(Human papillomavirus 9-valent Vaccine, Recombinant). GARDASIL 9 is indicated in girls and women 9 through 26 years of age for the prevention of the following diseases:

- Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58.
- Genital warts caused by HPV types 6 and 11.

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma in situ.
- CIN grade 1.
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3.
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 1.
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

Gardasil 9 is also indicated in boys and men 9 through 26 years for the prevention of the following diseases;

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58.
- Genital warts caused by HPV types 6 and 11.

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- AIN grades 1, 2, and 3.

Subsequent to this approval, the USPTO received patent term restoration applications for GARDASIL 9 (U.S. Patent Nos. 7,476,389 and 7,482,015) from Merck Sharp & Dohme Corp. for CSL Limited and The University of Queensland; the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 26, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of GARDASIL 9 represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for GARDASIL 9 is 2,662 days. Of this time, 2,296 days occurred during the testing phase of the regulatory review period, while 366 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 (21 U.S.C. 355(i)) became effective:* August 29, 2007. The applicant claims September 2, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 29, 2007, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): December 10, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for GARDASIL 9 (BLA 125508/0) was initially submitted on December 10, 2013.

3. *The date the application was approved:* December 10, 2014. FDA has verified the applicant's claim that BLA 125508/0 was approved on December 10, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,062 days or 1,254 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see DATES). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: *December 1, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29303 Filed 12–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0937–0191–30D]

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

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0937–0191, scheduled to expire on December 31, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before January 6, 2017.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0937–0191–30D for reference.

Information Collection Request Title: Application packets for Real Property for Public Health Purposes.

OMB No.: 0937–0191.

Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Property Assistance Program is requesting OMB's approval on a previously approved information collection, 0937–0191. The Federal Property and Administrative Services Act of 1949 (P.L. 81–152), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held

exempt from taxation under Section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Need and Proposed Use of the Information: State and local governments and non-profit institutions use these applications to apply for excess/surplus, underutilized/unutilized and off-site government real property. These applications are used to determine if institutions/organizations are eligible to purchase, lease or use property under the provisions of the surplus real property program.

Likely Respondents: State, local, or tribal units of government or instrumentalities thereof; not-for-profit organizations

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	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Applications for surplus Federal real property	15	1	200	3,000
Total	15	1	200	3,000

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–29361 Filed 12–6–16; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before February 6, 2017.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–5683.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.funn@hhs.gov* or (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–New–60D for reference.

Information Collection Request Title: Domestic Violence Housing First Demonstration Evaluation

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, in partnership with the Office for Victims of Crimes within the U.S. Department of Justice, is seeking approval by OMB for a new information collection request entitled, ''Domestic Violence Housing First (DVHF) Demonstration Evaluation.'' The Washington State Coalition Against Domestic Violence (WSCADV) is overseeing and coordinating an evaluation of the DVHF Demonstration project through a contract with ASPE. This quasi-experimental research study involves longitudinally examining the program effects of DVHF on domestic violence survivors' safety and housing stability. The findings will be of interest to the general public, to policy-makers, and to organizations working with domestic violence survivors.

Data collection will include in-depth, private interviews with 320 domestic violence survivors conducted by trained professional staff. At Time 1 study enrollment, they will be interviewed about their backgrounds, housing and safety obstacles, and services desired. There will be three follow-up interviews with them every six months after the Time 1 Interview (*i.e.,* 6, 12, and 18 months) to examine the match between needs and services, as well as their safety and housing stability. Study enrollment will take place over 15 months, so the annualized burden for the Time 1 and follow-up surveys is based on 12/15 (256) of the expected sample (320).

The primary service providers working with the domestic violence survivors will complete self-administered online questionnaires to provide more detailed program implementation data. Service providers will complete a survey about their work history and demographics and a survey about the services provided for each domestic violence survivor in their caseload that is a participant in the study (approximately 16 survivors per provider). This latter data collection will occur six months after a domestic violence survivor enrolls in the study over 15 months to correspond to the study enrollment period. Finally, the study will also include monthly data collection for 19 months from an agency point of contact (POC) in order to verify agency information (*e.g.,* the number of advocates working in the agency, advocate caseloads, dates of study participants' receipt of services).

Likely Respondents: The respondents are domestic violence survivors, primary service providers, and community agency points of contact who work with their agency data systems.