nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, is no longer authorized for emergency use by FDA.

As discussed, FDA does not have concerns with the use of any remaining viable inventory of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, that is the EUA labeled product and that was distributed prior to revocation of the EUA, when such product is used in conjunction with the cleared package insert/manufacturer instructions for use cleared as part of the July 27, 2023 510(k) cleared cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System . Importantly, the cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System product for which FDA had issued an EUA and the product for which FDA has cleared under 510(k) are manufactured under the same quality system with the same lot release criteria. Roche Molecular Systems, Inc. should instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System EUA labeled product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance issued on July 27, 2023. Roche Molecular Systems, Inc. should also instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023 and that the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA labeled product inventory may also be used in combination with the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System product, which FDA has cleared under 510(k). FDA encourages Roche Molecular Systems, Inc. to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of this EUA revocation and provide access to the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19724 Filed 8–30–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3904]

Identifying Priority Focus Areas for Future Guidance Development and Engagement With Interested Parties in Model-Informed Drug Development; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for Information.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) within the Food and Drug Administration (FDA or Agency) are announcing a request for information (RFI) for advancing model-informed drug development (MIDD). The purpose of this request is to obtain feedback on how to increase application of established MIDD approaches in regulatory decision making, to identify how emerging MIDD approaches are being incorporated within drug product development, and to identify opportunities to enhance interactions with FDA when discussing MIDD approaches. We intend to use the information submitted in response to this request to identify and prioritize potential focus areas for future policy or guidance development and enhance engagement with interested parties, including interactions as part of the

MIDD Paired Meeting Program and other formal meetings with drug developers.

DATES: Either electronic or written comments on the notice must be submitted by November 4, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–3904 for ''Identifying Priority Focus Areas for Future Guidance Development and Engagement with Interested Parties in Model-Informed Drug Development; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Yvonne Knight, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2142, Silver Spring, MD 20993, 301–796–2133, *Yvonne.Knight@fda.hhs.gov,* with the subject line ''MIDD Meetings Program for CDER''; or Christopher Egelebo, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 5340, Silver Spring, MD 20993, 240–402–8625, *Christopher.Egelebo@fda.hhs.gov*, with the subject line ''MIDD Meetings Program for CBER.''

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a request for information entitled ''Identifying Priority Focus Areas for Future Guidance Development and Engagement with Interested Parties in Model-Informed Drug Development.'' Information submitted in response to this notice will be used by CDER, including by its Quantitative Medicine Center of Excellence, and CBER to assist in identifying and prioritizing potential focus areas for future policy or guidance development and engagement with interested parties.

MIDD approaches integrate exposure-based biological and statistical models derived from nonclinical and clinical data sources in drug development and decision making. MIDD applications span the life cycle of new drug product development. MIDD approaches use a variety of quantitative methods (*e.g.,* population pharmacokinetic (popPK) modeling, exposure-response (E–R) modeling, physiologically based pharmacokinetic (PBPK) modeling, systems pharmacology/mechanistic modeling, disease progression modeling, drug-trial-disease modeling and simulation, artificial intelligence/machine learning (AI/ML) approaches) to help assess the risks and benefits of drug products, contribute to the evidentiary framework for efficacy and/or safety, and optimize dosing regimens for patients, among other applications. When successfully applied, MIDD approaches might reduce animal testing, improve clinical trial design and efficiency, inform identification of dosing regimens with improved benefit-risk profiles, increase the probability of regulatory success through synergetic engagement with interested parties, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials.

Beginning with Prescription Drug User Fee Act (PDUFA) VI, FDA began granting focused meetings as part of the MIDD Paired Meeting Pilot to: (1) provide a forum for regulatory interaction between drug developers and FDA on the application of MIDD approaches in specific drug development programs; and (2) provide

an opportunity for FDA to provide advice regarding how particular MIDD approaches can be used in a specific drug development program. Other deliverables as part of PDUFA VI included increasing regulatory science and review capacity in MIDD approaches and convening multiple workshops to identify best practices for MIDD (topics including E–R, PBPK, disease progression modeling, and immunogenicity assessments). In addition, FDA published or revised multiple guidances on MIDD. As part of PDUFA VII, the MIDD Paired Meeting Program has been continued and this RFI is to elicit public input on future focus areas for advancing MIDD. More information on the MIDD Paired Meeting program can be found at *https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program.*

II. Request for Information

FDA is interested in detailed comments on the topics listed in this section below to identify and inform future priorities for MIDD-related policy, including guidance development and engagement with interested parties. The topics identified in this section are not meant to be exhaustive. FDA is also interested in any other pertinent information that interested parties would like to share related to guidance and enhancing MIDD-related interactions with FDA. FDA encourages interested parties to provide the specific rationale and basis for their comments, including any available supporting data and information.

A. Methods and Best Practices

Several quantitative approaches, such as popPK, E–R, and PBPK, are routinely employed in drug development and regulatory assessment. The Agency aims to identify areas within these approaches that would benefit from the development of additional policies or guidance on methodology and best practices. In addition, with this RFI, the Agency is seeking input to explore potential guidance needs and appropriately identify and prioritize potential topics for guidance development in all emerging MIDD approaches for drug and biological products, including but not limited to, AI/ML used in both drug design and evaluation and digital-twin technology.

B. Context-Specific Considerations

MIDD approaches that leverage comprehensive information—including disease and patient population characteristics (*e.g.,* intrinsic and extrinsic factors), drug properties, placebo effects, nonclinical and clinical E–R relationships—are potent tools and can be utilized across all stages of the drug development life cycle to support decision making. This is particularly important for rare diseases and emerging therapeutic and prophylactic/preventative modalities where there may be practical and ethical challenges in conducting traditional drug development programs or where there is limited drug development experience. We seek input on the need to develop guidances that discuss considerations to facilitate MIDD methods development, application, uptake, and acceptance in specific therapeutic areas. Related topics include identification of opportunities for incorporation of real-world data, specific therapeutic modality considerations, and preclinical to clinical translations and to appropriately identify and prioritize potential topics in this area.

C. Regulatory Engagement

Building on the success of the MIDD Paired Meeting Program, FDA is interested in better understanding ways to facilitate discussion around MIDD approaches outside the MIDD Paired Meeting Program as part of regulatory meetings and regulatory submissions. This includes identifying what is currently working well and what are the barriers (*e.g.,* technical, regulatory) encountered while trying to interact with FDA on MIDD-related activities.

D. Communication of Policies and Interested Parties' Engagement

FDA continues to engage on MIDD approaches as part of external workshops with interested parties, including workshops described and completed under PDUFA VI. FDA seeks to identify and prioritize potential topics and better ways for communication and engagement with interested parties.

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19712 Filed 8–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Organ Transplantation

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Organ Transplantation (ACOT or Committee) is renewed. The effective date of the renewed charter is August 31, 2024.

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Division of Transplantation, HRSA, 5600 Fishers Lane, 08W67, Rockville, Maryland 20857; 301–443–8036; or *sgrant@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACOT provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under 42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended. ACOT provides advice and recommendations on proposed or implemented Organ Procurement and Transplantation Network policies (including those related to organ donation, procurement, allocation, transplantation, patient safety, and data collection, among other policy topics), and on such other matters that the Secretary of Health and Human Services determines. ACOT ensures checks and balances, transparency, and a focus on patient-centered practices. The topics covered by ACOT may be broad and cross-sectional.

The renewed charter for ACOT was approved on August 9, 2024. The filing date is August 31, 2024. Renewal of the ACOT charter gives authorization for the Committee to operate until August 31, 2026.

A copy of the ACOT charter is available on the ACOT website at *https://www.hrsa.gov/advisory-committees/organ-transplantation.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The