DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–2524]

Determination That BILTRICIDE (Praziquantel) Oral Tablet, 600 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that BILTRICIDE (praziquantel) oral tablet, 600 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

BILTRICIDE (praziquantel) oral tablet, 600 mg, is the subject of NDA 018714, held by Bayer Heathcare Pharmaceuticals, Inc., and initially approved on December 29, 1982. BILTRICIDE is indicated in patients aged 1 year and older for the treatment of the following infections:

- Schistosomiasis due to all species of schistosoma (for example, *Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni,* and *Schistosoma hematobium*), and
- Clonorchiasis and Opisthorchiasis due to the liver flukes, Clonorchis sinensis/Opisthorchis viverrini (approval of this indication was based on studies in which the two species were not differentiated).

In a letter dated February 8, 2024, Bayer Healthcare Pharmaceuticals, Inc. notified FDA that BILTRICIDE (praziquantel) oral tablet, 600 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Novitium Pharma LLC submitted a citizen petition dated July 18, 2025 (Docket No. FDA–2025–P–2524), under 21 CFR 10.30, requesting that the Agency determine whether BILTRICIDE (praziquantel) oral tablet, 600 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BILTRICIDE (praziquantel) oral tablet, 600 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BILTRICIDE (praziquantel) oral tablet, 600 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BILTRICIDE (praziquantel) oral tablet, 600 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BILTRICIDE (praziquantel) oral tablet, 600 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07059 Filed 4–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; HRSA AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 13, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Extension.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) is authorized under Part B of the RWHAP statute, codified in sections 2611 to 2631 of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP Part B ADAP is a state- and territory-administered program that provides Food and Drug Administration-approved medications to low-income people with HIV. RWHAP Part B ADAP funds may also be used to purchase health care coverage for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards, including funds for ADAP. HRSA RWHAP Part B ADAP requires the annual submission of an ADAP Data Report, which is composed of a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of de-identified client-level records (one record for each client enrolled in RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment and confirmation information, details on medication and/or health care coverage assistance received (including associated costs), and HIV clinical information.

HRSA is not proposing any changes to the collection, and there are no anticipated changes in the reporting burden.

A 60-day notice published in the **Federal Register** on January 30, 2026, vol. 91, No. 20; pp. 4085–86. There were no public comments.

Need and Proposed Use of the Information: The RWHAP statute specifies HRSA's responsibilities in administering grant funds, allocating funding, assessing HIV care outcomes (*e.g.,* viral suppression), and serving priority populations. HRSA uses the ADAP Data Report to evaluate the national impact of RWHAP ADAP by providing de-identified client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to assess the health outcomes of people with HIV receiving services through RWHAP ADAP, monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on communities, and track progress toward achieving the goals identified in Ending the HIV Epidemic in the United States.

Likely Respondents: State ADAPs of RWHAP Part B recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Recipient Report	54	1	54	6	324
Client Report	54	1	54	81	4,374
Total	54	.....	54	.....	4,698

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–07083 Filed 4–10–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Emergency Medical Services for Children Data Center (EDC)

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing period of performance extension with funding for EDC Award recipient.

SUMMARY: HRSA will provide additional funds to the University of Utah, Salt Lake City, Utah, the current EDC Program recipient, to extend the recipient's current period of performance by 12 months. This extension is necessary to support continuity of operations that facilitate pediatric readiness national data collection activities in hospital emergency departments (ED) and prehospital emergency medical services (EMS) agencies throughout the country. The current performance period ends June 30, 2026.