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 an 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 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 drug 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 drug product, VORANIGO (vorasidenib) indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 or isocitrate dehydrogenase-2 mutation following surgery including biopsy, sub-total resection, or gross total resection. Subsequent to this approval, the USPTO received a patent term restoration application for VORANIGO (U.S. Patent No. 9,579,324) from Servier Pharmaceuticals LLC and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VORANIGO 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 VORANIGO is 3,388 days. Of this time, 3,157 days occurred during the testing phase of the regulatory review period, while 231 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* April 30, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 30, 2015.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 20, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for VORANIGO (NDA 218784) was initially submitted on December 20, 2023.

3. *The date the application was approved:* August 6, 2024. FDA has verified the applicant's claim that NDA 218784 was approved on August 6, 2024.

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(s) for patent extension, this applicant seeks 1,474 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16271 Filed 8–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New–30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT, 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 September 25, 2025.

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: Meghan Gabriel, *Meghan.Gabriel@hhs.gov,* or (202) 465–0597, or *ASTP_Data@HHS.GOV.* 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: National Survey of Digital Health Companies.

Type of Collection: New.

Document Identifier 0990–New–30D.

Abstract

The 21st Century Cures Act (Cures Act) aimed to advance the exchange of electronic health information by promoting patient access through

standardized application programming interfaces (APIs). Digital health companies develop apps and health IT tools that enable human interaction with APIs to exchange electronic health information. Prior studies indicate widespread adoption of standardized APIs for interoperability with electronic health records (EHRs). Ongoing assessment of these technologies is crucial to examining the impacts of the Cures Act's health IT provisions and is critical to informing the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT's (ASTP/ONC's) policy efforts. With ASTP/ONC's support, the University of California, San Francisco (UCSF) conducted a 2022 survey of digital health companies assessing implementation of and experiences with healthcare APIs; findings from this survey work are published in the Journal of the American Medical Informatics Association. ASTP/ONC finds it essential to continue efforts to survey digital health companies to assess ASTP/ONC's implementation of statutorily mandated information blocking (42 U.S.C. 300jj–52) and APIs ''without special effort'' policies (42 U.S.C. 300jj–11) under the Cures Act. Information gathered from this effort will help inform ongoing ASTP/ONC efforts to help nurture an ecosystem of innovation and transparency in health care.

This is a 3-year request for OMB approval.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Digital Health Companies	282	1	.5	141
Total	282	1	.5	141

Catherine Howard,

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

[FR Doc. 2025–16295 Filed 8–25–25; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for reinstatement without revision.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the public to take this opportunity to comment on the information collection titled, ''Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Childcare and Indian Child Care Worker Positions,'' Office of Management and Budget (OMB) Control Number 0917–0028.

DATES: October 27, 2025. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Submit comments to Randolph Beasley III by email at *Randolph.Beasley@ihs.gov.*

Comments submitted in response to this notice will be made available to the public by publishing them in the 30-day **Federal Register** notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Thomas Hamby at *Thomas.hamby@ihs.gov* or 240–252–0331.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** on February 23, 2022 (87 FR 10218) and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit this collection to OMB for approval of reinstatement without revision, and to solicit comments on specific aspects for the proposed information collection.

Title: Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions (OMB No. 0917–0028). *Type of Information Collection Request:* Reinstatement without revision, of previously-approved information collection, 0917–0028, Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions. There are no program changes or adjustments in burden hours. *Form(s):* Addendum to Declaration for Federal Employment (OF 306), Indian Health Service, Child Care and Indian Child Care Worker Positions. *Need and Use of Information Collection:* This is a request for approval of the collection of information as required by section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law (Pub. L.) 101–630, 104 Stat. 4544, 4551 codified as amended at 25 United States Code (U.S.C.) Section 3207; the Crime Control Act of 1990, Public Law 101–647, title II, subtitle E, section 231, 104 Stat. 4789, 4808, codified as amended at 34 U.S.C. 20351 (formerly codified at 42 U.S.C. 13041, which was transferred to 34 U.S.C. 20351); and 42 CFR part 136, subpart K.

The IHS is required to compile a list of all authorized positions within the IHS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment, in a position having regular contact with, or control over, Indian children. 25 U.S.C. 3207(a)(1) and (2). Section 3207(a)(3) of Title 25 requires regulations prescribing the minimum standards of character for