DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Allotment Percentages to States for Child Welfare Services State Grants

AGENCY: Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

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.

EFFECTIVE DATE: The allotment percentages shall be effective for Fiscal Years 2006 and 2007.

FOR FURTHER INFORMATION CONTACT: Doris Lee, Grants Fiscal Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, telephone (202) 205–4626.

SUPPLEMENTARY INFORMATION: The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 421 of the Act. These figures are available on the ACF home page on the Internet: *http://www.acf.dhhs.gov/programs/cb/*. The allotment percentage for each State is as follows:

State	Allotment percentage
Alabama	58.78
Alaska	47.24
Arizona	57.42
Arkansas	61.90
California	46.47
Colorado	45.19
Connecticut	31.13
Delaware	48.21
District of Columbia	30.00
Florida	51.94
Georgia	53.36
Hawaii	51.93
Idaho	58.99
Illinois	46.53
Indiana	54.64
Iowa	54.61
Kansas	53.08
Kentucky	58.79
Louisiana	59.22
Maine	54.86
Maryland	41.44
Massachusetts	36.69
Michigan	51.78
Minnesota	46.01
Mississippi	63.49
Missouri	53.96
Montana	59.82
Nebraska	52.37
Nevada	50.48
New Hampshire	44.95
New Jersey	36.08
New Mexico	60.09
New York	41.97
North Carolina	55.13
North Dakota	56.01
Ohio	52.85
Oklahoma	58.07
Oregon	53.45
Pennsylvania	49.80
Rhode Island	50.10
South Carolina	58.79
South Dakota	55.37
Tennessee	55.42
Texas	53.07
Utah	60.24
Vermont	51.92
Virginia	46.92
Washington	47.22
West Virginia	61.73
Wisconsin	51.48
Wyoming	49.48
American Samoa	70.00
Guam	70.00
N. Mariana Islands	70.00
Puerto Rico	70.00
Virgin Islands	70.00

Dated: October 20, 2004.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0269]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by December 3, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Radioactive Drug Research Committees—(OMB Control Number 0910–0053)

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual

report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial). These studies require filing of an investigational new drug application (IND) under 21 CFR 312.1, and the associated information collections are covered in OMB approval number 0910–0014.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three chairpersons who were selected from Radioactive Drug Research Committees of different geographical areas and of varying levels of activity. These chairpersons were asked for their assessment of time expended, cost, and views on completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914	80	1	80	1	80
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1,190
361.1(d)(8)		50	6.8	340	0.1	34
Total						1,304

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Forms	No. of Recordkeepers	Annual Frequency per Recordkeeping	Hours per Recordkeeper	Total Hours
361.1(c)(2)		80	1 per qtr= 4 per yr	10	800
361.1(d)(5)		50	6.8	0.75	38
Total					838

[1]There are no capital costs or operating and maintenance costs associated with this collection of information

In the **Federal Register** of July 23, 2004 (69 FR 44037), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: October 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0469]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA's adverse experience