support of DGHP country offices. Specifically, it: (1) Coordinates all DGHP procurement and extramural activities in compliance with federal appropriations law, congressional intent, and global health policies; (2) facilitates and manages the development, clearance, and award of all new and ongoing DGHP field grants, cooperative agreements, and contracts; (3) provides technical assistance and guidance to country offices and DGHP branches on budget and extramural issues including assisting programs in determining the appropriate funding mechanism to support DGHP activities; (4) provides training and tools to DGHP country programs to improve budget and cooperative agreement management; (5) manages DGHP country budgets including conducting budget planning exercises, spend plan development and reporting, annual close-out processes, and analyses to inform country planning; (6) provides funding and budgetary data for regular reports including HHS and OMB reports, GAO and IG audits, country program reviews, and other requests for data; (7) liaises and collaborates with CDC financial and procurement-related units and offices including OFR and the Information Technology Services Office; (8) collaborates with other DGHP branches, other CDC and HHS programs and offices, other USG agencies, and other national and international organizations on overseas management and operations priorities; (9) develops strategies to improve the technical skills and problem-solving abilities of country program managers and locally employed staff who work in the budget and finance area; (10) provides short-term and long-term consultation and technical assistance for management and operations issues to DGHP country offices; (11) facilitates overseas purchasing and property management activities; (12) monitors risk management of country operations and extramural awards; (13) oversees property, facilities, motor pool, and records management; and (14) coordinates other logistics needs for DGHP overseas operations.

James Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2015–29914 Filed 11–24–15; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–16–15AUJ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: 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

Paul Coverdell National Acute Stroke Program (PCNASP)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stroke is the fifth leading cause of death in the United States and results in approximately 130,000 deaths per year. Stroke outcomes depend upon the rapid recognition of signs and symptoms of stroke, prompt transport to a treatment facility, and early rehabilitation. Improving outcomes requires a coordinated systems approach involving pre-hospital care, emergency department and hospital care, rehabilitation, prevention of complications, and ongoing secondary prevention.

Through the Paul Coverdell National Acute Stroke Program (PCNASP), CDC has been continuously working to measure and improve acute stroke care using well-known quality improvement strategies coupled with frequent evaluation of results. PCNASP awardees are state health departments who work with participating hospitals and EMS agencies in their jurisdictions to improve quality of care for stroke patients.

Nine awardees were funded under five-year cooperative agreements effective July 1, 2015. Awardees and their selected hospital partners will systematically collect and report data on stroke care data across the continuum of care which includes pre-hospital (EMS), in-hospital, and post-hospital phases of care. In addition, PCNASP awardees will also request information from hospitals that admit and treat stroke patients in awardees' jurisdictions. This information is needed to understand the capacity and infrastructure of the systems for acute stroke care.

Hospitals will transmit pre-hospital and post-hospital information to their awardee quarterly. The average burden per response is 15 minutes for pre-hospital and post-hospital information transmission. There is no burden for hospitals to transmit in-hospital data, because awardees use their own processes to extract in-hospital data from hospitals' electronic systems. Each hospital will collect and transmit hospital inventory information to its PCNASP awardee annually. This average burden per response is 30 minutes.

The average burden per response for awardees to transmit pre-hospital, in-hospital, and post-hospital data to CDC will vary between 30–90 minutes. The burden will be 30 minutes each for independent submission of information relating to the pre-hospital, in-hospital, and post-hospital phases of patient care. Alternatively, the burden will be 90 minutes for awardees who transmit pre-, in-, and post-hospital data as one

combined file. CDC accepts file transmissions as individual phases or combined. In addition, each PCNASP awardee will prepare an annual aggregate hospital inventory file for transmission to CDC. The average burden of reporting hospital inventory information for each PCNASP awardee is eight hours per response.

All patient, hospital, and EMS provider data that is submitted to CDC by PCNASP awardees will be de-identified and occur through secure data systems. Proposed data elements and quality indicators may be updated over time to include new or revised items based on evolving recommendations and standards in the field to improve the quality of stroke care.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 382.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PCNASP Hospital Partners	Pre-hospital quality of care data	78	4	15/60
	Post-hospital quality of care data	20	4	15/60
	Hospital inventory data	315	1	30/60
PCNASP Awardee	Pre-hospital quality of care data	9	4	30/60
	In-hospital quality of care data	9	4	30/60
	Post-hospital quality of care data	9	4	30/60
	Hospital inventory data	9	1	8

Leroy A. 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. 2015–30061 Filed 11–24–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–1153]

Determination That TYLENOL WITH CODEINE (Acetaminophen With Codeine Phosphate) Oral Tablets, 325 Milligrams/7.5 Milligrams, 325 Milligrams/15 Milligrams, 325 Milligrams/30 Milligrams, and 325 Milligrams/60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 milligrams (mg)/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Baluss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6278, Silver Spring, MD 20993–0002, 301–796–3469.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, are the subject of ANDA 85–056 held by McNeil Ortho Pharmaceuticals, Inc., and were initially approved July 9, 1976. TYLENOL WITH CODEINE is indicated for the relief of mild to moderately severe pain.

In a letter dated January 26, 1993, McNeil Ortho Pharmaceuticals, Inc. notified FDA that TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 7, 2015 (Docket No. FDA–2015–P–1153), under 21 CFR 10.30, requesting that the Agency determine whether TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were withdrawn from sale for reasons of safety or effectiveness.