delivered as intended, gauge the degree to which program performance indicator targets are being achieved, and help agencies improve their programs to better deliver effective PCRS. Until grantees transition to PEMS, it is essential that they be allowed to continue to collect aggregate PCRS data using the existing forms.

Each health department funded to conduct PCRS will prepare and submit aggregate PCRS data to the CDC annually. Completion of two data collection forms is necessary for evaluation of aggregate PCRS data, and it is estimated that one hour is needed to complete each form; therefore, 65 health departments × 2 responses × 1 hour = 130 hours. There is no cost to respondents.

ESTIMATES OF ANNUAL BURDEN

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health Departments	65	2	1	130
Total				130

Dated: August 4, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–18332 Filed 8–10–04; 8:45 am]

BILLING CODE 4163–18–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) agency shall enter into agreements with financial institutions doing business in the State to develop and operate a data match system for the purpose of securing information leading to the enforcement of child support orders. Under sections 452(1) 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 Tape	4501	4	.5	9002
Election Form	333	1	.5	166.5

Estimated Total Annual Burden Hours: 9168.5.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@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, Attn: Desk Officer for ACF, e-mail address: *katherine_t._astrich@eop.gov.*

Dated: August 5, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–18362 Filed 8–10–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0497]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Pharmacogenomic Data Submissions

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 September 10, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Draft Guidance for Industry on Pharmacogenomic Data Submissions (OMB Control Numbers 0910–0014, 0910–0001, and 0910–0338)—Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drugs (INDs), new drug applications (NDAs), or biologic liscensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements in parts 312, 314, and 601 (21 CFR 312, 314, and 601) for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, or BLAs for human drugs and biologics.

Burden Estimate: The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 and are approved by OMB under control numbers 0910–0014 (part 312—INDs; approved until January 1, 2006); 0910–0001 (part 314—NDAs and annual reports; approved until March 31, 2005); and 0910–0338 (approved until August 31, 2005).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 20 sponsors will submit approximately 80 VGDSs and that, on average, each VGDS will take approximately 10 hours to prepare and submit to FDA.

In the **Federal Register** of November 4, 2003 (68 FR 62461), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection estimates.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary genomic data submissions	20	4	80	10	800

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

Dated: August 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18360 Filed 8–6–04; 12:04 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Designating Aliens For Expedited Removal

AGENCY: Bureau of Customs and Border Protection, DHS.

ACTION: Notice.

SUMMARY: This notice authorizes the Department of Homeland Security to place in expedited removal proceedings any or all members of the following class of aliens: Aliens determined to be inadmissible under sections 212(a)(6)(C) or (7) of the Immigration and Nationality Act who are present in the U.S. without having been admitted or paroled following inspection by an immigration officer at a designated port-of-entry, who are encountered by an immigration officer within 100 air miles of the U.S. international land border, and who have not established to the satisfaction of an immigration officer that they have been physically present in the U.S. continuously for the fourteen-day (14-day) period immediately prior to the date of encounter. DHS believes that exercising its statutory authority to place these individuals in expedited removal proceedings will enhance national security and public safety by facilitating prompt immigration determinations, enabling DHS to deal more effectively with the large volume of persons seeking illegal entry, and ensure removal from the country of those not granted relief, while at the same time protecting the rights of the individuals affected.