Center for Health Statistics, CDC. The NHANES will begin again in February 1999 and will be conducted on a continuous, rather than periodic, basis from that point on. The plan is to sample about 5,000 persons annually. They will receive an interview and a physical examination. A dress rehearsal of 555 sample persons is needed to test computer-assisted personal interviews (including translations into Spanish), examination protocols, automated computer systems and quality control procedures. Participation in the dress rehearsal and main survey will be completely voluntary and confidential.

NHANES programs produce descriptive statistics which measure the health and nutrition status of the general population. Through the use of questionnaires, physical examinations, and laboratory tests, NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors related to health such as coronary heart disease, arthritis, osteoporosis, pulmonary and infectious diseases, diabetes, high blood pressure, high cholesterol, obesity, smoking, drug and alcohol use, environmental exposures, and diet. NHANES data are used to establish the norms for the general population against which health care providers can compare such patient characteristics as height, weight, and nutrient levels in the blood. Data from NHANES can be compared to those from previous surveys to monitor changes in the health of the U.S. population. NHANES will also establish a national probability sample of genetic material for future genetic research for susceptibility to disease.

Users of NHANES data include Congress; the World Health Organization; Federal agencies such as NIH, EPA, and USDA; private groups such as the American Heart Association; schools of public health; private businesses; individual practitioners; and administrators. NHANES data are used to establish, monitor, and evaluate recommended dietary allowances, food fortification policies, programs to limit environmental exposures, immunization guidelines and health education and disease prevention programs. Approval was received on 5/29/98 for only a pilot test of the revised survey—without the genetic research component. This submission is time-sensitive and requests emergency approval just so the dress rehearsal and the start of the survey will not be delayed. Another submission requesting three year approval for the dress rehearsal and the full survey will be filed on a normal, non-emergency schedule.

The survey description, contents, and uses are the same as those in the **Federal Register** notice for the pilot test. The total cost to respondents for the period covered by this notice and the related request for OMB approval (from 2/99–1/02) is estimated at $1,889,440.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
1. Screening interview only	40,401	1	0.167	6,747
2. Screener and household interviews only	2,130	1	0.434	924
3. Screener, household, and SP interviews only	3,198	1	1.100	3,518
4. Screener, household, and SP interviews and primary MEC exam only	15,771	1	6.613	104,294
5. Screener, household, and SP interviews, primary MEC exam and full MEC replicate exam	789	1	11.613	9,163
6. Screener, household, and SP interviews, MEC exam and dietary replicate interview only (5% + optional 15%)	3,156	1	8.363	26,394
7. Home exam	213	1	2.700	575
8. Telephone followup of elderly-option	3,501	1	0.750	2,626
Total				154,240

Charles Gollmar,

Deputy Director for Policy Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–26710 Filed 10–5–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Allotment Percentages for Child Welfare Services State Grants

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Biennial publication of allotment percentages for States under the Title IV–B subpart 1, Child Welfare Services State Grants Program.

SUMMARY: As required by section 421(c) of the Social Security Act (42 U.S.C. 621(c)), the Department is publishing the allotment percentage for each State under the Title IV–B subpart 1, Child Welfare Services State Grants Program. Under section 421(a), the allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: Effective for Fiscal Years 2000 and 2001.

FOR FURTHER INFORMATION CONTACT: Joanne Moore, Division of Formula, Entitlement and Block Grants, Office of Financial Services, Administration for Children and Families, 370 L'Enfant Promenade, SW, Washington DC 20447.

SUPPLEMENTARY INFORMATION: The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 421 of the Act. The allotment percentage for each State is as follows:

State	*Allotment percentage*
Alabama	58.86
Alaska	48.32
Arizona	56.49
Arkansas	61.23
California	48.11
Colorado	47.56
Connecticut	30.50
Delaware	43.70
District of Columbia	30.00
Florida	50.48
Georgia	53.07
Hawaii	46.55
Idaho	59.04
Illinois	45.23
Indiana	53.43
Iowa	54.82
Kansas	52.99
Kentucky	59.58
Louisiana	59.37
Maine	56.68
Maryland	43.06
Massachusetts	39.41
Michigan	49.40
Minnesota	48.04
Mississippi	64.10

State	Allotment percentage
Missouri	53.09
Montana	60.28
Nebraska	53.65
Nevada	46.86
New Hampshire	45.14
New Jersey	35.85
New Mexico	61.22
New York	40.37
North Carolina	54.63
North Dakota	59.12
Ohio	51.83
Oklahoma	59.71
Oregon	53.10
Pennsylvania	49.26
Rhode Island	49.39
South Carolina	59.24
South Dakota	58.25
Tennessee	54.60
Texas	54.23
Utah	60.77
Vermont	53.91
Virginia	48.05
Washington	48.52
West Virginia	62.25
Wisconsin	52.11
Wyoming	55.30
American Samoa	70.00
Guam	70.00
Northern Marianas	70.00
Puerto Rico	70.00
Virgin Islands	70.00

Dated: September 29, 1998.

James A. Harrell,

Deputy Commissioner, Administration for Children, Youth and Families.

[FR Doc. 98–26663 Filed 10–5–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0721]

Agency Information Collection Activities: Proposed Collection; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed reinstatement of an existing information collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for premarket approval applications (PMA's).

DATES: Submit written comments on the collection of information by December 7, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

I. Premarket Approval of Medical Devices—21 CFR Part 814 and FDAMA Sections 201, 202, 205, 207, 208, 209, 216, 217, and 403 (OMB Control Number 0910–0231—Extension)

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth requirements for premarket approval of certain medical devices. Under section 515 of the act, an application must contain several pieces of information, including: Full reports of all information concerning investigations showing whether the device is safe and effective; a statement of components; a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device; and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMA's for class III (premarket approval) medical devices. The regulations will facilitate the approval of PMA's for devices that have been shown to be safe and effective and otherwise meet the statutory criteria for approval. The regulations will also ensure the disapproval of PMA's for devices that have not been show to be safe and effective and that do not otherwise meet the statutory criteria for approval.

Under § 814.15, an applicant may submit in support of a PMA studies from research conducted outside the United States, but an applicant must explain in detail any differences between standards used in a study to support the PMA's and those standards found in the Declaration of Helsinki. Section 814.20 provides a list of information required in the PMA, including: A summary of information in the application, a complete description of the device, technical and scientific information, and copies of proposed labeling. Section 814.37 provides requirements for an applicant who seeks to amend a pending PMA. Section 814.82 sets forth postapproval requirements FDA may propose, including periodic reporting on safety effectiveness, and reliability, and display in the labeling and advertising of certain warnings. Other potential post approval requirements include the maintenance of records to trace patients and the organizing and indexing of records into identifiable files to enable FDA to determine whether there is