ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	List of Blood Isolates	6,000	1	1
	Manual Categorization of Positive Blood Cultures.	6,000	1	1
	Exposures to Blood/Body Fluids	600	50	1
	Healthcare Personnel Post-exposure Prophylaxis.	600	10	15/60
	Healthcare Personnel Demographic Data	600	200	20/60
	Healthcare Personnel Vaccination History	600	300	10/60
	Annual Facility Survey	600	1	8
	Healthcare Worker Survey	600	100	10/60
	Healthcare Personnel Influenza Vaccination Form.	600	500	10/60
	Healthcare Personnel Influenza Antiviral Medication Administration Form.	600	50	10/60
	Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers.	600	1	10/60
	Post-Season Survey on Influenza Vaccination Programs for Healthcare Workers.	600	1	10/60
	Central Line Insertion Practices Adherence Monitoring Form (CLIP).	6,000	100	10/60
	Laboratory Testing	600	100	15/60
	MDRO Prevention Process and Outcome Measures Monthly Monitoring Form.	6,000	24	10/60
	MDRO or CDAD Infection Event Form	6,000	72	30/60
	Laboratory Identified MDRO or CDAD Event Form (LabID).	6,000	240	30/60
	Registration Form	6,000	1	5/60
	High Risk Inpatient Influenza Vaccine—Summary Form Method A.	6,000	5	16
	High Risk Inpatient Influenza Vaccine—Numerator Data Form Method B.	2,000	250	10/60
	High Risk Inpatient Influenza Vaccine—Summary Form Method B.	2,000	5	4
	High Risk Inpatient Influenza Vaccine—Denominator Data Form Method B.	2,000	250	5/60
	Hemovigilance Module Annual Survey	500	1	2
	Hemovigilance Module Monthly Reporting Plan.	500	12	2/60
	Hemovigilance Module Blood Product Incident Reporting—Summary Data.	500	12	2
	Hemovigilance Module Monthly Reporting Denominators.	500	12	30/60
	Hemovigilance Incident	500	72	10/60
	Hemovigilance Adverse Reaction	500	120	10/60

Dated: July 13, 2009.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–09–09CD]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. Alternatively, to obtain a copy of the data collection plans and instrument, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, NE., MS–D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to *omb@cdc.gov*.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the

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.

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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