use of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Laboratory Medicine Best Practices Project (LMBP)—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

CDC is seeking approval from the Office of Management and Budget (OMB) to collect information from healthcare organizations in order to conduct a systemic review of laboratory practice effectiveness. The purpose of information collection is to include completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in systematic reviews of practice effectiveness. CDC has been sponsoring the Laboratory Medicine Best Practices (LMBP) initiative to develop new systematic evidence reviews methods for making evidence-based recommendations in laboratory medicine. This initiative supports the CDC's mission of improving laboratory practices.

The focus of the Initiative is on pre- and post-analytic laboratory medicine practices that are effective at improving health care quality. While evidence-based approaches for decision-making have become standard in healthcare, this has been limited in laboratory medicine. No single-evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available certainly warrant such a model.

The Laboratory Medicine Best Practices Initiative began in October 2006, when CDC convened the Laboratory Medicine Best Practices Workgroup (Workgroup), a multidisciplinary panel of experts in several fields including laboratory medicine, clinical medicine, health services research, and health care performance measurement. The Workgroup has been supported by staff at CDC and the Battelle Memorial Institute under contract to CDC.

To date, the Laboratory Medicine Best Practices (LMBP) project work has been completed over three phases. During Phase 1 (October 2006–September 2007) of the project, CDC staff developed systematic review methods for conducting evidence reviews using published literature, and completed a proof-of-concept test. Results of an extensive search and review of published literature using the methods for the topic of patient specimen identification indicated that an insufficient quality and number of studies were available for completing systematic evidence reviews of laboratory medicine practice effectiveness for multiple practices, and hence for making evidence-based recommendations. These results were considered likely to be generalizable to most potential topic areas of interest.

A finding from Phase 1 work was that laboratories would be unlikely to publish quality improvement projects or studies demonstrating practice effectiveness in the peer reviewed literature, but that they routinely conducted quality improvement projects and had relevant data for completion of evidence reviews. Phase 2 (September 2007–November 2008) and Phase 3 (December 2008–September 2009), involved further methods development and pilot tests to obtain, review, and evaluate published and unpublished evidence for practices associated with the topics of patient specimen identification, communicating critical value test results, and blood culture contamination. Exploratory work by CDC supports the existence of relevant unpublished studies or completed quality improvement projects related to laboratory medicine practices from healthcare organizations. The objective for successive LMBP evidence reviews of practice effectiveness is to supplement the published evidence with unpublished evidence to fill in gaps in the literature.

Healthcare organizations and facilities (laboratory, hospital, clinic) will have the opportunity to voluntarily enroll in an LMBP network and submit readily available unpublished studies; quality improvement projects, evaluations, assessments, and other analyses relying on unlinked, anonymous data using the LMBP Submission Form. LMBP Network participants will also be able to submit unpublished studies/data for evidence reviews on an annual basis using this form. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden (in hours)	Total burden (in hours)
Healthcare Organizations	150	1	40/60	100
Total				100

Dated: July 15, 2009.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–17266 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–F–0303]

Ajinomoto Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ajinomoto Co., Inc., has filed a petition proposing that the food additive regulations be amended 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. Ajinomoto Co., Inc., also proposes that this additive be identified as advantame.

DATES: Submit written or electronic comments on the petitioner's

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