Dated: December 10, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director.

[FR Doc. 2012–30180 Filed 12–13–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–0604]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

School Associated Violent Death Surveillance System (0920–0604, Expiration 1/31/2013)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Violence Prevention (DVP), National Center for Injury Prevention and Control (NCIPC) proposes to maintain a system for the surveillance of school-associated homicides and suicides. The system relies on existing public records and interviews with law enforcement officials and school officials. The purpose of the system is to (1) estimate the rate of school-associated violent death in the United States and (2) identify common features of school-associated violent deaths. The system will contribute to the understanding of fatal violence associated with schools, guide further research in the area, and help direct ongoing and future prevention programs.

Violence is the leading cause of death among young people, and increasingly recognized as an important public health and social issue. In 2006, over 3,200 school-aged children (5 to 18 years old) in the United States died violent deaths due to suicide, homicide, and unintentional firearm injuries. The vast majority of these fatal injuries were not school associated. However, whenever a homicide or suicide occurs in or around school, it becomes a matter of particularly intense public interest and concern. NCIPC conducted the first scientific study of school-associated violent deaths (SAVD) during the 1992–99 academic years to establish the true extent of this highly visible problem. Despite the important role of schools as a setting for violence research and prevention interventions, relatively little scientific or systematic work has been done to describe the nature and level of fatal violence associated with schools. Until NCIPC conducted the first nationwide investigation of violent deaths associated with schools, public health and education officials had to rely on limited local studies and estimated numbers to describe the extent of school-associated violent death.

SAVD is an ongoing surveillance system that draws cases from the entire United States in attempting to capture all cases of school-associated violent deaths that have occurred. Investigators review public records and published press reports concerning each school-associated violent death. For each identified case, investigators also interview an investigating law enforcement official (defined as a police officer, police chief, or district attorney), and a school official (defined as a school principal, school superintendent, school counselor, school teacher, or school support staff) who are knowledgeable about the case in question. Respondents will only be interviewed once. Researchers request information on both the victim and alleged offender(s)—including demographic data, their academic and criminal records, and their relationship to one another. Data are also collected on the time and location of the death; the circumstances, motive, and method of the fatal injury; and the security and violence prevention activities in the school and community where the death occurred, before and after the fatal injury event. The data collection process has been revised to update items included in the surveys administered to law enforcement and school staff and to incorporate use of Computer Assisted Telephone Interviewing software to further reduce respondent burden. To obtain as much detailed information as possible concerning each identified case, investigators seek to obtain the initial law enforcement investigative report.

All data are secured through the use of technical, physical, and administrative controls. Hard copies of data are to be kept under lock and key in secured offices, located in a secured facility that can be accessed only by presenting the appropriate credentials. Digital data are password protected and then stored (and backed up routinely) onto a secure Local Area Network that can only be accessed by individuals who have been appropriately authorized. Study data are reported in the aggregate, such that no individual case can be identified from the reports. Data collection will be discontinued for the early part of 2013 as we wait for the 30-day notice to post and approval of our revision package.

There are no costs to the respondents other than their time.

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 (in hours)
School Officials	School Interview	35	1	1	35

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Police Officials	Law Enforcement Interview	35	1	1	35
Total					70

Dated: December 10, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director.

[FR Doc. 2012–30183 Filed 12–13–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0711]

Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing a docket to obtain comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004.

DATES: Submit either electronic or written comments by February 12, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0711, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–0711. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1056.

SUPPLEMENTARY INFORMATION:

I. Background

Food allergy is an immune-mediated sensitivity to foods that can lead to life-threatening adverse reactions. Because there is no cure for food allergy, allergic consumers must use avoidance to prevent allergic reactions. Successful avoidance requires, among other things, that allergic consumers and their caregivers be able to read and understand the ingredient lists on packaged foods.

To help consumers more easily identify ingredients in foods that may cause an allergic reaction, the President signed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Pub. L. 108–282), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by defining the term ''major food allergen'' and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of major food allergens on the product label using the common or usual name of that major food allergen. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) now defines a major food allergen as ''[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans'' and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

FALCPA provides two mechanisms through which ingredients may become exempt from the major food allergen labeling requirement. An individual may petition for an exemption by providing scientific evidence, including the analytical method used, that an ingredient ''does not cause an allergic response that poses a risk to human health.'' (21 U.S.C. 403(w)(6)(C)). Alternatively, an individual may submit a notification that contains either scientific evidence showing that an ingredient ''does not contain allergenic protein'' or that a determination has previously been made through a premarket approval process that the ingredient ''does not cause an allergic response that poses a risk to human health.'' (21 U.S.C. 403(w)(7)(A)).

In addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. Most cross-contact can be avoided by controlling the production environment. These controls can include a wide range of activities, such as establishing personnel and traffic patterns that minimize the potential to transfer an allergen from one product to another.

FDA has used several risk management strategies to reduce the risk from unlabeled major food allergens, such as targeted inspections or discussions with industry organizations. However, we have not established regulatory thresholds or action levels for major food allergens. The establishment of regulatory thresholds or action levels for major food allergens would help us