health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, ''the Departments'') certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, ''Prescription Drug and Health Care Spending'' issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1405); *Frequency:* Annual; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 1,684,080. (For policy questions regarding this collection, contact Christina Whitefield at 301–492–4172.)

Dated: June 23, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–13769 Filed 6–27–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Disabilities, The President's Committee for People with Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The President's Committee for People with Intellectual Disabilities (PCPID) will host a virtual meeting for its members to identify emerging topics to examine in the Committee's Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a presentation and discussion format.

DATES: Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST).

AGENDA: The Committee will discuss survey responses, collectively discuss emerging issues facing people with intellectual disabilities, and the preparation of the PCPID Report to the President, including its proposed content and format, and related data collection and analysis required to complete the writing of the Report.

ADDITIONAL INFORMATION: For further information, please contact Mr. David Jones, Director, Office of Intellectual Developmental Disabilities, 330 C Street SW, Switzer Building, Room 1126, Washington, DC 20201. Telephone: 202–795–7367. Fax: 202–795–7334. Email: *David.Jones@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Stakeholder input is very important to the PCPID. Comments and suggestions especially from people with intellectual and developmental disabilities, are welcomed. If there are comments or feedback you would like to share with the PCPID as it begins to prioritize its work, please share them through the following *ACL.gov link: https://acl.gov/form/pcpid?j=1555178&sfmc_sub=191090082&l=6707_HTML&u=34777761&mid=515008575&jb=0.*

Comments received by June 30, 2022 will be shared with the PCPID at the July 28th meeting. Comments received after June 30, 2022 will be compiled and shared with the PCPID quarterly.

Webinar/Conference Call: The virtual meeting is scheduled for Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST) and may end early if discussions are finished. The meeting will be held through a zoom meeting platform. In order to participate, you must register in advanced of the meeting at the following link: *https://www.zoomgov.com/meeting/register/vJIsdeCpqzgsEiNHISQhI6VBwprCzIlu8BU.*

BACKGROUND INFORMATION ON THE COMMITTEE: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID Charter stipulates that the Committee shall: (1) provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President and the Secretary of Health and Human Services to promote full participation of people with intellectual disabilities in their communities, such as: (A) expanding educational opportunities; (B) promoting housing opportunities; (C) expanding opportunities for competitive integrated employment; (D) improving accessible transportation options; (E) protecting rights and preventing abuse; and (F) increasing access to assistive and universally designed technologies; and (3) provide advice to the President and the Secretary of Health and Human Services to help advance racial equity and support for people with intellectual disabilities within underserved communities.

Dated: June 22, 2022.

Jill Jacobs,

Commissioner, Administration on Disabilities.

[FR Doc. 2022–13699 Filed 6–27–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1496]

Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment; 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 ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance is intended to facilitate the development of drugs and biologics for the adjuvant treatment of renal cell carcinoma and provides recommendations for the sponsor on this topic. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival, and interpretation of trial results. This guidance finalizes the draft guidance of the same title issued on October 2, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2022.

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–2020–D–1496 for ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sundeep Agrawal, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2379, Silver Spring, MD 20993–0002, 240–402–4683; or Stephen Ripley, Center for 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 guidance for industry entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance provides recommendations to sponsors regarding the development of drugs regulated by CDER and CBER for the adjuvant treatment of renal cell carcinoma. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of renal cell carcinoma, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Adjuvant renal cell carcinoma clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA-National Cancer Institute public workshop held on November 28, 2017. This final guidance provides recommendations on these issues to facilitate adjuvant renal cell carcinoma clinical trials. This guidance finalizes the draft guidance entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment'' issued on October 2, 2020 (85 FR 62310). FDA considered comments received on the draft guidance as the guidance was finalized. The final guidance includes changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: June 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13752 Filed 6–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1497]

Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment; 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 ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance is intended to facilitate the development of drugs and biologics for the adjuvant treatment of muscle-invasive bladder cancer and provides recommendations for the sponsor on this topic. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival, and interpretation of trial results. This guidance finalizes the draft guidance of the same title issued on October 1, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2022.

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–2020–D–1497 for ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant 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 this 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 or to the 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.