ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Burden per response (in hr)
Jurisdiction Receptionist or Operator	Telephone screener	800	1	5/60
Coroner	National Survey of Medical Examiners and Coroners.	576	1	30/60
Medical Examiner	National Survey of Medical Examiners and Coroners.	64	1	30/60

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–20642 Filed 8–22–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0666]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB No. 0920–0666), exp. 12/31/2015—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. The NHSN consists of six components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility (LTCF), Dialysis, and Outpatient Procedure.

The new Dialysis Component was developed in order to separate reporting of dialysis events from the Patient Safety Component. The new component will tailor the NHSN user interface for dialysis users to simplify their data entry and analyses processes as well as provide options for expanding the Dialysis Component in the future to include dialysis surveillance in settings other than outpatient facilities.

The new Outpatient Procedure Component was developed to gather data on the impact of infections and other outcomes related to outpatient procedures that are performed in settings such as Ambulatory Surgery Centers (ASCs), Hospital Outpatient Departments (HOPDs), and physicians' offices. Three event types will be monitored in this new component: Same Day Outcome Measures, Prophylactic Intravenous (IV) Antibiotic Timing, and Surgical Site Infections (SSI).

This revision submission includes two new NHSN components and their corresponding forms. The Dialysis Component consists of changes to three previously approved forms and the addition of four new forms. These new forms include component specific monthly reporting plan, prevention process measures monthly monitoring, patient influenza vaccination, and patient influenza vaccination denominator forms. The Outpatient Procedure Component consists of four new forms: Component specific annual survey, monthly reporting plan, event, and monthly denominators and summary forms.

Further, the breadth of organism susceptibility data required on all of the healthcare-associated infection (HAI) report forms (i.e., BSI, UTI, SSI, PNEU (VAP and VAE), DE, LTUTI, and MDRO Infection Surveillance) has been reduced for the purposes of streamlining, simplification, and removing undue burden where possible. Significant changes were made to the NHSN Biovigilance Component forms as a result of a subject matter expert and stakeholder working groups. This includes the removal of the monthly incident summary form. A brand new form was added (Form 57.600—State Health Department Validation Record) to collect aggregate validation results that will be gathered by state health departments when conducting facility-level validation of NHSN healthcare-associated infection (HAI) data within their jurisdictions using the CDC/NHSN Validation Guidance and Toolkits.

Additionally, minor revisions have been made to 32 other forms within the package to clarify and/or update surveillance definitions.

The previously approved NSHN package included 48 individual collection forms; the current revision request adds nine new forms and removes one form for a total of 56 forms. The reporting burden will increase by 542,122 hours, for a total of 4,104,776 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form No. and name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Registered Nurse (Infection Preventionist)	57.100: NHSN Registration Form	2,000	1	5/60
Registered Nurse (Infection Preventionist)	57.101: Facility Contact Information	2,000	1	10/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form No. and name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Registered Nurse (Infection Preventionist)	57.103: Patient Safety Component—Annual Hospital Survey.	6,000	1	30/60
Registered Nurse (Infection Preventionist)	57.105: Group Contact Information	6,000	1	5/60
Registered Nurse (Infection Preventionist)	57.106: Patient Safety Monthly Reporting Plan.	6,000	12	35/60
Registered Nurse (Infection Preventionist)	57.108: Primary Bloodstream Infection (BSI)	6,000	36	32/60
Registered Nurse (Infection Preventionist)	57.111: Pneumonia (PNEU)	6,000	72	29/60
Registered Nurse (Infection Preventionist)	57.112: Ventilator-Associated Event	6,000	144	22/60
Infection Preventionist	57.114: Urinary Tract Infection (UTI)	6,000	27	29/60
Staff RN	57.116: Denominators for Neonatal Intensive Care Unit (NICU).	6,000	9	3
Staff RN	57.117: Denominators for Specialty Care Area (SCA)/Oncology (ONC).	6,000	9	5
Staff RN	57.118: Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	6,000	54	5
Registered Nurse (Infection Preventionist)	57.120: Surgical Site Infection (SSI)	6,000	36	29/60
Staff RN	57.121: Denominator for Procedure	6,000	540	5/60
Laboratory Technician	57.123: Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables.	6,000	12	5/60
Pharmacy Technician	57.124: Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables.	6,000	12	5/60
Registered Nurse (Infection Preventionist)	57.125: Central Line Insertion Practices Adherence Monitoring.	1,000	100	5/60
Registered Nurse (Infection Preventionist)	57.126: MDRO or CDI Infection Form	6,000	72	29/60
Registered Nurse (Infection Preventionist)	57.127: MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	6,000	24	12/60
Registered Nurse (Infection Preventionist)	57.128: Laboratory-identified MDRO or CDI Event.	6,000	240	15/60
Registered Nurse (Infection Preventionist)	57.130: Vaccination Monthly Monitoring Form–Summary Method.	100	5	14
Registered Nurse (Infection Preventionist)	57.131: Vaccination Monthly Monitoring Form–Patient-Level Method.	100	5	2
Registered Nurse (Infection Preventionist)	57.133: Patient Vaccination	100	250	10/60
Registered Nurse (Infection Preventionist)	57.137: Long-Term Care Facility Component—Annual Facility Survey.	250	1	45/60
Registered Nurse (Infection Preventionist)	57.138: Laboratory-identified MDRO or CDI Event for LTCF.	250	8	15/60
Registered Nurse (Infection Preventionist)	57.139: MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	250	12	5/60
Registered Nurse (Infection Preventionist)	57.140: Urinary Tract Infection (UTI) for LTCF.	250	9	27/60
Registered Nurse (Infection Preventionist)	57.141: Monthly Reporting Plan for LTCF	250	12	5/60
Registered Nurse (Infection Preventionist)	57.142: Denominators for LTCF Locations ...	250	12	3
Registered Nurse (Infection Preventionist)	57.143: Prevention Process Measures Monthly Monitoring for LTCF.	250	12	5/60
Registered Nurse (Infection Preventionist)	57.150: LTAC Annual Survey	400	1	30/60
Registered Nurse (Infection Preventionist)	57.151: Rehab Annual Survey	1,000	1	25/60
Occupational Health RN/Specialist	57.200: Healthcare Personnel Safety Component Annual Facility Survey.	50	1	8
Occupational Health RN/Specialist	57.203: Healthcare Personnel Safety Monthly Reporting Plan.	50	9	10/60
Occupational Health RN/Specialist	57.204: Healthcare Worker Demographic Data.	50	200	20/60
Occupational Health RN/Specialist	57.205: Exposure to Blood/Body Fluids	50	50	1
Occupational Health RN/Specialist	57.206: Healthcare Worker Prophylaxis/Treatment.	50	30	15/60
Laboratory Technician	57.207: Follow-Up Laboratory Testing	50	50	15/60
Occupational Health RN/Specialist	57.210: Healthcare Worker Prophylaxis/Treatment-Influenza.	50	50	10/60
Medical/Clinical Laboratory Technologist	57.300: Hemovigilance Module Annual Survey.	500	1	2
Medical/Clinical Laboratory Technologist	57.301: Hemovigilance Module Monthly Reporting Plan.	500	12	1/60
Medical/Clinical Laboratory Technologist	57.303: Hemovigilance Module Monthly Reporting Denominators.	500	12	1
Medical/Clinical Laboratory Technologist	57.304: Hemovigilance Adverse Reaction	500	48	15/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form No. and name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Medical/Clinical Laboratory Technologist	57.305: Hemovigilance Incident	500	12	10/60
Staff RN	57.400: Outpatient Procedure Component—Annual Facility Survey.	5,000	1	5/60
Staff RN	57.401: Outpatient Procedure Component—Monthly Reporting Plan.	5,000	12	15/60
Staff RN	57.402: Outpatient Procedure Component Event.	5,000	25	40/60
Staff RN	57.403: Outpatient Procedure Component—Monthly Denominators and Summary.	5,000	12	40/60
Registered Nurse (Infection Preventionist)	57.500: Outpatient Dialysis Center Practices Survey.	6,000	1	1.75
Staff RN	57.501: Dialysis Monthly Reporting Plan	6,000	12	5/60
Staff RN	57.502: Dialysis Event	6,000	60	13/60
Staff RN	57.503: Denominator for Outpatient Dialysis	6,000	12	6/60
Staff RN	57.504: Prevention Process Measures Monthly Monitoring for Dialysis.	600	12	30/60
Staff RN	57.505: Dialysis Patient Influenza Vaccination.	250	75	10/60
Staff RN	57.506: Dialysis Patient Influenza Vaccination Denominator.	250	5	10/60
Epidemiologist	57.600: State Health Department Validation Record.	152	50	15/60

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Impact of Japanese Encephalitis Vaccination in Cambodia, Funding Opportunity Announcement (FOA) CK14–001, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–3:00 p.m., October 17, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Impact of Japanese Encephalitis Vaccination in Cambodia, FOA CK14–001''.

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–20531 Filed 8–22–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0002]

Withdrawal of Approval of New Animal Drug Applications; Quali-Tech Products, Inc.; Bambermycins; Pyrantel; Tylosin; Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs) held by Quali-Tech Products, Inc., at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 3, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–453–6843; email: *david.alterman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., has requested that FDA withdraw approval of the following four NADAs because the products, used to manufacture Type C medicated feeds, are no longer manufactured or marketed: NADA 097–980 for Quali-Tech TYLAN–10 (tylosin phosphate) Premix, NADA 118–815 for Q.T. BAN–TECH (pyrantel tartrate), NADA 132–705 for FLAVOMYCIN (bambermycins), and NADA 133–335 for STAFAC (virginiamycin) Swine Pak 10.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 097–980, 118–815, 132–705, and 133–335, and all supplements and