impact to the community of maintaining the status quo will be analyzed.

The public is cordially invited to participate in the scoping process, review of the draft Environmental Impact Statement, and the public meeting.

The scoping meeting will be held at the Victory Theater on Thursday, November 18, 1999 from 5 p.m. to 8 p.m.

At the scoping meeting, the public will be asked to identify any significant issues that they believe should be analyzed in the Environmental Impact Statement. The Victory Theater is located at 14 South Second Street, between East San Fernando and East Santa Clara Streets in San Jose, California.

Release of the draft EIS for public comment and the public meeting will be announced in the local newspaper, as these dates are established.

FOR FURTHER INFORMATION CONTACT: George F. Doñes, General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, San Francisco, California 94102, (415) 522–3497, Fax: (415) 522–3215, Email: *george.dones@gsa.gov*

Approved: October 28, 1999.

Kenn N. Kojima,

Regional Administrator.

[FR Doc. 99–28700 Filed 11–2–99; 8:45 am]

BILLING CODE 6820–JC–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 64 FR 25897, dated May 13, 1999) is amended to reflect the reoganization of the Scientific Resources Program, National Center for Infectious Diseases.

Section C–B, Organization and Functions, is hereby amended as follows:

After the title for the *Scientific Resources Program (CRL)*, delete the functional statement and insert the following:

(1) Provides animals, animal and human blood products, glassware, mammalian tissue cultures, microbiological media, special reagents, and other laboratory materials in support of research and service activities to NCID laboratories and other CDC organizations; (2) installs, fabricates, modifies, services, and maintains laboratory equipment used in the research and service activities of CDC; (3) develops and implements applied research programs to expand and enhance the use of animal models necessary to support research and diagnostic programs and to improve breeding and husbandry procedures; (4) conducts both basic and applied research in cell biology and in the expansion of tissue culture technology as a research and diagnostic tool for infectious disease activities; (5) provides services for NCID investigators in protein and DNA synthesis and sequencing; (6) maintains a bank of serum and other biological specimens of epidemiological and special significance to CDC's research and diagnostic activities; (7) obtains and distributes experimental and orphaned vaccines, drugs, antisera, antitoxins, and immune globulins; (8) manages and distributes the inventory, maintains the computerized system database, and provides general technical service support for dispensing, lyophilizing, capping, and labeling CDC Reference Reagents; (9) provides support for liquid nitrogen freezers; (10) administratively and technically supports the CDC Animal Policy Board and the Atlanta Area Animal Care and Use Committee; (11) provides computer support services for the Program's activities; (12) receives, categorizes, processes and distributes specimens to CDC laboratories for reference diagnostic testing, research studies, and epidemics and reports diagnostic test results to submitting organizations; (13) manages all CDC exports and ensures compliance with regulations and serves as CDC liaison with Department of Commerce for export related issues; (14) maintains the CDC Atlanta laboratory water treatment systems; (15) provides collaborative development and production services to produce high priority reference reagents and specialized diagnostics for internal NCID investigators.

Dated: October 25, 1999.

Jeffrey P. Koplan,

Director.

[FR Doc. 99–28739 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Form OCSE–396A, Child Support Enforcement Program Financial Report and Form OCSE–34A. Child Support Enforcement Program Quarterly Report of Collections.

OMB No.: 0970–0181.

Description: These forms are used by States to report the administrative costs of operating the Child Support Enforcement Program and to report the collections of child support payments made under Title IV–D of the Social Security Act during each fiscal quarter. These forms also reports the portion of the collected payments distributed to the custodial parent or to the Federal or State governments. The information is used to calculate quarterly grant awards, annual incentive payments to the State, and is published in an Annual 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
OCSE–396A	54	4	8	1,728
OCSE–34A	54	4	8	1,728

Estimated Total Annual Burden Hours: 3,456.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of

Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW.; Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 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, 725 17th Street, NW, Attn: ACF Desk Officer.

Dated: October 27, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–28677 Filed 11–2–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0260]

Agency Information Collection Activities; Submission for OMB review; Comment Request; Medical Devices; Recall Authority

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.

DATES: Submit written comments on the information collection by December 3, 1999.

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 20501, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Medical Devices; Recall Authority—21 CFR Part 810

Section 518(e) (21 U.S.C. 360h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) provides that if FDA finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of such device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Under this statutory authority, FDA issued regulations under part 810 (21 CFR part 810).

The regulation in § 810.10(d) provides that FDA may require the person named in the cease distribution and notification order to submit certain information to the agency. Section 810.11(a) requires that a request for a regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA. In lieu of a written request for a regulatory hearing, the person named in the cease distribution and notification order may submit a written request asking that the order be modified or vacated as provided in § 810.12(a). Under § 810.12(b), a written request for review of a cease distribution and notification order must identify each ground upon which the requestor relies in asking that the order be modified or vacated and address an appropriate cease distribution and notification strategy. A written request must also address whether the order should be amended to require a recall of the device that was the subject of the order.

Section 810.14 states that the person named in the cease distribution and notification order or a mandatory recall order must develop a strategy for complying with the order that is appropriate for the individual circumstances and submit the strategy to the agency for review. Section 810.15(a) requires that the person named in the cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order, and § 810.15(b) through (c) prescribes the contents and implementation of such notification. Section 810.15(d) requires the person named in the order to ensure that followup communications are sent to all who fail to respond to the initial communications. Under § 810.15(e), recipients of such letters must follow instructions in the letter and notify consignees of the order. Section 810.16 requires that the person named in a cease distribution and notification order or a mandatory recall order submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports must be submitted will be specified in the order. Lastly, § 810.17 provides that the person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and must include a copy of the most current status report submitted to the agency.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to learn quickly about serious problems with medical devices, and to remove dangerous and defective devices from the market.

In the preamble to the final rule (61 FR 59004 at 59018, November 20, 1996), hereinafter referred to as the November 1996 final rule, the agency requested comments on the information collection provisions of the new regulation. The 60-day comment period closed January 21, 1997. The agency received two comments. The comments stated that: (1) The information collection requirements in this regulation are redundant and time and resource consuming, and (2) FDA should provide for the use of electronic media for complying with this rule.

FDA disagrees with the comment that the information collection requirements for the medical device recall authority are redundant and time and resource consuming. Almost all recalls are carried out under the voluntary recall procedures in part 7 (21 CFR part 7). As discussed in the November 1996 final rule, for cease distribution and notification orders and recall orders, FDA interprets the standard in §§ 810.10(a) and 810.13 to match closely to the elements of a class I voluntary recall under part 7, subpart C, for which the agency has a long record of experiences. FDA will initiate a mandatory recall under section 518(e) of the act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention;