

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 17, 2005

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: Children's Justice Act Program (CJA).

OMB No.: 0980-0196.

Description: The Program Instruction, prepared in response to the enactment of the Children's Justice Act (CJA), as set forth in Title II of Pub. L. 108-36, child Abuse Prevention and Treatment Act Amendments of 2003, provides direction to the States and the territories to accomplish the purposes of assisting States in developing, establishing and operating programs designed to improve: (1) The handling of child abuse and neglect cases, particularly child sexual abuse and exploitation, in a manner that limits additional trauma to the child victim; (2) the handling of cases of suspected child abuse or neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, particularly child sexual abuse and exploitation; and (4) the handling of cases involving children with disabilities or serious health-related problems who are victims of abuse and neglect. This Program

Instruction contains information collection requirements that are found in Pub. L. 108-36 at Sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Application | 52 | 1 | 40 | 2,080 |
| Annual Report | 52 | 1 | 20 | 1,080 |

Estimated Total Annual Burden Hours: 3,120.

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 of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@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 16, 2005.

Bob Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0082]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document

entitled "Class II Special Controls Guidance Document: Automated Fluorescence *in situ* Hybridization (FISH) Enumeration Systems." This guidance document describes a means by which automated FISH enumeration systems may comply with the requirements of special controls for class II devices.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify automated FISH enumeration systems into class II (special controls). This guidance document is immediately in effect as the special control for automated FISH enumeration systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Automated Fluorescence *in situ* Hybridization (FISH) Enumeration Systems" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send