TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans. No.	ET req status	Party name
		G	Thoratec Corporation.
		G	International Technidyne Corporation.
	20100659	G	Theodore J. Leonsis.
		G	Washington Sports & Equipment Limited Partnership.
		G	Washington Sports & Equipment Limited Partnership.
	20100662	G	Oak Hill Capital Partners III, L.P.
		G	Wellspring Capital Partners III, L.P.
		G	Dave & Buster's Holdings, Inc.
	20100663	G	Iconix Brand Group, Inc.
		G	The Edward W. Scripps Trust.
		G	Character Licensing, LLC.
	20100677	G	Thomas H. Lee Equity Fund VI, L.P.
		G	Sterling Financial Corporation.
		G	Sterling Financial Corporation.
	20100678	G	Thomas H. Lee Parallel Fund VI, L.P.
		G	Sterling Financial Corporation.
		G	Sterling Financial Corporation.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau Of Competition Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2010–13725 Filed 6–8–10; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Canoga Avenue Facility, Los Angeles County, California, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 14, 2010, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and its contractors and subcontractors who worked at the Canoga Avenue Facility, Los Angeles County, California, from January 1, 1955 through December 31, 1960 for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective June 13, 2010, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Interim Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by e-mail to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2010–13795 Filed 6–8–10; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Spreading Techniques To Radically Reduce Antibiotic Resistant Bacteria (Methicillin Resistant Staphylococcus aureus, or MRSA)." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 25th, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by July 9, 2010.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (*attention:* AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Dons Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Spreading Techniques To Radically Reduce Antibiotic Resistant Bacteria (Methicillin Resistant Staphylococcus aureus, or MRSA)

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. Alarmingly, 70% of HAIs are due to bacteria that are resistant to commonly used antibiotics, with Methicillin Resistant Staphylococcus aureus (MRSA) being the most rapidly growing, and among the most virulent, pathogens. Resistance is increasing rapidly in all types of hospitals (Huang 2007). Despite evidence that routinely applied, simple interventions do work, most hospitals have failed to make notable progress in reducing MRSA infections. Hospitals in some European countries and select U.S. hospitals, however, have succeeded with impressive results.

Sites that have already achieved dramatic decreases in their MRSA infection rates have done so by implementing precautions to prevent transmission, using system redesign approaches. Further, many hospitals have successfully instituted isolation procedures for patients suspected to be MRSA carriers. In doing so, these hospitals have followed the broadly disseminated guidelines for hand hygiene and contact isolation precautions. This study is a follow up to a recent study implemented in 6 hospital systems in the Indianapolis metropolitan area that used a "MRSA intervention bundle" composed of active surveillance screening, contact isolation precautions, and increased hand hygiene. Preliminary data from that initial study suggest a 60% decrease in MRSA rates in participating intensive care units (ICUs) (Doebbeling, B. Redesigning Hospital Care for Quality and Efficiency Applications of Positive Deviance and Lean in Reducing MRSA. Presentation at AHRQ Annual Meeting, Rockville, MD. Sept 2009).

This project, a case study, will utilize the same guidelines and precautions that were applied in the original study, and will add an innovative feature that will use electronic medical record systems to improve identifying, communicating and tracking MRSA infections among healthcare systems. More specifically, this study has five aims:

(1) Further test the "MRSA intervention bundle" from the original Indianapolis MRSA study, and test the intervention in additional units in the 4 original Indianapolis hospital systems and an additional 3 hospital systems beyond Indianapolis;

(2) Identify and monitor healthcare associated community onset (HACO) MRSA cases and controls who receive care in participating hospitals and affiliated settings, identify strategies to reduce HACO MRSA and demonstrate reduction of HACO MRSA;

(3) Assess the relative effectiveness of various antibiotics in abatement or eradication of MRSA carriage in hospital patients;

(4) Evaluate the effectiveness of the tested implementation strategies and innovations by applying information technology to enable consistent collection, sharing, analysis and reporting of data;

(5) Disseminate findings and promote outreach to target audiences and other stakeholders.

While many secondary data are available for this study, Aims 1 and 2 involve primary data collection. Use of the intervention bundle requires that opinion leaders and front line workers be equipped with techniques used in the reorganization of healthcare delivery to improve health outcomes (Singhal and Greiner, 2007; IHI, 2005). These techniques will assist in identifying goals, implementing the interventions to meet local needs and measuring and feeding back progress on key processes and outcomes to staff and others.

The study also incorporates an additional informatics surveillance system to allow participating hospitals to more efficiently communicate, share and track MRSA infections. This system will save infection control and clinicians' time-for example, by electronically identifying patients with a known history of drug-resistant infections when they first contact a new institution.

This study is being conducted by AHRQ through its contractor, Indiana University and the Regenstrief Institute, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the aims of this project the following data collections will be implemented:

• Electronic medical record data on MRSA infections and screening rates will be collected from an existing and unique healthcare information exchange (Indiana Network for Patient Care or INPC) in the Indianapolis area, and the CDC's National Healthcare Safety Network (Aims 1–5). This data will be used to calculate the rate of MRSA Nosocomial Bloodstream Infections among individuals admitted to the project units at all seven participating hospitals. Screening rates for MRSA at time of admission and at discharge or transfer will also be collected on project units. This data will be used to evaluate the impact of the intervention on infection rates within the participating hospital units.

• Observational data on hand washing will be collected for at least three hours each week per hospital (Aims 1, 2, and 4). Observations will be conducted in 10-minute blocks per patient selected. In total, 18 observations per hospital will be conducted each week. Hand hygiene rates will be based on observing the number of opportunities for hand hygiene and the number of actual times completing hand hygiene. Hand hygiene opportunities include when a provider enters a patient room, moves from a contaminated site to a clean site, helps with an invasive procedure, or leaves a patient room.

• Social Network Analysis (SNA) Questionnaire, will be administered twice, pretest and posttest, to about 75 healthcare workers with direct patient care on project units (Aims 1, 4, and 5). The purpose of this questionnaire is to reveal the communicative patterns of complex groups and teams in order to identify: (1) The strength and frequency of the connections between members, (2) the level of knowledge members have concerning the structure of the network, and (3) the evaluation by members concerning the overall success of the network.

• Culture Questionnaire will also be administered twice, pretest and posttest, to about 75 healthcare workers with direct patient care (Aims 1, 4, and 5). The purpose of this questionnaire is to understand the cultural beliefs, attitudes, and knowledge of the hospital staff.

• Implementation Assessment Interviews of key informants will be conducted with about 4 individuals on the implementation team at each hospital and will be conducted quarterly (Aims 1, 4, and 5). This will allow the project team to understand and monitor how the intervention is proceeding on project units. By monitoring progress, the barriers and facilitators that could affect the project implementation can be identified.

• Patient Healthcare Use Questionnaire will be mailed to a sample of patients from the 7 participating hospitals (Aims 2 and 4). The purpose of this survey is to identify risk factors for developing healthcare associated community onset (HACO) MRSA infections during a 12-month period after discharge from a healthcare facility.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours associated with the hospital's time to participate in this research. Electronic medical record data will be collected weekly from 7 participating hospitals, however only two of these hospitals will use their staff to perform this data collection. Over the course of the project electronic medical record data will be extracted 52 times and each data extraction will take about 10 hours. Observational data will be collected 18 times each week from all participating hospitals, however only 3 hospitals will use their staff to perform the observations. The project will require 52 weeks of observations per hospital and will last 10 minutes per observation.

Both the social network analysis questionnaire and the culture questionnaire will be administered twice, pretest and posttest, to about 75 personnel at each of the 7 hospitals. The social network analysis questionnaire will take about 15 minutes to complete while the culture questionnaire will take 30 minutes. The implementation assessment questionnaire will be administered quarterly to 3 key informants at each hospital and will take about one hour.

The patient healthcare use questionnaire will be completed by 200 patients sampled from the 7 participating hospitals. Each patient will respond once which will require about 15 minutes. The total annualized burden hours for all the associated data collections are estimated to be 2,458.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be $77,387.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of hospitals	Number of responses per hospital	Hours per response	Total burden hours
Electronic Medical Record Data Collection	2	52	10	1,040
Observational Data Collection	3	936	10/60	468
Social Network Analysis Questionnaire	7	150	15/60	263
Culture Questionnaire	7	150	30/60	525
Implementation Assessment Interviews	7	16	1	112
Patient Healthcare Use Questionnaire	200	1	15/60	50
Total	226	na	na	2,458

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of hospitals	Total burden hours	Average hourly wage rate *	Total cost burden
Electronic Medical Record Data Collection	2	1040	$30.03	$31,231
Observational Data Collection	3	468	20.98	9,819
Social Network Analysis Questionnaire	7	263	38.28	10,068
Culture Questionnaire	7	525	38.28	20,097
Implementation Assessment Interviews	7	112	45.33	5,077
Patient Healthcare Use Questionnaire	200	50	21.90	1,095
Total	226	2,458	na	77,387

* Based upon the mean of the average wages for Nursing Care Providers ($30.03), Primary Care Physicians ($84.97), Allied Health Providers ($20.98), Administrators, Chief Executives ($76.23) and All Workers ($21.90); National Compensation Survey: Occupational wages in the United States May 2008, "U.S. Department of Labor, Bureau of Labor Statistics."

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this project to the Federal Government over a two-year period. The total cost of this project is $1.8 million which includes $785,000 for project development, $70,000 for data collection activities, $235,000 for data analysis, $125,000 for publication of the results, $170,000 for project management and $415,000 for overhead costs.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$785,000	$262,000
Data Collection Activities	70,000	35,000
Data Processing and Analysis	235,000	78,000
Publication of Results	125,000	125,000
Project Management	170,000	57,000
Overhead	415,000	138,000

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Total	1,800,000	900,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 28, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–13728 Filed 6–8–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 9, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control Number 0910–0338)—Extension

Under Section 351 of the Public Health Services Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR Part 601).

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of additional collection of information requirements follows.

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65. The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12 (a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant