Name of grant recipient that returned funds for reallotment	FY 2021 reallotment amount
Cow Creek Band of Umpqua Tribe of Indians	7,302
Hopland Band of Pomo Indians	1,755
Jicarilla Apache Nation	16,873
Kalispel Tribe of Indians	7,921
Makah Tribe	31,196
Muckleshoot Indian Tribe	37,669
Nooksack Indian Tribe	38,535
Paiute Indian Tribe of Utah	61,183
Quileute Tribe	1,673
Round Valley Indian Tribes	558
Sac and Fox Nation of Oklahoma	44,538
Samish Indian Nation	331
Shawnee Tribe	3,600
Spokane Tribe of Indians	19,905
The Delaware Tribe of Indians	15,579
Total	323,063

The list of grant recipients that were awarded these funds was published in a Dear Colleague Letter that is posted to ACF's website at *https://www.acf.hhs.gov/ocs/resource/dear-colleagues.*

Pursuant to the statute cited above, these funds were reallotted on September 28, 2022, to all but three types of FFY 2022 LIHEAP grant recipients by distributing them under the formula that Congress set for FFY 2022 funding. The three types of recipients that did not receive funds were (1) those whose allocations would have been less than $25; (2) tribes or tribal organizations that agreed with their co-territorial states to receive set amounts for the entire fiscal year; and (3) states or territories that were held to the additional minimum floor required by the FY 2022 appropriations act after including the reallotment amount. No sub-recipients of these recipients or other entities may apply for these funds.

The reallotted funds may be used for any purpose authorized under LIHEAP. Grant recipients must add these funds to their total LIHEAP funds payable for FFY 2022 for purposes of calculating statutory caps on administrative costs, carryover, Assurance 16 activities, and weatherization assistance. Grant recipients must also (1) ensure that these funds are included in the amounts that ACF pre-populated on Line 1.1 of their FFY 2022 Carryover and Reallotment Reports; (2) reconcile these funds, to the extent that they received them, on a separate Federal Financial Form (SF–425); and (3) record, on their FFY 2022 Household Reports, households that receive benefits at least partly from these funds. State recipients must also ensure that these funds are included in the Grantee Survey sections of their FFY 2022 LIHEAP Performance Data Forms.

OCS recommends that, after receiving them, grant recipients obligate these funds before obligating any other federal LIHEAP funds.

Statutory Authority: 42 U.S.C. 8626(b).

Karen D. Shields,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2022–26447 Filed 12–5–22; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0691]

Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 or Programmed Cell Death-Ligand 1 Blocking Antibodies for Treatment of Patients With Cancer; 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 ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer.'' This guidance provides recommendations for sponsors of investigational new drug applications (INDs) and biologics license applications (BLAs) on the use of pharmacokinetic (PK)-based criteria to support the approval of alternative dosing regimens for programmed cell death receptor-1 (PD-1) or programmed cell death-ligand 1 (PD-L1) blocking antibodies. This guidance is based on accumulated scientific and regulatory experience for PD-1 and PD-L1 drugs, and as such, does not address development of alternative dosing regimens for other drugs or biologics, changes in route of administration, or novel formulations of previously approved PD-1/PD-L1 products. This guidance finalizes the draft guidance of the same title issued on August 26, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 6, 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–2021–D–0691 for ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer.'' 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. 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: Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Silver Spring, MD 20993, 301–796–1508.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer.'' This guidance provides recommendations for sponsors of INDs and BLAs on the use of PK-based criteria to support the approval of alternative dosing regimens for PD-1 or PD-L1 blocking antibodies. The guidance is based on accumulated scientific and regulatory experience for PD-1 and PD-L1 drugs, as such, does not address development of alternative dosing regimens for any other drugs or biologics, changes in route of administration, or novel formulations of previously approved PD-1/PD-L1 products.

Sponsors may seek approval of alternative intravenous (IV) dosing regimens that are different from those tested in the original clinical efficacy and safety trials that served as the basis of approval of the current dosing regimen, or in the pre-approval setting, dosing regimens that differ from those tested in earlier PK and efficacy studies conducted during development. These alternative IV dosing regimens are typically designed to change doses and dosing intervals. Longer dosing intervals can minimize patient burden and reduce risks associated with more frequent administration (*e.g.,* infusion reactions), as well as exposure to communicable diseases (*e.g.,* SARS–CoV–2) associated with visits to hospitals or infusion centers. The guidance describes the criteria for using the PK-based approach and the documents that should be included in the submissions seeking approval.

This guidance finalizes the draft guidance of the same title issued on August 26, 2021 (86 FR 47649). FDA considered comments received on the draft guidance as it finalized the guidance. Changes from the draft to the final guidance include: (1) PK-based approach to support approval of alternative dosing regimens for PD-1/PD-L1 blocking antibody products may apply to pre- and post-approval setting and (2) this approach may apply to PD-1/PD-L1 monotherapies and combination regimens where the dose and/or dose schedule of the PD-1/PD-L1 is the only proposed change. In addition, editorial changes were made 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 ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use another 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; 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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26464 Filed 12–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1828]

E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials; International Council for Harmonisation; 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 ''E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials.'' The final guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The guidance revises the draft guidance for industry entitled ''E19 Optimisation of Safety Data Collection'' issued in June 2019. The final guidance provides recommendations regarding appropriate use of a selective approach to safety data collection in some late-stage pre- or post-marketing studies of drugs where the safety profile, with respect to commonly occurring adverse events, is well understood and documented. The final guidance is intended to advance important clinical research questions through the conduct of clinical investigations that collect relevant patient data, which will enable an adequate benefit-risk assessment of the drug for its intended use, while reducing the burden to patients from unnecessary tests that may yield limited additional information.

DATES: The announcement of the guidance is published in the **Federal Register** on December 6, 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–2019–D–1828 for ''E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval 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 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration,