

included with this revised PRA submission, were already accounted for in the PRA package OMB approved on December 22, 2010. Specially, the burden associated with completing the Prima Facie Evidence cover sheet, was included in the burden estimate for submitting a reimbursement request. The burden associated with reading the guidance paper on reporting data inaccuracies was already included in the burden estimate for disclosing data inaccuracies. *Form Number:* CMS-10321 (OCN: 0938-1087); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions: State, Local, or Tribal Governments; *Number of Respondents:* 13,200; *Number of Responses:* 71,330; *Total Annual Hours:* 1,927,575. (For policy questions regarding this collection, contact Dave Mlawsky at (410) 786-6851. For all other issues call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 28, 2011.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: June 23, 2011.

Michelle Shortt,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0481]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Uses

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 reporting and recordkeeping requirements for "New Animal Drugs for Investigational Uses."

DATES: Submit electronic or written comments on the collection of information by August 29, 2011.

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: 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: 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.

New Animal Drugs for Investigational Uses—21 CFR Part 511 (OMB Control Number 0910-0117—Extension)

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to approve new animal drugs. Section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6)

information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse.

The Agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms,

academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents to this collection of information are the persons who use new animal drugs investigatively.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4)	206	6.01	1,238	1	1,238
511.1(b)(5)	206	.34	70	8	560
511.1(b)(6)	206	.01	2	1	2
511.1(b)(8) (ii)	206	.07	15	2	30
511.1(b)(9)	206	.07	15	8	120
Total					1,950

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3)	206	2.30	473	1	473
511.1(b)(3)	206	6.01	1238	1	1,238
511.1(b)(7)(ii)	206	6.01	1238	3.5	4,333
511.1(b)(8)(i)	206	6.01	1238	3.5	4,333
Total					10,377

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 206 respondents. We use this estimate consistently throughout the table and calculate the “No. of Responses per Respondent” by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.*, the number of respondents, the number of recordkeepers, the number of NCIEs received, *etc.*) is derived from Agency records.

Dated: June 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0010]

Cooperative Agreement To Support Shellfish Safety Assistance Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety is announcing its intent to award a single source cooperative agreement to support the Interstate Shellfish Sanitation Conference (ISSC). The purpose of this cooperative agreement is to enhance the FDA molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products.

DATES: Important dates are as follows:

1. The application due date is July 15, 2011.
2. The anticipated start date is September 1, 2011.

3. The opening date is June 28, 2011.

4. The expiration date is July 16, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

For Programmatic and Technical Concerns and Questions: Paul DiStefano, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1410.

For Administrative and Financial Concerns and Questions: Gladys Melendez-Bohler, Office of Acquisitions and Grants Services (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-11-023, 93.103.

A. Background

The CFSAN Office of Food Safety is announcing its intent to award, a single source cooperative agreement to the ISSC in the amount of \$325,000 for fiscal year 2011, direct and indirect costs combined. Subject to the