Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator.

FFR (SF 425) instructions for CDC Grantees are now available at *http://grants.nih.gov/grants/forms.htm.* For further information, contact *GrantsInfo@nih.gov.* Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: *http://www.cdc.gov/od/pgo/funding/grants/eramain.shtm.*

Getting Started—eRA Commons Registration

The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (*https://commons.era.nih.gov/commons/*). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the ''List of Commons Registered Organizations'' query found at: *http://era.nih.gov/commons/.* Organizations not yet registered can go to *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp* for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the Principle Investigator (PI) on the application must also be registered in the Commons. The PI must hold a PI account *and* be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: *http://era.nih.gov/commons/index.cfm.*

Inquiries

General questions concerning using the eRA Commons should be directed to the eRA Commons Helpdesk at: eRA Commons Help Desk Web: *http://ithelpdesk.nih.gov/eRA/.* (Preferred method of contact).
Toll-free: 1–866–504–9552
Phone: 301–402–7469
TTY: 301–451–5939
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Standard Time.
Email: *commons@od.nih.gov.*

Dated: June 5, 2012.

Alan A. Kotch,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–14049 Filed 6–8–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) DNA Samples

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: The National Health and Nutrition Examination Survey (NHANES) will not be receiving DNA proposals in the near future. NHANES is changing its plan for making DNA available for genetic research and its proposal guidelines. NHANES will announce when it will reopen its repository for use of DNA specimens for research protocols once it has developed its new plan of operation.

DATES: Effective date is date of publication in the **Federal Register.**

ADDRESSES: Geraldine McQuillan, Ph.D., Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, Phone: 301–458–4371, Fax: 301–458–4028, EMail: *NHANESgenetics@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Geraldine McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, Phone: 301–458–4371, Fax: 301–458–4028, E-Mail: *NHANESgenetics@cdc.gov.*

Juliana Cyril,

Deputy Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–14056 Filed 6–8–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Extension to HS Transportation Requirement.

OMB No.: 0970–0260.

Description: The Office of Head Start is proposing to renew authority to collect information regarding the Head Start transportation requirement without changes. The transportation requirement provides the requirement that each child be seated in a child restraint system while the vehicle is in motion, and the requirement that each bus have at least one bus monitor on board at all times. Waivers would be granted when the Head Start or Early Head Start grantee demonstrates that compliance with the requirement(s) for which the waiver is being sought will result in a significant disruption to the Head Start program or the Early Head Start program and that waiving the requirement(s) is in the best interest of the children involved.

Respondents: Head Start and Early Head Start program grants recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per respondent	Total burden hours
Form	275	1	1	275

Estimated Total Annual Burden Hours: 275

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email address: *infocollection@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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–14059 Filed 6–8–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–E–0133; FDA–2011–E–0136]

Determination of Regulatory Review Period for Purposes of Patent Extension; CYSVIEW (Previously HEXVIX)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CYSVIEW (previously HEXVIX) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of the application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CYSVIEW (hexaminolevulinate hydrochloride). CYSVIEW is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for CYSVIEW (U.S. Patent Nos. 7,247,655 and 7,348,361) from Photocure ASA, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated June 9, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CYSVIEW represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CYSVIEW is 3,103 days. Of this time, 2,770 days occurred during the testing phase of the regulatory review period, while 333 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* November 30, 2001. The applicant claims October 29, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 30, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 30, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for CYSVIEW (NDA 22–555) was submitted on June 30, 2009.

3. *The date the application was approved:* May 28, 2010. FDA has verified the applicant's claim that NDA 22–555 was approved on May 28, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 686 days or 564 days, respectively, of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 10, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review