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Acting Director, Office of Research Integrity.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request, Proposed Projects

Title: IRS Project 1099.
OMB No.: New Collection.
Description: A voluntary program which provides States' Child Support

Enforcement agencies upon there request access to all of the earned and unearned income information reported to IRS by employers and financial institutions. The IRS 1099 information is used to locate noncustodial parents and to verify income and employment, which has proven essential to accurately establishing and enforcing child support obligations.

Respondents: State, Local, or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE 1099 Request Records	43	12	1	1,032

Estimated Total Annual Burden Hours: 1,032.

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, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. 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: December 15, 1997.

Bob Sargis,

Acting Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0517]

Changes in Medical Device Tracking and Postmarket Surveillance Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Changes in medical device tracking and postmarket surveillance authority under the Food and Drug Administration Modernization Act of 1997. The topic to be discussed is postmarket controls, including tracking and/or surveillance of devices.

Date and Time: The meeting will be held on January 15, 1998, 9 a.m. to 3 p.m.

Location: The meeting will be held at the University of Maryland Auditorium, 9640 Gudelsky Dr., Rockville, MD.

Contact: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4692, FAX 301-594-4610.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by January 5, 1998. Written comments may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, by January 5, 1998.

If you need special accommodations due to a disability, please contact Casper E. Uldriks at least 7 days in advance of the meeting.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HF1-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

The agency is interested in discussing the statutory changes concerning tracking and postmarket surveillance under the Food and Drug Administration Modernization Act of 1997 and whether the agency should develop additional criteria to use to determine whether tracking or postmarket surveillance requirements should be ordered by FDA. The agency would like to supplement the statutory criteria with additional nonbinding criteria to help determine which devices may need to be added or removed from the list of devices subject to tracking and/or postmarket surveillance requirements. FDA intends to publish its revised lists by February 19, 1998, the effective date of the new law.

By way of example, additional criteria that would support a tracking order might include the likelihood of a recall, or the likelihood of irreversible clinical outcomes. Additional criteria that might not support a tracking order, for example, might include current, standard clinical practices that mitigate risk. Additional criteria that would support a postmarket surveillance order might include, for example, the use of a new technology or the need to assess a new public health issue based on measurable outcomes. Additional criteria that would not support a