for Infectious Diseases, CDC, M/S P02/MLR, P.O. Box 2087 (Foothills Campus), Fort Collins, Colorado 80522, telephone 970/221–6415.

Dated: September 8, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–24335 Filed 9–12–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care Quarterly Case Record Report; Republication, In **Federal Register** Document 97–23469 (Volume 62, Number 171), Page 46743 the word ''Disaggregate'' replaces the word ''Desegregate'' and ''Respondents: States and Territories'' replaces ''Respondents: State, Local or Tribal Govt.'' For the convenience of the reader, the document is being republished in its entirety.

OMB No.: New Request.

Description: This legislatively-mandated report collects program and participants data on children receiving direct CCDF funds. Disaggregate data will be collected and will be used to determine the participants and program characteristics, as well as cost and level of child care services. The data will be used to provide a report to Congress.

Respondents: States and Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	20	4,360

Estimated Total Annual Burden Hours: 4,360.

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, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

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, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Laura Oliven.

Dated: September 9, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–24280 Filed 9–12–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0022]

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 October 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, 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.

Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control No. 0910–0171—Reinstatement)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services (the Secretary) may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801.421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting, fitting, and checking the performance of a hearing aid through distribution of a User Instructional Brochure. The User Instructional Brochure must also contain technical data about the device, instructions for its use, maintenance and care, a warning statement, a notice about the medical evaluation requirement, and a statement if the aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the User Instructional Brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon

request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the User Instructional Brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users and provide a copy of the User Instructional Brochure to any health care professional, user, or prospective user who requests a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by signing a written statement. Finally, the regulation requires that the dispenser retain for 3 years copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the User Instructional Brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.

The respondents to this collection of information are hearing aid manufacturers, distributors, dispensers, health professionals, or other for profit organizations.

In 1993, FDA conducted an audit of hearing aid dispensers in four FDA districts to determine the level of compliance with existing hearing aid requirements. The estimates relating to § 801.421(a)(1) and (a)(2) in the reporting and recordkeeping burden tables below are based on information obtained in this audit. This audit revealed that medical evaluations were obtained in 32 percent of the sales and signed waivers were obtained in 60 percent of the sales.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Respondents	Total Annual Responses	Hours per Response	Total Hours
801.420	40	5	200	40	8,000
801.421(a)(1)	9,900	52	514,800	0.10	51,480
801.421(a)(2)	19,900	97	960,300	0.30	288,090
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,940	5	49,700	0.17	8,449
Total Burden Hours					836,019

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	162	1,600,000	0.25	400,000
Total					400,000

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

Dated: September 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24348 Filed 9–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[MB–110–N]

RIN: 0938–AH93

Medicaid Program; Final Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the final Federal fiscal year (FFY) 1997 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs. We are publishing this notice in accordance with the provisions of section 1923(f)(1)(C) of the Social Security Act and implementing regulations at 42 CFR 447.297 through 447.299. The final FFY 1997 State disproportionate share hospital (DSH) allotments published in this notice supersede the preliminary FFY 1997 DSH allotments that were published in the **Federal Register** on January 31, 1997.

EFFECTIVE DATE: The final DSH payment adjustment expenditure limits included