ACTION: Notice

SUMMARY: The Administration on Aging (AoA) 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 State Annual Long-Term Care Ombudsman Report and Instructions for Older Americans Act Title VII.

DATES: Submit written or electronic comments on the collection of information by March 12, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: *louise.ryan@aoa.hhs.gov.*

Submit written comments on the collection of information to: U.S. Department of Health and Human Services: Administration on Aging, Washington, DC 20201. Attention: Louise Ryan.

FOR FURTHER INFORMATION CONTACT: Louise Ryan by telephone: (202) 357–3503 or by email: *louise.ryan@aoa.hhs.gov.*

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, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA'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.

Under section 712(c), and section 712(h) (1)-(3) of the Older Americans Act, as amended, states are required to provide information on ombudsmen activities to AoA, which AoA is then required to present to Congress. The reporting system, the National Ombudsman Reporting System (NORS), was developed in response to these directives and other needs pertaining to the Long Term Care Ombudsman Program and approved by the Office of Management and Budget for use for the first time in FY 1995–96; it was extended a second time with slight modifications for use in FY 1997–2001 and extended for the third time with no change for use from FY 2002–2006. It was extended, with modifications, a fourth time for use from FY 2007–2008. It was extended a fifth time with no modifications. This current (sixth) request is to extend, with no modifications, use of the existing State Annual Long-Term Care Ombudsman Report (and Instructions) for use from FY 2012–2014. The current form and instructions are posted on the AoA Web site at: *http://www.aoa.gov/AoARoot/AoA_Programs/Elder_Rights/Ombudsman/index.aspx.* AoA estimates the burden of this collection of information as follows: Approximately one and one-half hour per respondent, with 52 State Agencies on Aging responding annually for a total of 78 hours.

Dated: January 6, 2012.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2012–323 Filed 1–10–12; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Head Start Health Managers Descriptive Study.

OMB No.: New Collection.

Description

The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity that will provide descriptive data about the Head Start Health Component. The goals of the Head Start Health Manager Descriptive Study are (1) to describe the characteristics of Health Managers and related staff in Head Start (HS) and Early Head Start (EHS) programs; (2) to identify the current landscape of health programs and services being offered to children and families; (3) to determine how health initiatives are prioritized, implemented, and sustained; and (4) to identify the programmatic features and policy levers that exist to support health services including staffing, environment, and community collaboration. These objectives will be accomplished through an online survey of all HS/EHS Health Managers, including American Indian/Alaskan Native and Migrant and Seasonal Head Start grantees. The survey responses will be further informed by semi-structured interviews conducted with a subsample of Head Start Health Managers, teachers, and family service workers.

Respondents

The target respondents for this data collection are Head Start Health Managers at the grantee and delegate level; however data will also be collected from Head Start Directors, Teachers, and Family Service Workers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Head Start Health Managers Survey	2,879	1	1.25	3,599
Head Start Director Survey	2,879	1	.25	720

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Semi-structured interviews Head Start Health Managers	40	1	.75	30
Semi-structured interviews Head Start Teachers and Family Service Workers	60	1	.75	45

Estimated Total Annual Burden Hours: 4394.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 4, 2012.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–262 Filed 1–10–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–P–0743 and FDA–2011–P–0822]

Determination That AVALIDE (Hydrochlorothiazide and Irbesartan), Oral Tablets, 25 Milligrams/300 Milligrams and 12.5 Milligrams/75 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 milligrams (mg)/300 mg and 12.5 mg/75 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hydrochlorothiazide and irbesartan, oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Inglese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6210, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, are the subject of NDA 20–758, held by Sanofi-Aventis, and initially approved on September 30, 1997. AVALIDE is indicated for treatment of hypertension in patients whose blood pressure is not adequately controlled on monotherapy. AVALIDE is also indicated for initial therapy for hypertension in patients who are likely to need multiple drugs to achieve their blood pressure goals.

AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

EAS Consulting Group, LLC on behalf of Aurobindo Pharmaceuticals, Ltd. submitted a citizen petition dated October 11, 2011 (Docket No. FDA–2011–P–0743), under § 10.30 (21 CFR 10.30), requesting that the Agency