

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families****Submission for OMB Review; Comment Request**

*Title:* Head Start Eligibility Verification.

*OMB No.:* 0970-0374.

*Description:* The requirements for establishing proof of eligibility for the enrollment of children in Head Start programs are documented in 45 CFR 1305.4 (e). Each child's record must include a signed document by an employee identifying those documents which were reviewed to determine eligibility. Presently there is no uniform

document which the employee must sign. This form will be used to facilitate an efficient and accurate determination of children's eligibility for Head Start enrollment.

*Respondents:* Head Start grantees.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Eligibility Verification .....	1,600	750	0.08	96,000

*Estimated Total Annual Burden Hours:* 96,000.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*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, Fax: 202-395-7285, Email: [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2012-28138 Filed 11-19-12; 8:45 am]

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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 (CFDA No. 93.645).

**SUMMARY:** As required by section 423(c) of the Social Security Act (42 U.S.C. 623(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 423(a), the allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

**DATES:** *Effective Date:* The allotment percentages shall be effective for Fiscal Years 2014 and 2015.

**FOR FURTHER INFORMATION CONTACT:** Deborah Bell, Grants Fiscal Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, telephone (202) 401-4611.

**SUPPLEMENTARY INFORMATION:** The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 423 of the Act. These figures are available on the ACF homepage on the Internet: <http://www.acf.dhhs.gov/programs/cb/>. The allotment percentage for each State is as follows:

State	Allotment percentage
Georgia .....	56.50
Hawaii .....	48.28
Idaho .....	60.31
Illinois .....	47.24
Indiana .....	57.13
Iowa .....	51.66
Kansas .....	51.07
Kentucky .....	59.06
Louisiana .....	53.44
Maine .....	53.78
Maryland .....	38.87
Massachusetts .....	35.75
Michigan .....	56.74
Minnesota .....	46.65
Mississippi .....	61.31
Missouri .....	54.07
Montana .....	56.75
Nebraska .....	49.86
Nevada .....	54.72
New Hampshire .....	44.88
New Jersey .....	36.63
New Mexico .....	58.63
New York .....	38.75
North Carolina .....	56.40
North Dakota .....	46.22
Ohio .....	54.68
Oklahoma .....	55.29
Oregon .....	54.75
Pennsylvania .....	49.18
Rhode Island .....	47.35
South Carolina .....	59.57
South Dakota .....	49.19
Tennessee .....	56.09
Texas .....	52.09
Utah .....	59.41
Vermont .....	50.06
Virginia .....	44.51
Washington .....	46.91
West Virginia .....	59.92
Wisconsin .....	52.31
Wyoming .....	43.29
American Samoa .....	70.00
Guam .....	70.00
N. Mariana Islands .....	70.00
Puerto Rico .....	70.00
Virgin Islands .....	70.00

**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

State	Allotment percentage
Alabama .....	57.91
Alaska .....	44.94
Arizona .....	57.33
Arkansas .....	59.25
California .....	47.26
Colorado .....	46.95
Connecticut .....	30.73
Delaware .....	50.17
District of Columbia .....	30.00
Florida .....	52.15

Dated: November 1, 2012.

**Bryan Samuels,**

*Commissioner, Administration on Children,  
Youth and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-1131]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drug Applications and Supporting Regulations, and Form FDA 356V

**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 paperwork associated with applications for new animal drugs.

**DATES:** Submit either electronic or written comments on the collection of information by January 22, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (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:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PIFO, Rm. 410B, Rockville, MD 20850, 301-796-3794.

**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 extension 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

#### Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance #152, and Form FDA 356V—21 CFR 514.5, 514.1, 514.4, and 514.8 (OMB Control Number 0910-0032)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 of Title 21 of the Code of Federal Regulations describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes

the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file a NADA seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. FDA allows applicants to submit a complete NADA or to submit information in support of a NADA for phased review followed by submission of an administrative NADA when FDA finds all the applicable technical sections are complete.

Section 514.1 of Title 21 of the Code of Federal Regulations interprets section 512(b)(1) of the FD&C Act and further describes the information that must be submitted as part of a NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval.

FDA estimates the burden of the collections of information as follows: