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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0792]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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 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; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Environmental Health Specialists Network (EHS-NET) Program (OMB No. 0920–0792, expires 2/28/2015)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting OMB approval for three additional years to use this generic clearance for a research program focused on identifying the environmental causes of foodborne illness.

To date, EHS-Net has conducted four studies under this generic clearance. The first study collected data on improper cooling of hot foods, a food handling practice associated with foodborne illness and outbreaks. The second study collected data on the relationship between kitchen manager food safety certification and foodborne illness risk factors in restaurants. Public health agencies are increasingly encouraging or requiring certification as a foodborne illness prevention measure, yet little is known about its effectiveness. The third study collected data on the environmental factors associated with contamination of the retail deli environment with *Listeria,* a foodborne illness pathogen ranked 3rd in terms of the number of deaths it causes. The fourth study collected data on restaurant managers' and workers' food allergen knowledge, attitudes, and practices. Food allergens are an important food safety issue for restaurants.

The data from the first two studies have been disseminated to environmental public health/food safety regulatory programs and the food industry in the form of presentations at conferences and meetings, scientific journal publications, and Web site postings. We will continue to analyze and present the data from all four studies, and expect that they will continue to provide valuable and useful data about environmental factors associated with foodborne illness outbreaks and food safety issues.

This revision will provide OMB clearance for EHS-Net data collections conducted in 2015 through 2018 (approximately one per year). The program is revising the generic information collection request (ICR) in the following ways:

(1) Because of the re-announcement and re-competition of the EHS-Net cooperative agreement in 2015, it is likely that the sites in which data will be collected will differ from the sites in which data were collected previously.

(2) We revised the estimated study sample size and burden downward. Thus, the estimated burden has been reduced.

(3) We have eliminated proposed sample weighting analyses.

Reducing foodborne illness first requires identification and understanding of the environmental factors that cause these illnesses. We need to know how and why food becomes contaminated with foodborne illness pathogens. This information can then be used to determine effective food safety prevention methods. Ultimately, these actions can lead to increased regulatory program effectiveness and decreased foodborne illness. The purpose of this food safety research program is to identify and understand environmental factors associated with foodborne illness and outbreaks. This program is conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative project of CDC, FDA, USDA, and local and state sites.

Environmental factors associated with foodborne illness include both food safety practices (*e.g.,* inadequate cleaning practices) and the factors in the environment associated with those practices (*e.g.,* worker and retail food establishment characteristics). To understand these factors, we need to continue to collect data from those who prepare food (*i.e.,* food workers) and on the environments in which the food is prepared (*i.e.,* retail food establishment kitchens). Thus, data collection methods for this generic package include: (1) Manager and worker interviews/surveys, and (2) observation of kitchen environments. Both methods allow data collection on food safety practices and environmental factors associated with those practices.

For each data collection, we will collect data in approximately 47 retail food establishments per site. Thus, there will be approximately 376 establishments per data collection (an estimated 8 sites × 47 establishments). We expect a manager/establishment

response rate of approximately 60 percent; thus, we will need to attempt to recruit 627 managers/establishments via telephone in order to meet our goal of 376 establishments. Each manager will respond to the recruiting script only once for approximately 3 minutes. Thus, the maximum burden for the manager recruiting attempts will be 31.35 hours (627 managers × 3 minutes). We will collect interview/survey data from a manager in each establishment. Each manager will respond only once for approximately 30 minutes. Thus, the maximum burden for the manager interview/survey will be 188 hours (376 managers × 30 minutes). In total, the average burden for managers will be 219.35 hours (31.35 hours for recruiting plus 188 hours for the interview/survey).

For each data collection, we will recruit a worker from each participating establishment to provide interview/survey data. Each worker will respond to the recruiting script only once for approximately 3 minutes. Thus, the maximum burden for the worker recruiting attempts will be 18.8 hours (376 workers × 3 minutes). We expect a worker response rate of 90 percent (339 workers). Each worker will respond only once for approximately 10 minutes. Thus, the maximum burden for the worker interview/survey will be 56.5 hours (339 workers × 10 minutes). In total, the average burden per worker response will be 75.3 hours (18.8 hours for recruiting + 56.5 hours for the interview/survey).

There is no cost to respondents other than their time. The total estimated annual burden for the data collection will be 295 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Retail managers	Manager Telephone Recruiting Script	627	1	3/60	31
Retail managers	Manager Interview/survey	376	1	30/60	188
Retail food workers	Worker Recruiting Script	376	1	3/60	19
Retail food workers	Worker Interview/survey	339	1	10/60	57
Total					295

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0543]

Agency Information Collection Activities; Proposed Collection; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the current burden hours on regulated industry of complying with the guidance underlying this collection of information.

DATES: Submit electronic or written comments on the collection of information by March 13, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.