further expanded the program to increase the collection of nontax debts owed to the Federal Government and to assist families in collecting past-due child support. It required the development and implementation of procedures necessary to collect past-due support by administrative offset by agencies. As a result, this program is now known as the Tax Refund and Administrative Offset Program (TROP/ADOP).

Purpose: Pursuant to Public Laws 97–35 enacted by Congress on August 13, 1981, Public Law 101–508 signed by the President in November 1990 and Public Law 104–134 enacted into law on April 26, 1996, the Debt Collection Improvement Act of 1996, and pursuant to the Executive Order 13019 dated September 28, 1996, the OCSE will match the tax refund records against Federal payment certification records and Federal financial assistance records. The purpose is to facilitate the collection of delinquent child support obligations from persons who may be entitled or eligible to receive certain Federal payments or Federal assistance. State child support agencies submit cases of delinquent child support claims to the OCSE for submission to the Financial Management Service (FMS). These cases are sent by on-line dial-up access via personal computer, tape and cartridge via mail, Mitron tape, file transfer, or electronic data transmission. The Office of Child Support Enforcement serves as a conduit between state child support enforcement agencies and the FMS by processing weekly updates of collection data and distributing the information back to the appropriate State child support agency. The information will be disclosed by OCSE to state child support agencies for use in the collection of child support debts, through locate action wage withholding or other enforcement actions.

Respondents: State and local governments. (50 States, District of Columbia, Guam, Puerto Rico, and Virgin Islands.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Standard forms	54	30	2	3,240

Estimated Total Annual Burden Hours: 3,240.

* The 1,620 transmittals (54 x 30) represent 5.2M offset requests per year.

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 Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20047, 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: July 10, 1997.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 97–18677 Filed 7–15–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: ACF–196 Temporary Assistance for Needy Families Financial Reporting Form.

OMB No.: New.

Description

Description for **Federal Register** Notice of why the information is being collected, what it is and how it will be used. Provide specifics where relevant: The form provides specific data regarding claims and provides a mechanism for States to request grant awards and certify availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. The following citations should be noted in regards to this collection: 405(c)(1); 409(a)(7); and 409(a)(1).

Respondents: States, Puerto Rico, Guam and the District of Columbia

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196 ...	54	4	8	1,728

Estimated Total Annual Burden Hours: 1,728.

Additional Information

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by October 1, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Bob Driscoll at (202) 401–6465.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street N.W., Washington, D.C. 20503, (202) 401–9313.

Dated: July 10, 1997.

Bob Driscoll,

Reports Clearance Officer.

[FR Doc. 97–18676 Filed 7–15–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0266]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by August 15, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Detention and Banned Medical Devices (21 CFR 800.55, 800.55(k), 895.21, and 895.22) (OMB Control Number 0910–0114—Reinstatement)

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. On March 9, 1979, FDA issued a final regulation on administrative detention procedures, which includes, among other things, certain reporting requirements (§ 800.55(g) (21 CFR 800.55(g))) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final regulation for banned devices contains certain reporting requirements (§§ 895.21(d) and 895.22(a) (21 CFR 895.21(d) and 895.22(a))). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the **Federal Register**, and this notice will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The notice will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Respondents to this collection of information are those manufacturers, distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)[2]	0	0	0	0	0
Total	.....	.....	.....	.....	25

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]No devices were banned during the past 3 years (§§ 895.21 and 895.22). Therefore, no burden has been imposed upon industry. When the prosthetic hair fibers were banned, there were no firms in the United States that were manufacturing or distributing the products. Thus, FDA has put zeroes in the columns estimating reporting and recordkeeping burdens.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Total	.....	.....	.....	.....	20

There are no capital costs or operating and maintenance costs associated with this collection of information.

Over the past 3 years, there has been an average of one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained over the last 3 years.

Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18592 Filed 7–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0265]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by August 15, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational Device Exemptions Reports and Records (21 CFR Part 812) (OMB Control Number 0910–0078—Reinstatement)

This information is collected under the statutory authority of the Federal Food, Drug, and Cosmetic Act (the act) regarding investigational devices (section 520(g) (21 U.S.C. 360j(g))). An investigational device exemption (IDE) allows a device, which would otherwise be subject to provisions of the act such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of this section, as explained in part 812 (21 CFR part 812) in § 812.1, is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. Under §§ 812.20, 812.25, and 812.27, information collected in the application includes sponsor information; a report of prior investigations including reports of all prior clinical, animal, and laboratory testing of the device, a bibliography of all publications, and a summary of all other unpublished information; an investigational plan including study, purpose, protocol, risk analysis, device description, and monitoring procedures; a description of the methods, facilities, and controls used for the manufacture, processing, packing, and storage of the device; investigator information including agreements and certifications; institutional review board (IRB) information; information on the amount to be charged for the device; device labeling; and informed consent materials.

Section 812.10, regarding waiver of IDE requirements, states that if a sponsor does not wish to comply with certain requirements of part 812, the sponsor may voluntarily submit a waiver request.

Under § 812.35, when an investigational plan changes, a sponsor is required to submit a supplemental application to FDA, and the sponsor may not begin a part of an investigation at a facility until the IRB has approved the investigation, FDA has received the certification of IRB approval, and FDA has approved the supplemental application relating to that part of the investigation.

Section 812.140 requires investigators to maintain records, including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required, under the same section, to maintain records including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, if of nonsignificant risk, an explanation of nonsignificant risk determination, records on device name and intended use, study objectives, investigator information, IRB information, and statement on the extent that good manufacturing practices will be followed.

Section 812.150 requires investigators to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, progress reports, deviations from investigational plan, failure to obtain informed consent, and final report. Sponsors are required to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, withdrawal of FDA approval, current investigator lists, progress reports, notification of recall and device disposition, final report, failure to obtain informed consent, and significant risk device determination.

The following parts of the IDE regulations are covered by other sections of part 812, and thus are not mentioned as separate reporting or recordkeeping burden requirements. The requirements for § 812.18, regarding import and export requirements for IDE's, are already covered under § 812.20(b)(1). Section 812.18 states that foreign companies are required to be sponsored by a U.S. agent, whose identity is required under the IDE application. This is not an additional information collection, and a separate requirement for information is not essential just because this is an imported device. Sections 812.40, 812.45, and 812.46, regarding the general responsibilities of sponsors, are described under §§ 812.20, regarding actual application and 812.150, regarding recordkeeping.

Section 812.5, regarding the labeling of investigational devices, is included under § 812.20(b)(10), where the submitter is required to enclose a copy of the label that bears information required by § 812.5 (i.e., name and place of business of manufacturer, packer, or distributor, the quantity of contents if appropriate, and the following statement: ''CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use''). This label shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. The label will also not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated. If the device is being used solely for animal research, the label shall bear the following statement: ''CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects.'' This section's burden is required under § 812.20(b)(10), therefore a separate burden estimate is not required.