

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]

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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]

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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]

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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
oir_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.