ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Data collection method	Number of respondents	Number of responses per respondent	Average burden per response
	Focus Groups (Online)	120	1	1
	Short Surveys	8,001	1	10/60
	Medium Surveys	13,334	1	25/60
	In-depth Surveys	1,292	1	1

Dated: September 22, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–25005 Filed 9–28–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–240]

Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and extension of public comment period.

SUMMARY: On August 23, 2011, the Director of the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) published a notice in the **Federal Register** (76 FR 52664) announcing its intent to ''review its approach to classifying carcinogens and establishing recommended exposure limits (RELs) for occupational exposures to hazards associated with cancer.'' As part of this effort, NIOSH requested initial input on issues, and answers to 5 questions. NIOSH has also created a new NIOSH Cancer and RELs Policy Web Topic Page [see *http://www.cdc.gov/niosh/topics/cancer/policy.html*] to provide additional details about this effort and progress updates.

Written comment was to be received by September 22, 2011. NIOSH has received a request to extend the comment period to permit the public more time to gather and submit information. NIOSH is extending the public comment period to Friday, December 30, 2011.

Public Comment Period: Written or electronic comments must be received on or postmarked by Friday, December 30, 2011.

ADDRESSES: Written comments, identified by docket number NIOSH–240, may be submitted by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.
- *Facsimile:* (513) 533–8285.
- *E-mail: nioshdocket@cdc.gov.*

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at *http://www.cdc.gov/niosh/docket,* and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number NIOSH–240.

FOR FURTHER INFORMATION CONTACT: T.J. Lentz, telephone (513) 533–8260, or Faye Rice, telephone (513) 533–8335, NIOSH, MS–C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: September 23, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011–25039 Filed 9–28–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

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) announce the following meeting for the aforementioned committee:

Times and Dates

8 a.m.–6 p.m., October 25, 2011.

8 a.m.–1:15 p.m., October 26, 2011.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ''Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include discussions on: Child/adolescent immunization schedules; adult immunization schedule; human papillomavirus vaccine; hepatitis B vaccine; meningococcal vaccines; influenza; 13-valent pneumococcal conjugate vaccine; measles, mumps, and rubella (MMR) vaccine; febrile seizures and vaccines; pertussis; immunization coverage among children and adolescents; and vaccine supply.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Stephanie B. Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., MS–A27, Atlanta, Georgia 30333, telephone (404) 639–8836; E-mail *ACIP@CDC.GOV.*

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 Agency for Toxic Substances and Disease Registry.

Dated: September 21, 2011.

Elaine L. Baker,

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

[FR Doc. 2011–25012 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 31, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *FAX:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 203—(OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1—REPORTING REQUIREMENTS

21 CFR Section	Requirement
203.11	Applications for reimportation to provide emergency medical care.
203.30(a)(1) and (b)	Drug sample requests (drug samples distributed by mail or common carrier).
203.30(a)(3), (a)(4), and (c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
203.31(a)(1) and (b)	Drug sample requests (drug samples distributed by means other than the mail or a common carrier).
203.31(a)(3), (a)(4), and (c)	Drug sample receipts (drug samples distributed by means other than the mail or a common carrier).
203.37(a)	Investigation of falsification of drug sample records.
203.37(b)	Investigation of a significant loss or known theft of drug samples.
203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.

TABLE 2—RECORDKEEPING REQUIREMENTS

21 CFR Section	Requirement
203.23(a) and (b)	Credit memo for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions for returned drugs.
203.30(a)(2) and 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized by the appropriate State authority to prescribe the product.
203.31(d)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.