the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, is the subject of NDA 006035, held by Edison Therapeutics LLC, and initially approved on November 19, 1946. METHERGINE is indicated for routine management of uterine atony, hemorrhage, and subinvolution of the uterus following delivery of the placenta. It is also indicated for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Gland Pharma Limited submitted a citizen petition dated November 21, 2025 (Docket No. FDA–2025–P–6392), under 21 CFR 10.30, requesting that the Agency determine whether METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.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this time, FDA has determined under § 314.161 that METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, 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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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 METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, 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. ANDAs that refer to METHERGINE (methylergonovine maleate) injection, 0.2 mg/mL, 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. 2026–05309 Filed 3–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1864]

Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in Abbreviated New Drug Applications; 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 ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs.'' This guidance is intended to assist applicants who submit abbreviated new drug applications (ANDAs) for liquid-based and/or other semisolid products applied to the skin, including integumentary and mucosal (*e.g.,* vaginal) membranes (referred to as ''topical products''). This guidance provides recommendations for physicochemical and structural (collectively, ''Q3'') characterizations that can be used to identify the dosage form of a proposed generic (test) topical product, and to describe properties of the drug product that may be critical to its performance (to support a demonstration of bioequivalence (BE)). This guidance finalizes the draft guidance of the same title issued on October 21, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on March 18, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidance 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–2022–D–1864 for ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs.'' 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: Rachel Erdman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1715, Silver Spring, MD 20993–0002, 301–348–3984, *Rachel.Erdman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs.'' This guidance is intended to assist applicants who submit ANDAs for liquid-based and/or other semisolid products applied to the skin, including integumentary and mucosal (*e.g.,* vaginal) membranes. This guidance document provides recommendations for physicochemical and structural (collectively, ''Q3'') characterizations that can be used: (1) to identify the dosage form of a proposed generic (test) topical product and (2) to describe properties of the drug product that may be critical to its performance (to support a demonstration of BE). This guidance does not address Q3 characterization of topical products for purposes of product quality control.

Basic Q3 characterization of a topical product can be used to describe its dosage form (*e.g.,* an emulsion). The nomenclature used to describe the dosage form of topical products (*e.g.,* solutions, suspensions, gels, lotions, creams, shampoos, ointments, pastes, etc.) is not precisely defined by a systematic classification of the compositional, physicochemical, or structural attributes of the drug product. Consequently, for topical products, it may not be possible to infer the Q3 attributes of a particular dosage form based upon the dosage form nomenclature.

Comprehensive Q3 characterization of a topical product can be used to establish a detailed profile of Q3 attributes that specifically describes the nature of that product and identifies a collection of attributes that describe the arrangement of matter (*e.g.,* the polymorphic form(s) of the active ingredient(s) and/or the pH of the drug product) that may modulate the systemic or local availability of the active ingredient(s) from the product. Because Q3 characterization describes essential attributes of a drug product that may be critical to its performance, differences in Q3 attributes between a test product and the reference standard selected by FDA can indicate a risk that the differences may impact the respective bioavailability and/or BE of the two products. Conversely, a demonstration that there are no differences in Q3 attributes between a test and reference standard substantially mitigates the risk of potential failure modes for BE that may otherwise arise from any differences in Q3 attributes.

This guidance provides recommendations on the types of characterizations that constitute a basic and comprehensive Q3 characterization. This guidance also describes the concepts of ''sameness,'' ''similarity,'' and ''difference'' in comparing Q3 characterizations of two topical products, and how a showing of ''Q3 sameness,'' ''Q3 similarity,'' or ''Q3 difference'' between a test topical product and the reference standard may impact what additional evidence may be recommended to demonstrate BE, as part of a comparative product characterization-based approach.

This guidance finalizes the draft guidance entitled ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs'' issued on October 24, 2022 (87 FR 64230). FDA received no comments on the draft guidance. Editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs.'' 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 in 21 CFR part 314 relating to abbreviated new drug applications (ANDAs) have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 314 for controlled correspondence related to generic drug development is approved under OMB control number 0910–0727. The collections of information in 21 CFR part 58 that support Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR parts 312 and 320 pertaining to Investigational New Drug Safety Reporting Requirements involving Bioavailability and Bioequivalence Studies in Humans have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 211.170 for recordkeeping requirements relating to

Current Good Manufacturing Practice (CGMP) sample retention have been approved under OMB control number 0910–0139.

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*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–05275 Filed 3–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than May 18, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Revision.

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)). The Delta Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of Delta Program-supported projects are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability. HRSA collects information from Delta Program award recipients using an OMB-approved set of performance measures and wants to revise that information collection.

Need and Proposed Use of the Information: The purpose of the data collection is for HRSA to assess Delta Program awardees' progress in meeting the program goals (as stated in the authorizing statute) and how well each awardee meets their community needs. Additionally, HRSA will be able to monitor and assess the impact of the Delta Program and ensure funds are effectively used to provide services that meet the target population's needs.

HRSA seeks to revise the approved information collection, which Delta Program awardees will submit to HRSA on an annual basis. The proposed revisions include modifying how HRSA displays race and ethnicity measures in the data collection platform by making it display as two separate questions for current Delta Program recipients. As the Delta Program recipients are currently in an active project period, this proposed revision would minimize any disruptions to their existing data collection processes and help maintain consistent data reporting to HRSA, while also starting to ease the transition toward SPD–15 compliance.

Additionally, the estimated total burden hours have increased to reflect the time required for current Delta Program awardees to complete data collection-related training for their internal staff as well as staff within their network partnerships. There are several additional contributing factors to the increase in estimated total burden. These grantee organizations vary in data collection and reporting capacity as well as vary in the number of network organizations they must coordinate with to report this data to HRSA. Furthermore, the grantee organization and its network organizations may not share the same data collection systems/platforms. As a result, this increase in total burden accounts for the time that Delta Program awardees will need to compile and review data quality from its network organizations prior to submitting the data to HRSA.

Likely Respondents: Respondents will be the Delta Program award 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 utilize 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
Delta States Rural Development Network Program Performance Measures	12	1	12	72.75	873
Total	12	1	12	72.75	873