DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Evaluation of the Head Start Designation Renewal System.

OMB No.: New Collection.

Description: In the fall of 2011, the Administration for Children and Families (ACF) within the US Department of Health and Human Services (HHS) significantly expanded its accountability provisions with the implementation of the Head Start Designation Renewal System (DRS). The DRS is designed to identify which Head Start and Early Head Start grantees are providing high quality, comprehensive services to the children and families in their communities. Where they are not, grantees are denied automatic renewal of their grant and must apply for continuing funding through an open competition process. Determinations are based on seven conditions designed to measure service quality, program operational quality, and fiscal and internal integrity.

The ACF is proposing to conduct an evaluation of the DRS. The purpose of the evaluation is to understand if the DRS is working as intended, as a valid, reliable, and transparent method for identifying high-quality programs that can receive continuing five-year grants without competition and as a system that encourages overall program quality improvement. It also seeks to understand how the system is working, the circumstances in which it works more or less well, and the contextual, demographic, and program factors and program actions associated with how well the system is working. The study will employ a mixed-methods design that integrates and layers administrative and secondary data sources, observational measures, and interviews to develop a rich knowledge base about what the DRS accomplishes and how it does so.

Respondents: Head Start program directors; other program managers including grantee agency directors, center directors, and education services coordinators; Head Start teachers; and members of Head Start governing bodies and local policy councils.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Quality Measures Follow Up Interview: Teachers	830	1	0.4	332	166
Quality Measures Follow Up Interview: Center Directors	350	1	1.5	525	263
Quality Measures Follow Up Interview: Program Directors	70	1	1.1	77	39
DRS Telephone Interview: Program Directors	35	1	1.25	44	22
DRS In-Depth Interview: Agency Directors	15	1	1	15	8
DRS In-Depth Interview: Program Directors	15	1	1.5	23	12
DRS In-Depth Interview: Policy Council/Governing Body	75	1	1.5	113	57
DRS In-Depth Program Managers	45	1	1.5	68	34
Competition In-Depth Interview: Agency and Program Directors	18	1	1.25	23	12
Competition In-Depth Interview: Policy Council/Governing Body	45	1	1.5	68	34
Competition In-Depth Interview: Program Managers	27	1	1.5	41	21
Competition Data Capture Sheet	500	1	0.15	75	38
Estimated Total Annual Burden Hours	.....	.....	.....	.....	706

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.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2013–13716 Filed 6–10–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0113]

Determination That CORDRAN (Flurandrenolide) Ointment USP, 0.025% and 0.05%, 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 CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for

flurandrenolide ointment, 0.025% and 0.05%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–2465.

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 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.

CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, are the subject of NDA 012806, held by Aqua Pharmaceuticals, and initially approved on October 18, 1965. CORDRAN Ointment is a topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

IGI Labs, Inc., submitted a citizen petition dated January 15, 2013 (Docket No. FDA–2013–P–0113), under 21 CFR 10.30, requesting that the Agency determine whether CORDRAN (flurandrenolide) Ointment USP, 0.05%, was voluntarily withdrawn or withheld from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 0.025% strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CORDRAN (flurandrenolide) Ointment USP, 0.025% and 0.05%, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CORDRAN (flurandrenolide) Ointment USP, 0.025% or 0.05%, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 6, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–13782 Filed 6–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database (OMB No. 0915–0310)—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111–264 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements in