Assistance, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the form OFA–0086: NEW Plan Guidance and NEW Program Report (OMB #0970–0174, expiration 8/31/2022). There are minor changes requested to both documents.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NEW Program Plan Guidance documents specify the information needed to complete a NEW program plan and explain the process for plan submission every third year and to complete the annual program report. The program plan is the application for NEW program funding and documents how the grantee will carry out its NEW program. ACF proposes a change in how draft plans are submitted. The program report provides HHS, Congress, and grantees information to document and assess the activities and accomplishments of the NEW program. ACF proposes to extend data collection with revisions that clarify that programs should not count more than once individuals who meet multiple categories; for example, persons age 20 are both youth and adults, but they should be counted as one or the other, not both.

Respondents: Indian tribes and tribal coalitions that operate NEW programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents (over 3 yrs.)	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
NEW Program Plan Guidance	40	[1] .333	29	386
NEW Program Report	40	1	15	600
Total Estimated Annual Burden				986

[1] We have used .333 responses per year to represent one submission of the NEW Program Plan Guidance during the 3-year approval period.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 612.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–06271 Filed 3–23–22; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0352]

Secura Bio, Inc.; Withdrawal of Approval of New Drug Application for FARYDAK (Panobinostat) Capsules, 10 Milligrams, 15 Milligrams, and 20 Milligrams

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for FARYDAK (panobinostat) Capsules, 10 milligrams (mg), 15 mg, and 20 mg, held by Secura Bio, Inc., 1995 Village Center Circle, Suite 128, Las Vegas, NV 89134. Secura Bio, Inc. has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of March 24, 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: On February 23, 2015, FDA approved NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, for multiple myeloma included a required postmarketing trial intended to verify the clinical benefit of FARYDAK.

On September 24, 2021, FDA published the **Federal Register** notice ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments,'' announcing that FARYDAK (panobinostat) Capsules would be discussed at an Oncologic Drug Advisory Committee Meeting (ODAC) scheduled for December 2, 2021 (86 FR 53067). On November 19, 2021, FDA met with Secura Bio, Inc. to discuss the planned ODAC meeting. The topics discussed included the lack of initiation of the postmarketing trial intended to verify clinical benefit.

On November 22, 2021, Secura Bio, Inc. submitted a letter asking FDA to withdraw approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing. In the letter, Secura Bio, Inc. stated they are requesting withdrawal of approval of the NDA for FARYDAK because it was not feasible for them to complete the required postmarketing clinical trials. On November 26, 2021, FDA acknowledged Secura Bio, Inc.'s request for withdrawal of approval of the NDA and waiver of its opportunity for hearing. FDA also cancelled the ODAC meeting scheduled for December 2, 2021, since the applicant's withdrawal request made discussion at an advisory committee meeting moot.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: March 18, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–06182 Filed 3–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0371]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 25, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (PHS Act) (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health.

Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience, and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features, including content and format; and the second topic area, target populations.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

I. Background

Pursuant to section 506(c) of the FD&C Act (21 U.S.C. 356(c)) and 21 CFR part 314, subpart H (or 21 CFR part 601, subpart E for biological products), FDA may grant accelerated approval to a drug product under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) or a biological product under section 351(a) of the PHS Act (42 U.S.C. 262(a)). This pathway enables faster approval of prescription drugs intended to treat serious or life-threatening illnesses. Accelerated approval may be based on a determination that a drug product has an effect on a surrogate endpoint (for example, a blood test result) that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit (*i.e.,* an intermediate clinical endpoint). In approving a drug under the accelerated