In the context of ACL, IL programs are supported through funding authorized by the Rehabilitation Act of 1973, as amended (The Act). Title VII, chapter 1 of the Act states the current purpose of the program is to ''promote a philosophy of independent living including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and the integration and full inclusion of individuals with disabilities into the mainstream of American society.''

ILS PPR and CIL PPR are being submitted separately because they are separate collections of different information from different parties. Separating these PRA processes reduces confusion and increases the Office of Independent Living Programs's (OILP's) ability to identify issues specific to CILs. This request is for CIL PPR, which is submitted annually by all CILs receiving IL Part C funds. The PPRs are used by ACL to assess grantees' compliance with title VII of the Act, and with 45 CFR 1329 of the Code of Federal Regulations and with applicable provisions of the HHS Regulations at 45 CFR part 75. The PPR serves as the primary basis for ACL's monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR also enables ACL to track performance outcomes and efficiency measures of the Centers for Independent Living (CIL) programs with respect to the annual and long-term performance targets established in compliance with GPRA. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 711A and section 721 of the Act.

ACL published a **Federal Register** Notice regarding the independent living programs information collection on February 23, 2017. Two-hundred and twenty-one individual comments were received. The responses indicated a need to make substantial changes to the collection. The current version of the CIL PPR that OILP is requesting an extension for was approved by OMB; the approval was extended and will expire on January 31, 2022. Further deliberation is needed to ensure that we appropriately address all of the concerns. OILP is proposing to extend the currently approved forms for one year while we work on a revision that addresses all the suggested changes. The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden of this collection of information as follows: 353 Centers for Independent Living will each complete one CIL PPR annually, and it will take an estimated 35 hours per CIL for an estimated total of 12,355 hours. This burden estimate is based partly on OILP's estimates of how long CILs probably take to find the information that PPRs ask for and partly on what CILs have told OILP about how long filling out the PPRs took.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Centers for Independent Living	353	1	35	12,355

Dated: July 29, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–16752 Filed 8–6–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0030]

Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out of State Distribution of Compounded Human Drug Products

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; extension of the period before FDA intends to begin enforcing the statutory 5 percent limit on out of state distribution of compounded human drug products.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the period for States to decide whether to sign the final standard memorandum of understanding (MOU) entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration'' (final standard MOU) before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU. FDA is extending the period, which was scheduled to end on October 27, 2021, to October 27, 2022. States may sign the final standard MOU at any time, including after the period is scheduled to end on October 27, 2022.

DATES: FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU as of August 9, 2021.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993–0002, 240–402–4078.

SUPPLEMENTARY INFORMATION: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician in a State licensed pharmacy or a Federal facility, to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate

investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (statutory 5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

In the **Federal Register** of October 27, 2020 (85 FR 68074), FDA announced the availability of the final standard MOU describing the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the final standard MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

In the October 27, 2020, **Federal Register** notice, FDA stated that it was providing a 365-day period for States to decide whether to sign the final standard MOU before FDA intended to begin enforcing the statutory 5 percent limit in States that do not sign the final standard MOU. Based on comments from stakeholders, it was FDA's understanding that this timeframe corresponds to a full legislative cycle for most States and would, therefore, afford sufficient time for States to modify their laws and regulations, if necessary in order to enter into the final standard MOU.

Following publication of October 27, 2020, **Federal Register** notice, FDA received requests to extend the period before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign. The requesters asserted that the time period of 365 days was insufficient to allow State governments to thoroughly evaluate the final standard MOU and modify their laws and regulations, if necessary in order to sign, because many State governments were focused on addressing concerns raised by the Coronavirus Disease 2019 (COVID–19) pandemic.

FDA has considered the requests and other relevant factors and is extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign the final standard MOU until October 27, 2022. FDA believes that an additional 1 year will allow sufficient time for States to consider the final standard MOU and modify their laws and regulations, if necessary. FDA's understanding is that emergency pandemic response activities have now begun to ease, permitting States more time to take up other issues. Accordingly, we believe a 1-year extension addresses the need that some States have expressed for additional time, without adding significant delay to FDA's implementation of the important public health protections afforded by section 503A(b)(3)(B) of the FD&C Act.

States may sign the final standard MOU at any time, including after the period is scheduled to end on October 27, 2022.

Dated: August 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16937 Filed 8–6–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3931]

Nonmetastatic Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Nonmetastatic Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' Recent approvals of several drug products for patients with nonmetastatic castration-resistant prostate cancer have been supported by randomized clinical trials demonstrating improvements in metastasis-free survival. This guidance intends to inform potential future applicants regarding the Agency's expectations for collection, analysis, and reporting of data pertaining to metastasis-free survival. This guidance finalizes the draft guidance of the same title issued on November 14, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on August 9, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–3931 for ''Nonmetastatic Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' Received comments 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