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.