environmental assessment by August 20, 2009.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1304.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9A4778) has been filed by Ajinomoto Co., Inc., c/o Ajinomoto Corporate Services LLC, 1120 Connecticut Ave. NW., suite 1010, Washington, DC 20036. The petition proposes to amend the food additive regulations in part 172 *Food Additives Permitted For Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of N-[*N*-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (CAS Reg. No. 714229–20–6) for use as a non-nutritive sweetener in tabletop applications and powdered beverage mixes.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: July 10, 2009.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E9–17250 Filed 7–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) Stored Biologic Specimens: Guidelines for Proposals to Use 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, serum, urine and limited plasma samples were collected and stored for future research projects. Specimens are currently available from NHANES III (conducted from 1988–1994) and from NHANES 1999–2008. In 1999, NHANES became a continuous survey with data release every two years. Specimens are available from two year survey cycles after the demographic file has been released to the public. Participants in the survey that began in 1999 signed a separate consent document agreeing to specimen storage allowing their biologic specimens to be used for approved research projects.

Specimens are stored in two Specimen Banks. Surplus samples that were initially used for laboratory assays included in the surveys, have since been stored at −70 °C and have been through at least two freeze-thaw cycles. They are stored at a commercial repository under contract to NCHS. In addition, on average, six vials of sera were also stored in vapor-phase liquid nitrogen at the CDC and ATSTR Specimen Packaging, Inventory and Repository (CASPIR) Repository in Lawrenceville, GA. These specimens have not undergone a freeze-thaw cycle. The CASPIR Repository is considered a long-term repository for the NHANES specimens. NCHS is making both of these collections available for research proposals. The research proposals that can use the surplused specimens will receive higher priority. Proposals that request the specimens in CASPIR need to justify the use of the unthawed specimens.

The purpose of this notice is to request comments on this program and the proposed cost schedule. After consideration of comments submitted, CDC will finalize and publish the cost schedule and accept proposals for use of the NHANES stored biologic samples. Please go to *http://www.cdc.gov/nchs/nhanes/proposal_guidelines.htm* for final proposal guidelines.

All interested researchers are encouraged to submit proposals. No funding is provided as part of this solicitation. 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:* August 20, 2009.
- *Invitation to Submit Proposals:* Can be submitted on an ongoing basis
- *Scientific Review Date:* Within two months of proposal submission.
- *Institutional Review Date:* Within one month of final proposal acceptance.
- *Anticipated distribution of samples:* one month after IRB approval.

ADDRESSES: To send comments and to request information, *contact:* Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782,

Phone: 301–458–4371,

Fax: 301–458–4028,

E-mail: gmm2@cdc.gov.

Internet: http://www.cdc.gov/nchs/about/major/nhanes/serum1b.htm.

Authority: Sections 301,306 and 308 of the Public Health Service Act (42 U.S.C. 241, 242k and 242M).

SUPPLEMENTARY INFORMATION:

The goals of NHANES are: (1) To estimate the number and percent of

persons in the U.S. population and designated subgroups with selected diseases and risk factors; (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 relationship between diet, nutrition and health; (6) to explore emerging public health issues and new technologies; and, (7) to establish and maintain a national probability sample of baseline information on health and nutrition status.

Specimens are available from the third National Health and Nutrition Examination Survey (NHANES III) and the continuous NHANES that started in 1999. Approximately 30,000 individuals were examined in NHANES III which began in the fall of 1988, and ended in the fall of 1994. This survey can be analyzed in two phases. Phase 1 was conducted from October 1988 to October 1991 and Phase 2 began October 1991 and ended October 1994. Though participants consented to storing samples of their blood for future testing only research projects that include results that are judged not to have clinical significance for participants will be accepted. Clinical significance is defined by the following criteria:

- The findings are valid and done by a CLIA-certified laboratory, and
- The findings may have significant implications for the subjects' health concerns, and
- A course of action to ameliorate, or treat the concerns is readily available.

There are approximately 368,473 serum samples available for research proposals using NHANES III samples. An aliquot of the samples will be reserved in perpetuity. *See: http://www.cdc.gov/nchs/about/major/nhanes/nh3data.htm* for more information on NHANES III.

Beginning in 1999, NHANES became a continuous, annual survey with examination of approximately 5,000 individuals a year and data release every two years. Proposed research projects and samples requested must come from this two-year design (i.e. request must be for 1999–2000 samples or 2001–2002, etc.). Samples from a single year of the survey will not be provided for research projects, but multiple two-year cycles may be requested. There are approximately 329,420 serum samples, 55,411 urine samples and 79,604 plasma samples available for research proposals. An aliquot of the samples will be reserved in perpetuity. For details of the sampling design see the Analytic Guidelines at: *http://www.cdc.gov/nchs/about/major/nhanes/nhanes2003–2004/analytical_guidelines.htm.*

Starting in 1999 to 2008 survey participants were informed in the consent document for future laboratory analysis that they would not receive the results from these studies. Therefore, only research projects that propose laboratory results that do not have clinical significance (see definition of clinical relevance above) to an individual will be accepted by NCHS. Clinical significance of a laboratory test will be judged by the NHANES Medical Officer, but the researcher should address this in the research proposal. *See http://www.cdc.gov/nchs/about/major/nhanes/nhanes2007–2008/current_nhanes_07_08.htm* for a copy of the current consent document.

All proposals for use of NHANES samples will be evaluated by a technical panel for scientific merit and by the NHANES Ethics Review Board (ERB) for any potential human subjects concerns. The NHANES ERB will review the proposal even if the investigator has received approval by their institutional review panel.

To determine if this limited resource should be used in the proposed projects, a 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 proposal should outline how the results from the laboratory 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 survey oversamples the two largest race/ethnic minority groups, non-Hispanic blacks and Mexican Americans along with other subgroups of the population. Sampling weights are therefore used to make national estimates of frequencies. The use of weights, sampling frame and methods of assessment of variables included in the data are likely to affect the proposed research. The Technical Panel will review the analysis plan and evaluate whether the proposal is an appropriate use of the NHANES population. The Technical Panel will also assure that the proposed project does not go beyond either the general purpose for collecting the samples in the survey, or of the specific stated goals of the proposal.

Investigators are encouraged to review the NHANES data, survey documents, manuals and questionnaires at: *http://www.cdc.gov/nchs/about/major/nhanes/nhanes99–02.htm* or for NHANES III: *http://www.cdc.gov/nchs/about/major/nhanes/nh3data.htm.*

Procedures for Proposals: All investigators (including CDC investigators) must submit a proposal for use of NHANES specimens.

Proposals are limited to a maximum of 10 single-spaced typed pages, excluding figures and tables, using 10 cpi type density. The cover of the proposal should include the name, address, and phone number and E-mail address of the principal investigator (PI) and the name of the institution where the laboratory analysis will be done. All proposals should be E-mailed to *gmm2@cdc.gov*. Proposals must include a cover page with the title of the proposal and the name, address, phone number and E-mail address of all investigators. Proposals from CDC investigators must also include investigators' scientific ethic verification number.

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

Proposals should include the following information:

(1) *Specific Aims:* List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested. NHANES is designed to provide prevalence estimates of diseases or conditions that are expected to affect between 5–10 percent of the population. Research proposals that expect much lower prevalence estimates need to provide more detail on why specimens from NHANES are needed for the project and provide details on how these data will be analyzed.

(2) *Background and Public Health Significance:* Describe the public health significance, scientific merit and practical utility of the assay. 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 public health policy or further scientific knowledge. The proposal should justify the need for specimens that are representative of the U.S. population. The proposer should convey how the results will be used and the relationship of the results to the data already collected in NHANES. The

proposer should include an analysis plan. The analyses ought to be consistent with the NHANES mission and the health status variables.

(3) *Research Design and Methods:* Describe the research design and the procedures to be used. A detailed description of laboratory methods including validity and reliability must be included with references. The volume of specimen and number of samples requested must be specified. Adequate methods for handling and storage of samples must also be addressed. The laboratory must demonstrate expertise in the proposed laboratory test including the capability for handling the workload requested in the proposal. The proposal should also include a justification for determination of sample size or a power calculation. If the researcher is requesting a sub-sample of specimens, a detailed description and justification, must be given. The researcher must describe how this sub-sample will be re-weighted to provide national estimates. The program will evaluate the study design and analysis plan in the proposal to determine whether the project is consistent with the design of the NHANES survey. Sub-samples are less useful to the research community when the data are released in the public domain, so such requests will receive a lower priority for the specimens. Restricting a research proposal to demographic categories that are design variables for the survey is encouraged if laboratory testing must be restricted.

(4) *Clinical Significance or results:* Since the consent document for specimen storage and continuing studies states that individual results will not be provided, the clinical significance of the proposed laboratory test should be addressed. The proposal should include a discussion of the potential clinical significance of the results and whether there is definitive evidence that results of the test would provide grounds for medical intervention even if many years have passed since the examination of the participant and collection of the sample. Any test with results that should be reported to a participant should be considered for inclusion in the concurrent survey, and is not appropriate for testing on the stored samples.

(5) *Qualification:* Provide 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.

(6) *Period of performance:* Specify the project period. Substantial progress must be made in the first year, and the project should be completed in two years. If additional time is needed for the research project a detailed justification with a timeline should be included. The investigator should address his/her ability to comply with this timeline or request and justify additional time for the project. Return of the specimens will be requested if progress is not made in the project at the end of the second year. Refund of payment for the specimens will not be returned in this situation. At the end of the project period, any unused samples must be returned to the NHANES Specimen Bank or discarded. The NCHS Project Officer must be consulted about the disposition of the samples.

(7) *Funding:* Include 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. The cost per specimen is $6.50. 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.

Submission of Proposals: Proposals can be submitted in MS Word format by e-mail to: Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, *Phone:* 301–458–4371 *Fax:* 301–458–4028, *e-mail: gmm2@cdc.gov.*

Approved Proposals: Approved projects will be provided specimens on receipt of a signed Materials Transfer Agreement (MTA) and a check (written to The Centers for Disease Control and Prevention) for the cost of the specimens. All laboratory results obtained from the samples will be sent back to NCHS to be linked to the sequence number that is the linking identifier on the public use files. All files will undergo disclosure review at NCHS. Within 90 days of the return of the data to NCHS these data may be released to the public.

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 samples as stated in this document and as agreed upon by the investigators and CDC.

Progress Reports: Brief progress reports will be submitted annually. This will be the basis for the NHANES ERB continuation reports that are required annually.

Disposition of Results and Samples: No samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Technical Panel and the NHANES ERB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be returned to the NHANES Specimen Bank or disposed of upon completion of the approved project. These results, once returned to NCHS, will be part of the public domain. The proposer will have 90 days for quality control review of the data before public release.

Proposed Cost Schedule for Providing NHANES Specimens: A nominal processing fee of $8.50 is proposed for each sample received from the NHANES Specimen Bank. The costs include both the collection, storage and processing of the specimens along with the review of proposals and the preparation of the data files. These costs were based on an assumption that NCHS will receive and process eight proposals in a year, each requesting 5,000 samples as shown in the table below.

The materials listed are for the recurring laboratory costs to dispense and prepare the samples during collection and for shipping; the computer software needed for the preparation of the data files and for the release of the data along with documentation on the NHANES Web page. Labor costs are based on a proposal administrator and computer programmers at NCHS to prepare the data files. The storage and pulling fees include the costs for the NHANES repository.

Total costs	Cost per vial
Labor	$1.15
Collection Storage	4.10
Pulling specimens	1.04
Shipping	0.32
Subtotal	6.61
CDC/FMO support (9%)	0.59
Subtotal	7.20
NCHS support (18%)	1.30
Total	8.50

Comments are solicited on the proposed cost schedule. Comments are due by: August 20, 2009.

Send Comments and Requests for Information to: Dr. Geraldine

McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, *Phone:* 301–458–4371; *Fax:* 301–458–4028, *e-mail: gmm2@cdc.gov*.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–17267 Filed 7–20–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0309]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL45); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#198) entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs For Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45. This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance is an annex to a VICH guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision),'' VICH GL3(R), that published in the **Federal Register** of November 23, 2007 (72 FR 65751). This draft VICH guidance document is intended to provide guidance on the application of reduced designs (i.e., bracketing and matrixing) for stability studies conducted in accordance with the principles outlined in VICH GL3(R).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance submit written or electronic comments on the draft guidance by August 20, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8268, *e-mail: dennis.bensley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#198) entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from: The European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Bracketing and Matrixing Designs for Stability Testing

The VICH Steering Committee held a meeting on February 11, 2008, and agreed that the draft guidance document entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45 should be made available for public comment. This draft VICH guidance document provides guidance on bracketing and matrixing study designs. Specific principles are defined in this guidance for situations in which bracketing or matrixing can be applied. This document is intended to address recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the VICH GL3(R), ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision).'' FDA and the VICH Expert Quality Working Group will consider comments about the draft guidance document.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections