

per state/territory (up to 168 total

individuals). Only one survey will be submitted for each state/territory.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Avg. burden per response (in hours) | Total/annual burden (in hours) |
|---|---|--|-------------------------------------|--------------------------------|
| Instrument 1: CCDF Lead Agency Survey | 168 | 1 | *0.75 | 126 |

* Note that this is the estimated time to complete the full survey, which could be completed by one individual or multiple individuals. Surveys completed by multiple individuals will take less time for each individual to provide a response.

Authority: Research funding set-aside authorized by the CCDBG Act of 2014 and funded by CCDF. Section 658O(a)(5) of CCDBG (as codified at 42 U.S.C. 9857 et seq) grants the Secretary of HHS the authority to reserve up to 1/2 percent of the total Discretionary and Mandatory CCDF funding “to conduct research and demonstration activities, as well as periodic external, independent evaluations of the impact of the program described by this subchapter on increasing access to child care services and improving the safety and quality of child care services, using scientifically valid research methodologies, and to disseminate the key findings of those evaluations widely and on a timely basis.”

Mary C. Jones,
ACF/OPRE Certifying Officer.
[FR Doc. 2024-17723 Filed 8-8-24; 8:45 am]
BILLING CODE 4184-23-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-0342]

Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.” The purpose of this guidance is to assist sponsors in the development of drug and biological products for the treatment of patients

with bacillus Calmette-Guérin (BCG)-unresponsive nonmuscle invasive bladder cancer (NMIBC). This draft guidance reflects proposed revisions to the final guidance entitled “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment,” published in February 2018, and incorporates changes based on review experience as well as the evolving landscape of drug development in bladder cancer, as noted by external experts.

DATES: Submit either electronic or written comments on the draft guidance by October 8, 2024 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”).

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-0342 for “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.” 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 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sundeep Agrawal, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-348-3914; or James Myers, Center of Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm., 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.” The purpose of this guidance is to assist sponsors in the development of drugs and biologics for the treatment of patients with BCG-unresponsive NMIBC. This guidance addresses select statistical and clinical

trial design issues specific to BCG-unresponsive NMIBC. These topics are further addressed in the International Council for Harmonisation guidances for industry entitled “E9 Statistical Principles for Clinical Trials” (September 1998) and “E10 Choice of Control Group and Related Issues in Clinical Trials” (May 2001), respectively.

This draft guidance reflects proposed changes to FDA’s guidance entitled “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment,” published in February 2018, and incorporates FDA’s current recommendations based on the Agency’s experience as well as the evolving landscape of drug development in this space, as noted by external experts. This guidance, when finalized, will replace the final guidance titled BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment published in February 2018.

Key changes include the following: (1) clarification on use of BCG substrains, (2) considerations for trial design and conduct in the setting of a recent worldwide shortage of BCG, (3) clarification on use of single arm vs. randomized trial designs (with more emphasis on randomized control trials), and (4) clarifications on assessing and reporting responses and assessing endpoints for trials.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001; the collections of

information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; and the collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910-0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2018-N-0073; FDA-2023-N-5656; FDA-2024-N-0802; FDA-2023-N-3848; FDA-2023-N-5746]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information