ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Semi-Structured Discussion and Information-Gathering Protocol	600	1	.5	300
Estimated Total Annual Burden Hours				300

In compliance with the requirements of Section 3506(c)(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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *OPREinfocollection@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 60 days of this publication.

Dated: March 31, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8–7139 Filed 4–7–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0172]

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

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 Use.''

DATES: Submit written or electronic comments on the collection of information by June 9, 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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 Use—21 CFR Part 511 (OMB Control Number 0910–0117)—Extension

FDA has authority under the Federal Food, Drug, and Cosmetic Act (the act) to approve new animal drugs. Section 512(j) of the act (21 U.S.C 360b(j)), authorized FDA to issue regulations for the investigational use of new animal drugs. The regulations which set forth conditions for investigational use of new animal drugs are codified under part 511 (21 CFR part 511). If a new animal drug is only for tests in vitro, or testing in laboratory research animals, the person distributing the new animal drug must maintain records showing: (1) The name and post office address of the expert or expert organization to whom the drug is shipped; and (2) the date, quantity, batch or code mark for each shipment for a period of 2 years after such shipment or delivery. Prior to 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) The identity of the new animal drug; (2) labeling; (3) a statement of compliance

of any non-clinical laboratory studies with good laboratory practices; (4) the 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 the pharmaceutical industry, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents for this collection of information are investigators who use new animal drugs for investigational purposes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	134	7.66	1,027	8	8,216
511.1(b)(5)	134	.19	25	140	3,500
511.1(b)(6)	134	.01	2	1	2
511.1(b)(8)(ii)	134	.11	15	20	300
511.1(b)(9)	134	6.7	20	8	160
Total					12,178

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
511.1(a)(3)	134	2.96	400	9	3,600
511.1(b)(3)	134	7.66	1,027	1	1,027
511.1(b)(7)(ii)	134	7.46	1,000	3.5	3,500
511.1(b)(8)(i)	134	7.46	1,000	3.5	3,500
Total					11,627

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

The burden estimates for reporting requirements, record preparation, and maintenance for this collection of information are based on agency communication with industry and agency records. Based on the number of sponsors subject to animal drug user fees, FDA estimates there are 134 respondents. This estimate is used consistently throughout the burden tables and for example, the ''annual frequency per respondent'' was calculated by dividing the total annual responses by the number of respondents. Additional information needed to make final calculations for the total burden estimates in tables 1 and 2 of this document, i.e., the hours per response, the hours per record, the number of NCIEs received, etc., was derived from agency records.

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

Dated: March 31, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7255 Filed 4–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0199] (formerly Docket No. 2006D–0526)

International Conference on Harmonisation; Guidance on E15 Pharmacogenomics Definitions and Sample Coding; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.'' The guidance was prepared