DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request; Proposed Projects

Title: Data Collection Plan for the Customer Satisfaction Evaluation of Child Welfare Information Gateway.

OMB No.: 0970–0303.

Description: The National Clearinghouse on Child Abuse and Neglect Information (NCCAN) and the National Adoption Information Clearinghouse (NAIC) received OMB approval to collect data for a customer satisfaction evaluation under OMB control number 0870–0303. On June 20, 2006, NCCAN and NAIC were consolidated into Child Welfare Information Gateway (CWIG). In response to this consolidation, the proposed information collection activities include revisions to the Customer Satisfaction Evaluation approved under OMB control number 0970–0303.

CWIG is a service of the Children's Bureau, a component within the Administration for Children and Families, and CWIG is dedicated to the mission of connecting professionals and concerned citizens to information on programs, research, legislation, and statistics regarding the safety, permanency, and well-being of children and families. CWIG's main functions are identifying information needs, locating and acquiring information, creating information, organizing and storing information, disseminating information, and facilitating information exchange among professionals and concerned citizens. A number of vehicles are employed to accomplish these activities, including, but not limited to, website hosting, discussions with customers, and dissemination of publications (both print and electronic).

The Customer Satisfaction Evaluation was initiated in response to Executive Order 12862 issued on September 11, 1993. The Order calls for putting customers first and striving for a customer-driven government that matches or exceeds the best service available in the private sector. To that end, CWIG's evaluation is designed to better understand the kind and quality of services customers want, as well as customers' level of satisfaction with existing services. The proposed data collection activities for the evaluation include customer satisfaction surveys, customer comment cards, selected publication surveys, and focus groups.

Respondents: Child Welfare Information Gateway customers.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per survey respondent	Average burden hours per survey response	Total burden hours
Customer Satisfaction Survey—Web Site Delivery	1,545	16	.0048	118.7
Customer Satisfaction Survey—E-mail Delivery	29	14	.0048	1.9
Customer Satisfaction Survey—Print Delivery	31	14	.0048	2.1
Customer Satisfaction Survey—Phone Delivery	171	14	.0063	15.1
Comment Card	264	3	.0048	3.8
Selected Publications Survey	85	11	.0048	4.5
Focus Group Guide	28	16	.0625	28

Estimated total annual burden hours: 174.1.

In compliance with the requirements of Section 3506(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 30 days of this publication.

Dated: January 15, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 08–186 Filed 1–18–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2008N–0005]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

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 proposed collection of information resulting from the guidance to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP).

DATES: Submit written or electronic comments on the collection of information by March 24, 2008.

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: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

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.

Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice—(OMB Control Number 0910–0563)—Extension

The guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to CGMP. Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements, or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance provides procedures that encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the dispute resolution (DR) Panel (the DR Panel).

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time-consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms prior to the issuance of Form FDA 483, the manufacturer can formally request DR and can use the formal two-tiered DR process described in the guidance.

Tier-one of the formal DR process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier two of the formal DR process would then be available for appealing that decision to the DR Panel.

The written request for formal DR to the appropriate ORA unit should be made within 30 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described below. The written request for formal DR to the DR Panel should be made within 60 days of receipt of the tier-one decision, and should include all supporting documentation and arguments, as described in the following paragraphs.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one DR or a request for tier-two DR;
- Name and address of manufacturer inspected (from Form FDA 483);
- Date of inspection (from Form FDA 483);
- Date the Form FDA 483 issued (from Form FDA 483);
- FEI Number, if available (from Form FDA 483);
- FDA employee names and titles that conducted inspection (from Form FDA 483);
- Office responsible for the inspection, e.g., district office (from Form FDA 483);
- Application number if the inspection was a preapproval inspection;
- Comprehensive statement of each issue to be resolved:
  - Identify the observation in dispute.
  - Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.
  - State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of Form FDA 483.
  - Identify possible solutions.
  - State expected outcome.
- Name, title, telephone and fax number, and e-mail address (as available) of manufacturer contact.

The guidance was part of the FDA initiative ''Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The agency formed the Dispute Resolution Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal DR process to resolve differences

related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained above. The guidance also covers the following topics.

• The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.

• Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.

• Public availability of decisions reached during the dispute resolution process to promote consistent application and interpretation of drug quality-related regulations.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: Based on the number of requests for tier-one and tier-two DR received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR, and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR, and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 of this document provides an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for Tier-One DR	2	1	2	30	60
Requests for Tier-Two DR	1	1	1	8	8
TOTAL					68

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

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

Dated: January 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1004 Filed 1–18–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0241]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Institutional Review Boards'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2007 (72 FR 57948), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0130. The approval expires on December 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: January 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1005 Filed 1–18–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0408]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this notice is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit a written or electronic request for participation in this program by February 21, 2008. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address of the site(s) you are offering. Facilities should also be advised that if a site visit involves a separate physical location of another firm under contract to the applicant that this site must be in agreement to participate in the program, as well as have a satisfactory compliance history.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, or if your