

Effective Date

This Order is effective on July 1, 2021, and will remain in effect through July 31, 2021, subject to revision based on the changing public health landscape.

Authority

The authority for this Order is Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.2.

Dated: June 24, 2021.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021-13842 Filed 6-24-21; 2:00 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Community Services Block Grant (CSBG) Model State Plan Applications (OMB No. 0970-0382)

AGENCY: Office of Community Services, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Community Services (OCS) requests a three-year extension of the forms Community Services Block Grant (CSBG) State Plan, CSBG Eligible Entity Master List, and the American Customer Survey Index (ACSI) (OMB #0970-0382, expiration 6/30/2021). There are minimal changes

requested to the State Plan and the Master List. No changes are proposed to the ACSI.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of 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.

SUPPLEMENTARY INFORMATION:

Description: Section 676 of the Community Services Block Grant (CSBG) Act requires states, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (CSBG State Plan). The CSBG State Plan must meet statutory requirements prior to CSBG grantees (states and territories) being funded with CSBG funds. Grantees have the option to submit a detailed plan annually or biannually. Grantees that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur.

OCS proposes to revise the automated CSBG State Plan format for states and territories by revising questions for clarity and system compatibility. OCS does not anticipate that these revisions will cause any additional burden to CSBG grantees as they have completed the automated plan for six years. It is anticipated that the burden will continue to diminish in subsequent years due to improved automation.

In addition to the CSBG State Plan, OCS requests that all grantees revise their CSBG Eligible Entity Master List in year one to add the executive director and website for each agency. Grantees will revise the Master List as necessary in subsequent years. As the CSBG Eligible Entity Master List is already completed and states have the information about their eligible entities (or sub-grantees), the burden will be minimal to the states to provide the additional requested information.

Lastly, the request includes a survey for the sub-grantees (or CSBG-eligible entities). The survey focuses on the customer service that the CSBG sub-grantees receive from the CSBG grantees. The survey is optional, and this will be the fifth time that the CSBG sub-grantees that chose to submit will complete it. There are no revisions proposed to the survey.

Respondents: State governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories, and local level sub-grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
CSBG State Plan Application for States	56	3	31	5,208	1,736
CSBG Eligible Entity Master List	56	3	2	336	112
CSBG ACSI Survey of Eligible Entities	1,007	1	.33	332	111

Estimated Total Annual Burden Hours: 1,848 hours for CSBG grantees; 111 for CSBG sub-grantees.

Authority: Sec. 676, Pub. L. 105-285, 112 Stat. 2735 (42 U.S.C. 9908)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021-13742 Filed 6-25-21; 8:45 am]

BILLING CODE 4184-27-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-E-1328]

Determination of Regulatory Review Period for Purposes of Patent Extension; Smallpox and Monkeypox Vaccine, Live

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 Smallpox and Monkeypox Vaccine, Live 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 August 27, 2021. 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 December 27, 2021. 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 August 27, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 27, 2021. 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-1328 for “Determination of Regulatory Review Period for Purposes of Patent Extension; Smallpox and Monkeypox Vaccine, Live.” 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 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 Smallpox and Monkeypox Vaccine, Live (Modified Vaccinia Ankara). Smallpox and Monkeypox Vaccine, Live, is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. Subsequent to this approval, the USPTO received a patent term restoration application for Smallpox and Monkeypox Vaccine, Live (U.S. Patent No. 7,335,364) from Bavarian Nordic A/S, and the USPTO requested FDA’s

assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of Smallpox and Monkeypox Vaccine, Live 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 Smallpox and Monkeypox Vaccine, Live is 5,650 days. Of this time, 5,315 days occurred during the testing phase of the regulatory review period, while 335 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: April 7, 2004. The applicant claims March 8, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 7, 2004, which was 30 days after FDA receipt of the IND.

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): October 25, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for Smallpox and Monkeypox Vaccine, Live (BLA 125678) was initially submitted on October 25, 2018.

3. The date the application was approved: September 24, 2019. FDA has verified the applicant's claim that BLA 125678 was approved on September 24, 2019.

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 1,825 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: June 22, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-13686 Filed 6-25-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-2099]

Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for Investigational New Drug Application and Bioavailability/Bioequivalence Studies; Draft 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 draft guidance for industry entitled “Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for Investigational New Drug Application and Bioavailability/Bioequivalence Studies.” The draft guidance provides recommendations for sponsors and sponsor-investigators to comply with the requirements of investigational new drug application (IND) safety reporting and safety reporting for bioavailability (BA) and bioequivalence (BE) studies. In doing so, the guidance provides recommendations related to the two IND safety reporting provisions that require assessment of aggregate data to facilitate appropriate IND safety reporting

practices. An earlier draft guidance for industry entitled “Safety Assessment for IND Safety Reporting” (December 2015) (the 2015 draft guidance) has been incorporated into this draft guidance. However, this content was revised to address feedback from stakeholders and comments received on the 2015 draft guidance. Concurrent with the publication of this draft guidance, we are withdrawing the 2015 draft guidance. Additionally, this draft guidance incorporates content from the final guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies” (December 2012) (the 2012 final guidance). This incorporated content remains largely unchanged in this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by September 27, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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”).

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