1000, 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 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. 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 is available from cell lines of Phase II (1991–1994) 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. Nevertheless, given the scientific importance of this resource, the CDC/NCHS Institutional Review Board (IRB) 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 IRB 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 IRB 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 deep-well format (96 specimens/per plate) ~7,300 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 NCHS Research Data Center.

Category (B): Age-race-sex studies using anonymized samples: A limited number of subsets may be distributed in 50uL 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 50uL 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 5 individuals in each statistical cell) of the samples.

These latter two research designs 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 samples in deep-well format (96 specimens/per plate) ~7,300 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 data must be conducted in the NCHS Research Data Center (RDC). The researcher will conduct the genetic laboratory analyses on the samples that are labeled with a unique random ID and are, therefore, anonymous to the researcher. To perform the data analyses, the researcher will then provide the results of the genetic laboratory tests with the random identification numbers to the Division of Health Examination Statistics (DHES). The random identification numbers are also anonymous to all staff, except the one person who has the crosswalk file. These results will be matched to the NHANES III data by that person. The resulting data file will be provided to the RDC. These analyses will be subject to all the confidentiality restrictions of the RDC (http://www.cdc.gov/nchs/r&d/rdc.htm). Because all the data analyses will be completed in the NCHS RDC, which charges for computer time and for RDC support time, it is recommended that the investigator develop the project proposal in conjunction with the NHANES Staff and Research Data Center staff. The investigator should perform preliminary analyses using NHANES public use data to determine whether the proposed research is feasible. Approval of these protocols by the RDC is required after approval by the Genetics Technical Panel. The RDC uses the following criteria for approval: risk of disclosure, consistency with the mission of NCHS, availability of RDC resources, and the feasibility of the project.

Although researchers sign confidentiality agreements to use the RDC, strict confidentiality protocols require that researchers with approved projects must complete their work using the facilities located within the Research Data Centers (currently only the Hyattsville, MD, facility is in operation). Two access methods are available for researchers to accomplish their tasks: onsite and remote. The costs and restrictions are different for each method. Onsite researchers have the ability to use the full capabilities of the SAS system with the only additional requirement being a disclosure review. Individual cells are suppressed if the minimum requirements for disclosure are not met. Additional restrictions limit the analysis capabilities of the remote access system. Under these situations, the printed output is scanned and screened prior to transmittal to the investigator. Strict minimal disclosure limits are adhered to and data items are suppressed if the minimums are not met. For remote access, all statistical cells with fewer than five observations are suppressed. Under the RDC option (protocol category A), the researcher may obtain aggregate statistics from statistical calculations which effectively use smaller statistical cell sizes for intermediate steps, such as performing regression analyses on detailed data, as long as the intermediate steps are never made available separately.

Category (B) Age-race-gender Studies: A limited number of subsets may be distributed in 50uL 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 10-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.

Proposals submitted for this category of review are limited to those requesting samples from within these age, 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 50uL 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 2 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 three proposal designs, the investigators will receive samples that are coded with a random identifier that is unique to that proposal.

DNA Samples

For proposals falling into category A, the laboratory will dilute the stock specimens that are currently in deep-well plates 1:2 and distribute 50 ul aliquots of diluted lysate. The amount of DNA in each aliquot will be approximately 180–1,500 nanograms (ng). Aliquots will be dispensed into deep-well plates for distribution to investigators. Each well will be bar-coded and labeled with a readable identifier. Approximately 20–22 sample sets of specimens from 7,300 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 deep-well plates. The amount of DNA in each aliquot will be 75 to 650 nanograms. Only a limited number of smaller specialized sets for category B or C are available. There are only 3 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 Specimen Bank

A nominal processing fee of $5.00 is charged for each sample received from the NHANES III DNA Specimen Bank if the full set of specimens (category A) are requested. If the more limited set of cryovials is requested, a cost of $38.00/vial is assessed to cover the manual selection of these 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 in accordance with the detailed requirements of the investigators. These costs were based on an assumption that NCEH and NCHS will receive and process 20 proposals in a year, each requesting 7,300 samples as shown in the table below or 5 subsets of 1000 samples in cryovials.

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 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 sample aliquoting space in the laboratory.

Total costs	Per sample for 7,300 samples in 96 well plates	Per sample for individual cryovials
Materials	$ 0.25	$ 1.90
Labor	2.90	22.00
Application review and other administrative expenses	0.35	2.69
Space	0.13	0.97
Subtotal	3.63	27.56
NCHS overhead (15%)	0.54	4.12
Subtotal	4.17	31.68
CDC/FMO overhead (20%)	0.83	6.32
Total cost per sample	5.00	38.00
Total cost per proposal	36,500	NA

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 September 9, 2002. 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. Only

20–22 full sets of samples (7,300 specimens) are available for this round of proposals. A limited set of individual cryovials will be available for less than the full set of samples. All letters of intent will be reviewed by Division of Health Examination Statistics 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's mission to monitor the nations's health.

Letters of intent should be submitted by September 9, 2002.

Ms. Kika Oraegbu, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1000, 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: Prepare proposals with a maximum of five single-spaced typed pages, excluding figures and tables, using ten 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 by the public. 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, phone number, and E-mail address, if available, of the PI, and the name of the institution where the DNA analysis will be done, and the category of proposal (A, B, C) that would be submitted. The cover page should be signed by the responsible institution representative. Proposals will be ranked by the technical panel on a scale of 1–10 with 10 being the highest rank for each category.

As there are only 20–22 full sets of samples (7,300 specimens) and only a limited set of individual cryovials for proposals requiring less than the full set of samples available for this round of proposals, proposals will be ranked by the technical panel on a scale of 1–10 with 10 being the highest rank for each category.

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 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 subsample 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. If a non-standard laboratory method is to be used, discuss its advantages over using existing methods. The characteristics of the laboratory assay, such as reliability, validity, and ''state-of-the-art,'' should be included with appropriate references. The potential difficulties and limitations of the proposed procedures should also be discussed. 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. 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 $5.00 for proposals that use the full set of samples (~7,300) and $38.00 for subsets. Reimbursement for the samples will be collected before the samples are released.

Proposals will be evaluated by a Genetics Technical Panel and, if approved, by the CDC/NCHS IRB for human subject concerns. The IRB review will be conducted, even though investigators' 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 October 7, 2002. All investigators who submitted letters of intent may submit proposals.

Electronic submission of proposals is encouraged. Please submit proposals to: Ms. Kika Oraegbu, National Center for Health Statistics, 6525 Belcrest Rd., Rm 1000, Hyattsville MD 20782, Phone: (301) 458–4367, FAX: (301) 458–4028, E-Mail: *KDO1@cdc.gov, Attention:* NHANES III Genetic Testing Program.

Approved Proposals

NCHS/NCEH 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, 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.

Progress Reports

A progress report will be submitted annually. CDC/NCHS 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 Genetics 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 destroyed 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.

Send Request for Information: Ms. Kika Oraegbu, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1000, 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: August 2, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–20038 Filed 8–7–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 02N–0332

Preparation for the International Conference on Harmonization Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document'' to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Washington, DC. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Washington, DC, September 9 to 12, 2002, at which discussion of the Common Technical Document and the future of ICH will continue.

Date and Time: The public meeting will be held on September 5, 2002, from 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, e-mail: Topperk@cder.fda.gov.

Registration and Request for Oral Presentation: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by August 29, 2002.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe,