Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five US territories. States will be required to complete the survey in order to demonstrate that they are complaint with Section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under 1905(a)(7) of the Act or under a demonstration project or waiver (*e.g.,* 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their 1903(l) compliance status on a continuous basis. As FMAP reductions are assigned quarterly per 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Home and Community Based Services (HCBS) Incident Management Survey; *Use:* The Survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) to assess incident management systems in 1915(c) waivers. States will be surveyed to identify methods and promising practices for identifying, reporting, tracking, and resolving incidents of abuse, neglect, and exploitation. The survey results will also be used to review the strengths and weaknesses of each state's incident management system and will inform guidance to help ensure compliance with sections 1902(a)(30(A) and 1915(c)(2)(A) of the Social Security Act. *Form Number:* CMS–10692 (OMB control number: 0938–1362); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 102; *Total Annual Hours:* 153. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

3.

Dated: April 8, 2022.

William N. Parham, III,

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

[FR Doc. 2022–07917 Filed 4–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Information: Technical Assistance Needs and Priorities on Implementation and Coordination of Early Childhood Development Programs in American Indian and Alaska Native Communities; Correction

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice; correction.

SUMMARY: The Administration for Children and Families published a document in the **Federal Register** of March 22, 2022 concerning a request for information on technical assistance needs and priorities on implementation and coordination of early childhood development programs in American Indian and Alaska Native communities. The document contained incorrect dates.

FOR FURTHER INFORMATION CONTACT: Moushumi Beltangady at *Moushumi.beltangady@acf.hhs.gov* or 202–260–3613.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 22, 2022, in FR Doc. 2022–05962 (Vol. 87, No. 55) on page 16195, in the first column, final line, correct the **DATES** caption to read:

DATES: Send comments on or before May 20, 2022.

Kathleen D. Hamm,

Deputy Assistant Secretary for Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

[FR Doc. 2022–07840 Filed 4–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0529]

Secura Bio, Inc.; Withdrawal of Approval of Relapsed or Refractory Follicular Lymphoma Indication for COPIKTRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is withdrawing approval of the relapsed or refractory follicular lymphoma indication for COPIKTRA (duvelisib) Capsules, approved under new drug application 211155, held by Secura Bio, Inc., 1995 Village Center Circle, Suite 128, Las Vegas, NV 89134. Secura Bio, Inc. voluntarily requested that the Agency withdraw approval of this indication and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of April 13, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA approved COPIKTRA (duvelisib) Capsules for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies (the follicular lymphoma indication) on September 24, 2018, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of COPIKTRA (duvelisib) Capsules for follicular lymphoma, the applicant was required to conduct a postmarketing trial to verify the clinical benefit of duvelisib for follicular lymphoma.

On November 22, 2021, FDA met with Secura Bio, Inc., to discuss the company's inability to conduct a

clinical trial to verify clinical benefit of duvelisib in follicular lymphoma. Because the confirmatory trial was not underway and would not be conducted, the Agency recommended withdrawal of approval of the follicular lymphoma indication pursuant to § 314.150(d) (21 CFR 314.150(d)). On November 24, 2021, Secura Bio, Inc. submitted a letter requesting withdrawal of approval of the follicular lymphoma indication for COPIKTRA (duvelisib) Capsules and waiving its opportunity for hearing.

Therefore, under § 314.150(d), approval of the follicular lymphoma indication for COPIKTRA (duvelisib) Capsules is withdrawn effective April 13, 2022. Withdrawal of approval of the follicular lymphoma indication does not affect any other approved indication for COPIKTRA.

Dated: April 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07931 Filed 4–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0603 and FDA–2021–D–0604]

Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff; 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 two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' and ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidances identified in this notice were developed in accordance with the final guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidance is published in the **Federal Register** on April 13, 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–0603 for ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' or Docket No. FDA–2021–D–0604 for ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' or ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Center for Devices