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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

order to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. HRSA uses the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and to provide the Secretary of HHS with an annual report of transplant center-specific survival data. The increase in burden, as reflected in this revised submission request, is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Baseline Pre-TED (Transplant Essential Data)	200	38	7,600	1	7,600
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	29	5,800	1	5,800
100-Day Post-TED	200	38	7,600	0.85	6,460
6-Month Post-TED	200	31	6,200	1	6,200
12-Month Post-TED	200	27	5,400	1	5,400
Annual Post-TED	200	104	20,800	1	20,800
Total	200		53,400		52,260

Dated: June 5, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–13790 Filed 6–10–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; Web-Based Media Literacy Parent Training for Substance Use Prevention in Rural Locations

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse, National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 27, 2013, pages 18612–18613 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Augie Diana, Health Scientist Administrator, Prevention Research Branch, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5163, Bethesda, MD 20892, or call non-toll-free number (301) 443–1942 or Email your request, including your address to: *dianaa@nida.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Web-based Media Literacy Parent Training for Substance Use Prevention in Rural Locations, 0925-New, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will develop a web-based media literacy substance use prevention intervention for use with parents and their elementary school children (approximately ages 7–12), and will evaluate the program in a randomized controlled trial to establish program efficacy in six rural communities in North Carolina and Texas. The primary objectives of the study are to assess the efficacy of a media literacy education program that is specifically designed to overcome barriers to prevention efforts in rural communities, and to provide the scientific basis for establishing the program, Media Detective Family, as an evidence-based substance use prevention curriculum. The findings will provide valuable information concerning: (1) The appropriateness of using technology for substance use prevention programming (i.e., internet, Smartphone, or tablet-based applications) to reach rural families with elementary school-aged children;