Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 and e-mail a copy to *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: September 30, 2010.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2010–25439 Filed 10–7–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Financial Institution Data Match.

OMB No.: 0970–0196.

Description: Section 466(a)(17) of the Social Security Act (the Act) requires States to establish procedures under which the State Child Support Enforcement IV–D agencies shall enter into agreements with financial institutions doing business in States for the purpose of securing information leading to the enforcement of child support orders. Under 452(l) and 466(a)(17)(A)(i) of the Act, the Secretary may aid State agencies conducting data matches with financial institutions doing business in multiple States by centrally matching through the Federal Parent Locator Service.

Respondents: Financial institutions doing business in two or more States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Data Match Result File	259	4	0.33	341.88
Election Form	122	1	0.50	61
Estimated Total Annual Burden Hours				402.88

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV Attn:* Desk Officer for the Administration for Children and Families.

Dated: October 5, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–25414 Filed 10–7–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0493]

Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

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 the additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded.

DATES: Submit either electronic or written comments on the collection of information by December 7, 2010.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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.

Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded—New

In the **Federal Register** of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded (2002 TEA final rule). The regulations in § 330.14 state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain "time and extent" criteria outlined in § 330.14(b). The regulations allow a "time and extent" application (TEA) to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data include not only the data and information listed in 21 CFR 330.10(a)(2) (§ 330.14(f)(1)) but also a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)) as well as an official or proposed compendial monograph (§ 330.14(i)).

In the 2002 TEA final rule, we estimated that 50 TEAs would be submitted to us annually by approximately 25 respondents (67 FR 3060 at 3073). We also estimated that the time required for preparing and submitting each TEA would be approximately 480 hours. We continue to believe that a respondent will spend approximately 480 hours preparing a TEA, but we no longer expect to receive 50 TEAs annually. Since 2003, we have received a total of 16 TEAs from 12 respondents. This is equivalent to 2.3 TEAs annually from 1.7 respondents. We now estimate that we will receive 2 TEAs annually from 2 respondents (see table 1 of this document).

We also estimated in the 2002 TEA final rule that we would receive three safety and effectiveness submissions for each condition found eligible for further consideration under a TEA (67 FR 3060 at 3072). We estimated that we would receive 90 submissions of safety and effectiveness data annually. And, we estimated that it would take approximately 800 hours to prepare and submit each safety and effectiveness submission. We believe that each submission, including serious adverse drug experiences and a compendial monograph, will take approximately 800 hours to complete (see table 1 of this document). However, we do not believe the estimated number of submissions is accurate. During the 8 years that have elapsed since publication of the 2002 TEA final rule, we have found 14 ingredients eligible under the TEA process and have received 16 submissions of safety and effectiveness data from 9 respondents. Therefore, we now estimate that we will receive two submissions of safety and effectiveness data annually from two respondents.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
330.14(c) and (d)[1]	2	1	2	480	960
330.14(f) and (i)[2]	2	1	2	800	1,600
Total					2,560

[1] TEA.
[2] Safety and effectiveness submission, including adverse events and compendial monograph.

Dated: October 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25375 Filed 10–7–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0171]

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Required Data Elements for Voluntary Establishment of Paternity Affidavits.

Description: Section 466(a)(5)(C)(iv) of the Social Security Act (the Act) requires States to develop and use an affidavit for the voluntary acknowledgement of paternity. The affidavit for the voluntary acknowledgement of paternity must include the minimum requirements specified by the Secretary under section 452(a)(7) of the Act. The affidavits will be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program, that collect information from parents of children that are born out of wedlock.

Respondents: Parents of children that are born out of wedlock provide the required information to State and Tribal IV–D agencies, hospitals, birth record agencies and other entities participating