We are looking for suggested topic areas and publicly available instruments in which—(1) The source of information is from consumers and patients who directly received care at an emergency department or caregivers who were directly involved in the care (for example, parents of young children); and (2) patients or caregivers identified the information as important to them in evaluating emergency department care (for example, wait time, medical staff and physician communication). Existing instruments that have been tested, have a high degree of reliability and validity, and evidence of wide use is preferred.

The following information would be especially helpful in any comments responding to this request for information:

- A brief cover letter summarizing the information requested above for submitted instruments and topic areas, respectively, and how the submission will help fulfill the intent of the patient experiences survey;
- (Optional) Information about the person submitting the material for the purposes of follow up questions about the submission which includes the following:
  - ++ Name.
  - ++ Title.
  - ++ Organization.
  - ++ Mailing address.
  - ++ Telephone number.
  - ++ Email address.
  - ++ Indication that the topic area or instrument is publicly available.
- When submitting topic areas, we encourage including to the extent available the following information:
  - ++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
  - ++ Relevant peer-reviewed journal articles or full citations.
- When submitting publicly available instruments or survey questions, we encourage including to the extent available the following information:
  - ++ Name of the instrument.
  - ++ Copies of the full instrument in all available languages.
  - ++ Topic areas included in the instrument.
  - ++ Measures derived from the instrument. Instrument reliability (internal consistency, test-retest, etc) and validity (content, construct, criterion-related).
  - ++ Results of cognitive testing.
  - ++ Results of field testing.
  - ++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).
  - ++ Relevant peer-reviewed journal articles or full citations.
  - ++ CAHPS® trademark status.
  - ++ Survey administration instructions.
  - ++ Data analysis instructions.
  - ++ Guidelines for reporting survey data.

We are developing this survey and plan to submit it to AHRQ for recognition as a Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey. The survey will be developed in accordance with CAHPS® Survey Design Principles and implementation instructions will be based on those for CAHPS® instruments (*https://www.cahps.AHRQ.gov/About-CAHPS/Principles.aspx*).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–29104 Filed 11–30–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0477]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions Reports and Records

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 January 2, 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 0910–0078. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

Investigational Device Exemptions Reports and Records—(OMB Control Number 0910–0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) added section 520(g)(6) to the FD&C Act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the FD&C Act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control, depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, i.e., devices that do not present a potential for serious harm, are

subject to the reduced burden of the abbreviated requirements. The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available. Section 812.10 permits the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety. Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations.

Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in the original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE.

Upon approval of an IDE application by FDA, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation that affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Section 812.150 requires a sponsor to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress. Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this information to determine if wider distribution of the device is in the interest of the public health. Section 812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device, and to ensure the integrity of the controlled clinical trials.

Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study, records of receipt, use or disposition of devices, records of each subject's case history and exposure to the device, informed consent documentation, study protocol, and documentation of any deviation from the protocol. Sponsors are required to maintain records including correspondence and reports concerning the study, records of shipment and disposition, signed investigator agreements, adverse device effects information, and, for a nonsignificant risk device study, an explanation of the nonsignificant risk determination, records of device name and intended use, study objectives, investigator information, investigational review board information, and statement on the extent that good manufacturing practices will be followed.

For a nonsignificant risk device investigation, the investigator's and sponsor's recordkeeping and reporting burden is reduced. Pertinent records on the study must be maintained by both parties, and reports are made to sponsors and institutional review boards (IRBs). Reports are made to FDA only in certain circumstances, e.g., recall of the device, the occurrence of unanticipated adverse effects, and as a consequence of certain IRB actions.

The estimate of the burden is based on the number of IDEs received in the last 3 years. In the **Federal Register** of May 24, 2012 (77 FR 31022), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments, one of which was outside the scope of the four collection of information topics on which the notice solicited comments and will not be discussed in this document. The other comment recommends streamlining the annual IDE report requirements to focus on the reporting of safety information only, rather than both safety and effectiveness. The comment notes that the effectiveness information is ''reviewed during FDA clinical site GCP compliance inspections'' and at the time of premarket application. FDA recognizes that part 812 provides limited information on the content of IDE annual reports; however, we believe that the specific content requirements for IDE annual reports are outside the scope of this PRA renewal notice. Section 812.150(b)(10) provides broad authority for FDA to request information regarding ongoing IDEs, and FDA will consider the need for additional guidance to IDE sponsors regarding the content of annual reports.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waivers—812.10	1	1	1	1	1
IDE Application—812.20, 812.25, and 812.27	356	1	356	80	28,480
Supplements—812.35 and 812.150	356	12	4,272	6	25,632
Treatment IDE Applications—812.36(c)	1	1	1	120	120
Treatment IDE Reporting—812.36(f)	1	1	1	20	20
Total					54,253

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original—812.140	356	1	356	10	3,560
Supplemental—812.140	356	12	4,272	1	4,272
Nonsignificant—812.140	356	1	356	6	2,136
Total					9,968

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Reports for Nonsignificant Risk Studies—812.150	1	1	1	6	6

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

Dated: November 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29095 Filed 11–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0307]

Agency Information Collection Activities; Proposed Collection; Comment Request; Antiparasitic Drug and Resistance Survey

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's ''Antiparasitic Drug and Resistance Survey.''

DATES: Submit either electronic or written comments on the collection of information by February 1, 2013.

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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–410B, Rockville, MD 20850, 301–796–3784, *JonnaLynn.capezzuto@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 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.

Antiparasitic Drug and Resistance Survey—21 CFR Part 514.4 (OMB Control Number 0910–NEW)

Resistance of parasites to one or more of the major classes of FDA approved antiparasitic drugs is a documented problem in cattle, horses, sheep, and goats in the United States. The results from this survey will provide FDA information that can be used to make decisions about future approaches to antiparasitic drugs. FDA will make the results of the survey publicly available.

FDA plans to survey members of veterinary professional organizations using an Internet-based survey instrument. The questions in the survey are designed to elicit professional opinions regarding the use of antiparasitic drugs and the awareness of antiparasitic drug resistance. The survey will query subjects on topics including: (1) Awareness of the issues related to antiparasitic resistance, (2) methods currently being used to detect and/or monitor for antiparasitic resistance, (3) management practices being used or recommended to manage or reduce antiparasitic resistance, and (4) labeling and marketing considerations for antiparasitic drugs.

FDA published a 60-day notice in the **Federal Register** on July 13, 2010 (75 FR 39948), requesting public comment on the proposed survey, and published a 30-day notice on May 23, 2011 (76 FR