

(ii) Additional Response:

Estimated number of respondents:	5,250
Est. number of responses per respondent per year:	× 1
Estimated number of responses:	5,250
Estimated hours per response:	× 1
Estimated response burden hours:	5,250
Total response burden hours for FAR 52.209-7:	13,150
b. FAR 52.209-9:	
Estimated number of respondents:	4,900
Est. number of responses per respondent per year:	× 2
Total annual responses (rounded):	9,800
Estimated hours per response:	0.5
Total response burden hours for FAR 52.209-9:	4,900
c. Total (a. + b.):	
Total number of respondents:	15,800
Responses per respondent:	× 5.95
Total responses:	94,050
Hours per response:19
Total response burden hours:	18,050
3. Annual Recordkeeping Burden	
Number of recordkeepers:	5,250
Hours per recordkeeper:	× 100
Total recordkeeping burden hours:	525,000

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration,

Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405-0001, telephone (202) 501-4755. Please cite OMB Control No. 9000-0174, Information Regarding Responsibility Matters, in all correspondence.

Dated: September 5, 2013.

Karlos Morgan,
Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0215]

Agency Forms Undergoing Paperwork 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 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Application form and related forms for the operation of the National Death Index (NDI), (OMB No. 0920-0215, Expiration 11/30/13)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain OMB approval to extend the data collection for Application form and related forms for the operation of the

National Death Index (NDI), OMB No. 0920-0215, expires 11/30/2013. Section 306 of the Public Health Service Act (42 U.S.C.), as amended, authorizes that the Secretary of Health and Human Services, acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The NDI is a national data base containing identifying death record information submitted annually to NCHS by all the state vital statistics offices, beginning with deaths in 1979. This request is for approval of forms used to request searches against the NDI file to obtain the states and dates of death and the death certificate numbers of deceased study subjects. The NDI Application Form is provided to all investigators who express an interest in the NDI. The Application Form is completed and submitted only by those investigators who actually decide to apply for use of the NDI services. The Request for a Repeat NDI File Search is used by those NDI users who already have an approved application on file. This form is used by researchers when they have additional study subjects that need to be identified as deceased. The final form used is the User Data Transmittal Format. The researcher uses this form when transmitting their data file to the NDI staff.

Using the NDI Plus service, researchers have the option of also receiving cause of death information for deceased subjects, thus reducing the need to request copies of death certificates from the states. The NDI Plus option currently provides the International Classification of Disease (ICD) codes for the underlying and multiple causes of death for the years 1979-2010. Health researchers must complete administrative forms in order to apply for NDI services, and submit records of study subjects for computer matching against the NDI file. A three-year clearance is requested. There is no cost to respondents except for their time. The total estimated annual burden hours are 182.

TABLE 1—ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form type	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Health Researcher/Investigator	Application Form	50	1	2.5
Health Researcher/Investigator	Repeat Request Form	70	1	18/60
Health Researcher/Investigator	Data Transmittal Form	120	1	18/60

LeRoy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Center for Disease Control and
 Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

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.

DATES: Fax written comments on the collection of information by October 11, 2013.

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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0449. Also include the FDA 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, *PRAStaff@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.

Postmarket Surveillance—21 CFR Part 822 (OMB Control Number 0910-0449)—Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f)

authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

In the **Federal Register** of May 16, 2013 (78 FR 28853), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Postmarket surveillance submission (§§ 822.9 and 822.10)	131	1	131	120	15,720
Changes to PS plan after approval (§ 822.21)	15	1	15	40	600
Changes to PS plan for a device that is no longer marketed (§ 822.28)	80	1	80	8	640
Waiver (§ 822.29)	1	1	1	40	40
Exemption request (§ 822.30)	16	1	16	40	640
Periodic reports (§ 822.38)	131	3	393	40	15,720
Total					33,360

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Reporting Burden Estimate. The burden captured in table 1 of this document is based on the data available in FDA's internal tracking

system. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because "it entails no burden other

than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument." (See 5 CFR 1320.3(h)(1).)

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturer records (§ 822.31)	131	1	131	20	2,620
Investigator records (§ 822.32)	393	1	393	5	1,965
Total					4,585

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.