greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's ability to assess and collect GDUFA fees and this user fee program has been reauthorized two times since GDUFA I, most recently in the Generic Drug User Fee Amendments of 2022 (GDUFA III). As described in the GDUFA III commitment letter applicable to this latest reauthorization, FDA agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

To receive approval for an ANDA submitted under section 505(j) of the FD&C Act (21 U.S.C. 355(j)), an applicant generally must demonstrate, among other things, that its proposed drug product is bioequivalent to the reference listed drug (RLD). As noted in 21 CFR 320.24, in vivo methods, in vitro methods, or both can be used to establish bioequivalence (BE). FDA recommends that applicants consult published PSGs when considering an appropriate BE study and/or other studies for a proposed drug product. PSGs provide recommendations for developing generic drug products and describe FDA's current thinking on the evidence needed to demonstrate that an ANDA is therapeutically equivalent to the specific RLD product.

As described in the GDUFA III commitment letter, FDA agreed to certain performance goals, including time frames and procedures for scheduling and conducting: (1) PSG teleconferences to provide feedback on the potential impact of a new or revised PSG on the applicant's development program; and (2) pre-submission PSG meetings and post-submission PSG meetings to provide a forum in which the applicant can discuss the scientific rationale for an approach other than the approach recommended in a new or revised PSG to ensure that the approach complies with the relevant statutes and regulations.

This guidance finalizes the draft guidance of the same title issued on February 21, 2023 (88 FR 10523). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates to clarify when applicants can submit PSG teleconference and PSG meeting requests, the topics that applicants can discuss during PSG teleconferences and PSG meetings, and when applicants should utilize other pathways to seek FDA's feedback. In addition, FDA made editorial 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 ''Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information pertaining to the submissions of controlled correspondence, GDUFA III meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

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: August 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2220]

Determination That PENNSAID (Diclofenac Sodium) Topical Solution 2%, 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, Agency, or we) has determined that PENNSAID (diclofenac sodium) Topical Solution 2%, 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: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@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.

PENNSAID (diclofenac sodium) Topical Solution 2%, is the subject of NDA 204623, held by Horizon Therapeutics Ireland DAC, and initially approved on January 16, 2014. PENNSAID is a nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knees. PENNSAID (diclofenac sodium) Topical Solution 2%, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Encube Ethicals Private Limited submitted a citizen petition dated May 6, 2024 (Docket No. FDA–2024–P–2220), under 21 CFR 10.30, requesting that the Agency determine whether PENNSAID (diclofenac sodium) Topical Solution 2%, 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 PENNSAID (diclofenac sodium) Topical Solution 2%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PENNSAID (diclofenac sodium) Topical Solution 2%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PENNSAID (diclofenac sodium) Topical Solution 2%, 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 PENNSAID (diclofenac sodium) Topical Solution 2%, 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. Additional ANDAs for this drug product may also 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.

Dated: August 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18615 Filed 8–19–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updates to the Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure

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

ACTION: Request for public comment on updates to uniform standard for waiver of the Ryan White HIV/AIDS Program core medical services expenditure requirement.

SUMMARY: The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Service Act requires that RWHAP Parts A, B, and C recipients expend 75 percent of Parts A, B, and C grant funds on core medical services for individuals who are identified with HIV/AIDS and eligible for RWHAP services under the statute, after reserving statutorily permissible amounts for administrative and clinical quality management costs. The statute also grants the Secretary authority to waive this requirement if certain factors are met. HRSA is proposing to update Policy Notice 21–01, ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement,'' pertaining to the associated data collection form to clarify applicants' proposed allocation of resources between core medical and support services.

DATES: Submit comments no later than September 19, 2024.

ADDRESSES: Written/and or electronic comments should be submitted to Division of Policy and Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, or *RyanWhiteComments@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: Kristina Barney, Senior Public Health Policy Analyst, Division of Policy and Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, email *RyanWhiteComments@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The RWHAP statute grants the Secretary authority to waive this requirement for RWHAP Parts A, B, or C recipients if certain factors are met and a waiver request is submitted to HRSA for approval. RWHAP Parts A, B, and C core medical services waiver requests, if approved, are effective for a 1-year budget period and apply to funds awarded under the Minority AIDS Initiative.

For a core medical services waiver request to be approved, core medical services must be available and accessible, regardless of the payment source, within 30 days to all RWHAP-eligible individuals identified in the recipient's service area. The recipient may use existing, non-RWHAP resources in the service area to ensure availability and access to core medical services. Additionally, there must be no AIDS Drug Assistance Program waiting lists in the recipient's service area. Finally, a public process must be used to obtain input from impacted communities on the availability of core medical services and the decision to request the waiver. Impacted communities include clients and RWHAP-funded core medical services providers. The same method used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes may be used to meet this requirement.

Policy Notice 21–01, ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement,'' outlines the requirements and includes the one-page ''HRSA RWHAP Core Medical Services Waiver Request Attestation Form'' that must be submitted to request a waiver.

HRSA proposes to modify Policy Notice 21–01 to reflect a new policy requiring that the proposed percentages of HIV service dollars allocated to core medical and support services be included on the waiver request form. This information will inform HRSA as to whether recipients are able to meet the statutory requirements found in sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act and will