TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.130; requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§ 312.145; Guidance Documents:					
Oversight of Clinical Investigations (2013)	88	1.5	132	4	528
Pharmacogenomic Data Submissions (2005)	1	1	1	50	50
Adaptive Designs for Clinical Trials of Drugs and Biologics (2019)	55	4.727	260	50	13,000
Subtotal Subpart F CDER			15,117		491,555
Total			142,114		22,872,609

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.52(a); transfer of obligations to a contract research organization	466	3.107	1,448	300	434,400
§ 312.57; records showing the receipt, shipment, or other disposition of the investigational drug and any financial interests.	13,000	1	13,000	100	1,300,000
§ 312.62(a); records on disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); records on case histories of individuals	2,192	6.587	14,439	40	577,560
Subtotal Subpart D CDER			41,887		2,831,960
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs.	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection reflects program changes and adjustments. We have revised the information collection to account for burden that may be incurred by respondents who choose to adopt or implement recommendations discussed in referenced Agency guidance documents intended to assist respondents in complying with regulatory requirements in part 312. We have also made adjustments to individual collection elements. As a result of these changes and adjustments, the information collection reflects an overall decrease in both annual responses and burden hours. Finally, we have removed burden we attribute to provisions in part 312, subpart I: Expanded Access to Investigational Drugs for Treatment Use and are revising OMB control number 0910–0814 to include burden associated with information collection applicable to these regulatory provisions for efficiency of Agency operations.

Dated: November 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25615 Filed 11–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2122]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRODELVY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TRODELVY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 24, 2022. 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 by May 23, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 24, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 24, 2022. Comments received by mail/hand delivery/courier (for written/paper

submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–E–2122 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TRODELVY.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management 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 or biologic 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 TRODELVY (sacituzumab govitecan-hziy). TRODELVY is indicated for the treatment of adult patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for TRODELVY (U.S. Patent No. 7,999,083) from Immunomedics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TRODELVY 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 TRODELVY is 2,856 days. Of this time, 2,150 days occurred during the testing phase of the regulatory review period, while 706 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:* 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.