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:* June 29, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 29, 2012.

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):* May 18, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for TRODELVY (BLA 761115) was initially submitted on May 18, 2018.

3. *The date the application was approved:* April 22, 2020. FDA has verified the applicant's claim that BLA 761115 was approved on April 22, 2020.

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 1,780 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: November 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25612 Filed 11–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authority

Notice is hereby given that I have withdrawn the delegations to the Director, Office for Civil Rights (OCR), or their successor, with respect to the Religious Freedom Restoration Act (RFRA) and the Religion Clauses of the First Amendment, as well as any other delegation of authority to OCR with respect to enforcing or complying with RFRA or the First Amendment.

On December 7, 2017, the then-Acting Secretary of the Department of Health and Human Services issued a notice, published on January 19, 2018 (83 FR 2804), that delegated authority for implementation and compliance with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.,* within the Department to the Director of OCR.

On January 15, 2021, the Secretary further delegated to OCR authority to receive and investigate complaints, conduct compliance reviews, provide technical assistance and training, evaluate complaint processing and provide reports, and ensure uniform compliance with the Religion Clauses of the First Amendment. This delegation was not published in the **Federal Register**.

The Department takes its obligations to comply with RFRA and the First Amendment seriously, and it will continue to do so. Department components have the greatest knowledge about their respective programs and are best able to determine whether the Department has a compelling interest in a particular action and whether less restrictive means are available to further that interest, critical aspects of the legal test under RFRA. Furthermore, under the current *Statement of Organization, Functions, and Delegations of Authority* for the Office of General Counsel (OGC), OGC provides legal advice to the Secretary, Deputy Secretary, and all subordinate organization components of the Department. *See* 85 FR 47228 (July 7, 2020). Department components, in consultation with OGC, have the responsibility, and are best positioned, to evaluate RFRA-based requests for exemptions, waivers, and modifications of program requirements in the programs they operate or oversee.

Department components, further, are best situated to craft exemptions or other modifications when required under RFRA and to monitor the impact of such exemptions or modifications on programs and those they serve. Moreover, they are best positioned to evaluate how their programs must be run to comply with the Free Exercise Clause and the Establishment Clause of the First Amendment.

I therefore rescind the December 7, 2017, and the January 15, 2021 delegations with respect to the Religion Clauses of the First Amendment and/or RFRA, as well as any other delegation of authority to OCR with respect to enforcing or complying with RFRA or the First Amendment. Effective today, I delegate responsibility to Department components to ensure full compliance with RFRA and other constitutional requirements. Department components must consult with OGC on such matters and provide appropriate consideration to RFRA- or Constitution-based objections or requests, as well as take any actions that may be appropriate.

This delegation of authority is effective upon date of signature.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–25632 Filed 11–23–21; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the 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.

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

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: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Charles Hall, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276–6575 or email your request, including your address to: *HallCh@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on September 14, 2021 (Vol. 86 FR 51168) 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 Cancer Institute (NCI), 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.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the 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.

Proposed Collection: Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute), 0925–0613, Expiration Date 3/31/2022, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Food and Drug Administration (FDA) require Investigational New Drug Application (IND) sponsors to maintain adequate records on the shipment and disposition of agents to investigators. The agent accountability effort for National Cancer Institute/Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program (NCI/DCTD/CTEP) is managed by the Pharmaceutical Management Branch (PMB) at CTEP. The Investigational Agent Accountability Records (a.k.a. Drug Accountability Record Forms—DARF) are used to provide a standardized method of tracking of agent disposition across all institutions participating in trials for which the NCI provides agent. Institutional auditors verify information on the agent accountability forms for compliance. In addition, PMB staff review Investigational Agent Accountability Record Forms against records maintained in PMB systems to ensure there is no inappropriate use or diversion of investigational agents. Additionally, the International Investigator Statement (IIS) will be used by non-U.S. investigators, that are unable to sign the FDA 1572 (OMB No. 0925–0753, Expiration 05/31/2024) to attest compliance with applicable country-specific regulations.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 4,831 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
A1: Investigational Agent Accountability Record Form (DARF).	Individuals	760	20	4/60	1,013
A2: Investigational Agent Accountability Record for Oral Agents Form (DARF-Oral).	Individuals	2,280	20	4/60	3,040
A3: Electronic Agent Accountability Record Form (eDARF).	Individuals	760	20	1/60	253
A4: International Investigator Statement (IIS) (Initial Response).	Individuals	2,100	1	15/60	525
Totals	.....	5,900	78,100	.....	4,831

Dated: November 18, 2021.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2021–25605 Filed 11–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Genetic Testing Registry (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the 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.

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

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