

safety, permanency, and well-being for children, youth, and families. The Children's Bureau desires to assess the quality and effectiveness of the technical assistance it supports, and several of these programs and projects are required to be evaluated, including those funded under Section 105 of The Child Abuse Prevention and Treatment Act, as amended [42 U.S.C. 5106]. Beginning in fiscal year (FY) 2010, the T/TA Network will comprise a group of 30 T/TA providers funded entirely or partially by the Children's Bureau through grants, contracts, and interagency agreements.

The cross-site evaluation uses a mixed-method, longitudinal approach to

examine the ICs (funded in FY 2009) and a new cohort of NRCs (funded in FY 2010). Proposed data collection methods are a longitudinal telephone survey of State child welfare directors (or their designees) and Tribal Child Welfare/Social Service Directors (or their designees), a Web-based survey of State and Tribal T/TA recipients, and aggregation of outputs from a Web-based technical assistance tracking system (OneNet) that will be used by the five ICs and 11 NRCs. A Web-based survey will be also administered to members of the T/TA Network. Data collected through these instruments will be used by the Children's Bureau to evaluate the

effectiveness of technical assistance delivered to State, local, Tribal, and other publicly administered or publicly supported child welfare agencies and family and juvenile courts and the overall functioning of the T/TA Network.

Respondents: Respondents to two of the survey instruments will be State and Tribal governments. Respondents to the third survey will be private institutions, including universities, not-for-profit organizations, and private companies. Private institutions, including universities and not-for-profit organizations will be respondents to the forms in the OneNet tracking system.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OneNet Form: General T/TA Event	16	26	0.25	104
OneNet Form: NRC T/TA Work Plan	11	45	0.20	99
OneNet Form: NRC T/TA Close-Out	11	45	0.08	39.60
OneNet Form: NRC T/TA Activity	11	528	0.20	1,161.60
OneNet Form: Implementation Project Monthly Report	5	62.40	0.17	53.04
Agency Results Survey	74	1	1	74
Training and Technical Assistance (T/TA) Activity Survey	160	3	0.25	120
Web-Based Network Survey	30	1	0.25	7.50
OneNet Form: Implementation Project Information	5	5.40	0.50	13.50
OneNet Form: Implementation Project T/TA Activity	5	280.80	0.33	463.32

Estimated Total Annual Burden Hours: 2,135.56.

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: 202-395-7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 4, 2010.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: CCDF—Reporting Improper Payments—Instructions for States.

OMB No.: 0970-0323.

Description: The Improper Payments Information Act of 2002 requires Federal agencies to annually report error rate measures. Section 2 of the Improper Payments Information Act provides for estimates and reports of improper payments by Federal agencies. Subpart K of 45 CFR, Part 98 requires preparation and submission of a report of errors occurring in the administration of CCDF grant funds once every three years. The information collected will be used to prepare the annual Agency Financial Report (AFR) and will provide information necessary to offer technical assistance to grantees.

Respondents: State grantees, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OMB #0970-0323 Record Review Worksheet	17	276.38	15.43	72,497.24
OMB #0970-0323 Data Entry Form	17	276.38	0.18	845.72

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OMB #0970-0323 State Improper Authorizations for Payment Report	17	1	639	10,863

Estimated Total Annual Burden Hours: 84,205.96

In compliance with the requirements of Section 506(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 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 60 days of this publication.

Dated: February 4, 2010.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-M-0513]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d)

and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness data were placed on the Internet from July 1, 2009, through September 30, 2009. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2009, THROUGH SEPTEMBER 30, 2009.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
BP090022/0/ FDA-2009-M-0513	Avioq, Inc., Rockville, MD	Avioq HIV-1 Microelisa System	September 21, 2009