Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO 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 biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product TAKHZYRO (lanadelumab-flyo). TAKHZYRO is indicated for prophylaxis to prevent hereditary angioedema in patients 12 years and older. Subsequent to this approval, the USPTO received a patent term restoration application for TAKHZYRO (U.S. Patent No. 8,816,055) from Dyax Corp., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TAKHZYRO 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 TAKHZYRO is 1,857 days. Of this time, 1,616 days occurred during the testing phase of the regulatory review period, while 241 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:* July 25, 2013. The applicant claims August 2, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 25, 2013, which was 30 days after FDA receipt of the IND.

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 26, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for TAKHZYRO (BLA 761090) was initially submitted on December 26, 2017.

3. *The date the application was approved:* August 23, 2018. FDA has verified the applicant's claim that BLA 761090 was approved on August 23, 2018.

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 application for patent extension, this applicant seeks 849 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20104 Filed 9–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0421]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the

following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 14, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: ASPE Generic Clearance for the Collection of Qualitative Research and Assessment.

Type of Collection: Extension.

OMB No. 0990–0421—Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting a three-year extension for their generic clearance for purposes of conducting qualitative research. The ICR is for an extension of the approved information collection assigned OMB control number 0990–0421, scheduled to expire on October 31, 2020. ASPE conducts qualitative research to gain a better understanding of emerging health and human services policy issues, develop future intramural and extramural research projects, and to ensure HHS leadership, agencies and offices have recent data and information to inform program and policy decision-making. ASPE is requesting approval for at least four types of qualitative research which include, but are not limited to: (a) Interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods.

ASPE's mission is to advise the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates many of the Department's evaluation, research and demonstration activities, and manages cross-Department planning activities such as implementation of the Evidence Act, strategic planning, legislative planning, and review of regulations. Integral to this role, ASPE will use this mechanism to conduct qualitative research, evaluation, or assessment, conduct analyses, and understand needs, barriers, or facilitators for HHS-related programs and services.

ASPE is requesting comment on the burden for qualitative research aimed at understanding emerging health and human services policy issues. The goal of developing these activities is to identify emerging issues and research gaps to ensure the successful implementation of HHS programs. The participants may include health and human services experts; national, state, and local health or human services representatives; public health, human services, or healthcare providers; and representatives of other health or human services organizations.

Need and Proposed Use of the Information: ASPE is requesting comment on the burden for qualitative research aimed at understanding emerging health and human services policy issues. The goal of developing these activities is to identify emerging issues and research gaps to ensure the successful implementation of HHS programs. The participants may include health and human services experts; national, state, and local health or human services representatives; public health, human services, or healthcare providers; and representatives of other health or human services organizations. The increase in burden from 747 in 2014 to 1,300 respondents in 2017 reflects an increase in the number of research projects conducted over the estimate in 2014. There is no change in request of burden hours from 2017 to 2020.

The total annual burden hours estimated for this ICR are summarized in the table below.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Health or Human Services Policy Stakeholder	Qualitative Research	1,300	1	1	1,300

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–20136 Filed 9–11–20; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Council of Research Advocates, September 14, 2020, 12:00 p.m. to September 14, 2020, 4:00 p.m., National Institutes of Health, Building 31, 9000 Rockville Pike, Bethesda, MD 20892 which was published in the **Federal Register** on August 14, 2020, 85 FR 49663.

This meeting notice is amended to change the meeting start time. The meeting will now be held from 1:00 p.m. to 4:00 p.m. on September 14, 2020. The meeting is open to the public.

Dated: September 8, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20119 Filed 9–11–20; 8:45 am]

BILLING CODE 4140–01–P