Signatures—Scope and Application'' (August 2003); (3) provide recommendations on using information technology service providers to provide services during a clinical investigation; (4) provide recommendations regarding the collection of data through digital health technologies; (5) facilitate the use of electronic signatures; and (6) facilitate the use of electronic systems, electronic records, and electronic signatures to improve the quality and efficiency of clinical investigations.

This guidance finalizes the draft guidance of the same title issued on March 16, 2023 (88 FR 16268). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) clarifying the applicability of part 11 (21 CFR part 11) to real-world data sources submitted to FDA; (2) clarifying the applicability of part 11 to clinical investigations conducted outside of the United States; (3) describing electronic systems deployed by regulated entities in clinical investigations and using a risk-based approach for validation; (4) clarifying the focus of FDA inspections of regulated entities; (5) providing recommendations for agreements between information technology service providers and regulated entities; (6) providing recommendations regarding data collection from digital health technologies used in clinical investigations; and (7) clarifying recommendations for the use of electronic signatures in clinical investigations, including information on submission of letters of non-repudiation to certify that an electronic signature is the legally binding equivalent of a traditional handwritten signature. In addition, editorial changes were made 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 ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' 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 part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR parts 314 and 601 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22562 Filed 10–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4310]

Center for Drug Evaluation and Research Quantitative Medicine Center of Excellence; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this notice to announce the establishment of the Center for Drug Evaluation and Research (CDER) Quantitative Medicine Center of Excellence (QM CoE). Quantitative medicine (QM) is used to inform premarket product review, post-market product assessment, policy development, and policy implementation within several CDER offices. The QM CoE will act as a coordinating body that drives innovation and facilitates integration of QM methodologies and principles across CDER. To realize this purpose, the QM CoE will introduce new activities and coordinate existing activities in key areas, including multidisciplinary education and exchange, development and implementation of applied science policy, knowledge management, and community engagement.

DATES: The formation of the QM CoE was announced on March 25, 2024. For more details, please visit *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-quantitative-medicine-center-excellence-qm-coe.*

FOR FURTHER INFORMATION CONTACT: Daphne Guinn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–837–7122, *Daphne.Guinn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

QM involves the development and application of exposure-based, biological, and quantitative modeling and simulation approaches derived from nonclinical, clinical, and real-world sources to inform: (1) drug development, (2) regulatory decision-making, and (3) patient care. The technical scope includes pharmaco-statistical modeling, mechanistic modeling, biomarker-endpoint development, artificial intelligence and machine learning, and clinical trial simulations and in silico predictions. Within CDER, QM approaches have been used to inform premarket product review, post-market product assessment, policy development, and policy implementation.

While CDER has been at the forefront of advancing QM over the decades, the efforts in outreach and education, scientific and regulatory initiatives, and operations have largely been decentralized. Recognizing the opportunity for synergy, CDER has begun a coordinated QM effort that maximally leverages its subject matter

experts, functional areas, and collective regulatory experience across different offices.

II. Objectives of QM CoE

The QM CoE will facilitate and coordinate the continuous evolution and consistent application of QM for drug development and regulatory decision-making to advance therapeutic medical product development, inform regulatory decision-making, and promote public health, by:

- spearheading QM-related policy development and best practices to facilitate the consistent use of QM approaches during the drug development and regulatory assessment;
- providing strategic direction for CDER's QM activities; and
- coordinating CDER's efforts around QM education, training, and community engagement.

III. Anticipated Outcomes of QM CoE

The QM CoE will harmonize existing activities and identify and initiate new activities in the areas of multidisciplinary education and exchange, science policy development and implementation, knowledge management, and community engagement. The centralization of QM efforts across CDER within the CoE will allow for operational optimization and consistent application of QM approaches to advance therapeutic medical product development, inform regulatory decision-making, and promote public health.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22580 Filed 10–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2314]

Determination That AUGMENTIN XR (Amoxicillin; Clavulanate Potassium) Extended-Release Tablets, 1 Gram; Equivalent to 62.5 Milligram Base, 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 AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gram (gm); equivalent to (EQ) 62.5 milligram (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, if all other legal and regulatory requirements are met.

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.

AUGMENTIN (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, is the subject of NDA 050785, held by US Antibiotics, LLC, and initially approved on September 25, 2002. AUGMENTIN XR is indicated for treatment of adults and pediatric patients with community-acquired pneumonia or acute bacterial sinusitis due to confirmed, or suspected beta-lactamase-producing pathogens (*i.e.,* H. influenzae, M. catarrhalis, H. parainfluenzae, K. pneumoniae, or methicillin-susceptible S. aureus) and S. pneumoniae with reduced susceptibility to penicillin (*i.e.,* penicillin minimum inhibitory concentrations EQ 2 microgram/milliliter).

AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma, USA, Inc. submitted a citizen petition dated May 9, 2024 (Docket No. FDA–2024–P–2314), under 21 CFR 10.30, requesting that the Agency determine whether AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, 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 AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, 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 AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, 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