A. Purpose

The clause at FAR 52.215–14, Integrity of Unit Prices, requires offerors and contractors under Federal contracts that are to be awarded without adequate price competition to identify in their proposals those supplies which they will not manufacture or to which they will not contribute significant value. The policies included in the FAR are required by 41 U.S.C. 3503 (a)(1)(A)(for the civilian agencies) and 10.U.S.C 2306a(b)(1)(A)(i)(for DOD and NASA). The rule contains no reporting requirements on contracts below the simplified acquisition threshold, construction and architect-engineering services, utility services, service contracts where supplies are not required, commercial items, and contracts for petroleum products.

B. Annual Reporting Burden

Respondents: 950.

Responses per Respondent: 10.

Annual Responses: 9500.

Hours per Response: 1 hour.

Total Burden Hours: 9,500.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0080, Integrity of Unit Prices.

Dated: August 22, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–21358 Filed 8–29–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–12–12PK]

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

Standardized National Hypothesis Generating Questionnaire—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the U.S. there is not a standard, national form or data collection system for illnesses caused by many enteric pathogens. Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.

CDC requests OMB approval to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire, from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to collect core elements data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Burden hours are calculated by approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak investigations x 45 minutes/response. There are no costs to respondents other than their time. The total estimated annualized burden is 3,000 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	No. of responses per respondent	Avg. burden per response (in hrs)
Ill individuals identified as part of an outbreak investigation.	Standardized National Hypothesis Generating Questionnaire (Core Elements).	4,000	1	45/60

Dated: August 23, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science, Office of the Directors, Centers for Disease Control and Prevention.

[FR Doc. 2012–21312 Filed 8–29–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0135]

Compliance Policy Guide Sec. 420.300 Changes in Compendial Specifications and New Drug Application Supplements; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide (CPG) Sec. 420.300 Changes in Compendial Specifications and New Drug Application (NDA) Supplements. CPG Sec. 420.300 is included in FDA's Compliance Policy Guides Manual available on the Agency's Web site at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm.*

DATES: The withdrawal is effective August 30, 2012.

FOR FURTHER INFORMATION CONTACT: Larry A. Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–1585.

SUPPLEMENTARY INFORMATION: This CPG was originally issued on October 1, 1980, in the Agency's Manual of Compliance Policy Guides. FDA is withdrawing CPG Sec. 420.300 because it is obsolete. Current guidance to FDA staff and industry regarding application requirement for changes in compendial specifications is provided in 21 CFR 314.70 and the Agency's Guidance for Industry: Changes to an Approved NDA or Abbreviated New Drug Application, which is available on the Internet at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM077097.pdf.*

Dated: August 16, 2012.

Dara A. Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2012–21415 Filed 8–29–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0360]

MDEpiNet 2012 Annual Meeting: The Medical Device Epidemiology Network as a Partnership for Building Global Medical Device Epidemiology and Surveillance Capabilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''MDEpiNet 2012 Annual Meeting: The Medical Device Epidemiology Network as a Partnership for Building Global Medical Device Epidemiology and Surveillance Capabilities.'' The topic to be discussed is setting strategic priorities and implementing an action plan for sustainable partnership toward improving regulatory science and the public health.

DATES: The public workshop will be held on September 11, 2012, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Greenbelt Marriott Hotel, 6400 Ivy Lane, Greenbelt, MD 20770, 301–441–3700.

FOR FURTHER INFORMATION CONTACT: Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993, 301–796–6689, email: *Danica.Marinac-Dabic@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., September 10, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration will not be available on the day of the workshop.

If you need special accommodations due to a disability, please contact Joyce Raines, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4319, Silver Spring, MD 20993, 301–796–5709, email: *joyce.raines@fda/hhs.gov;* no later than September 5, 2012.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Danica Marinac-Dabic (see *Contact Person*) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., September 5, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 7, 2012.

Comments: FDA is holding this public workshop to provide updates and obtain stakeholders' input on the Medical Device Epidemiology Network (MDEpiNet) as a partnership for building global medical device epidemiology and surveillance capabilities. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is October 9, 2012.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*