Page 9 – Stacey Moltchanoff, Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.)

II. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

Dated: January 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00394 Filed 1–10–23; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1203]

Prescription Drug User Fee Act of 2023 VII Meetings Program for Model-Informed Drug Development Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The seventh iteration of the Prescription Drug User Fee Act (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022, highlights the goal of advancing model-informed drug development (MIDD). The Food and Drug Administration (FDA or Agency) is announcing the continuation of the MIDD Paired Meeting Program that affords sponsors who are selected for participation the opportunity to meet with Agency staff to discuss MIDD approaches in medical product development. Meetings under the program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) during fiscal years 2023–2027. This program is being conducted to fulfill FDA's performance commitment under PDUFA VII. For this program, MIDD is defined as the application of exposure-based, biological, and/or statistical models derived from non-clinical and clinical data sources to address drug development and/or regulatory issues (see **SUPPLEMENTARY INFORMATION**, I. Background, and II. Eligibility and Selection for Participation of this notice). For each approved proposal, the program consists of two meetings between sponsors or applicants and the relevant center that provide an opportunity for drug developers and FDA to discuss the application of MIDD approaches to the development and regulatory evaluation of medical products in development.

DATES: FDA will accept requests to participate in the program on a continuous basis beginning on October

1, 2022, through June 1, 2027. See section III of this notice for instructions about how to request participation in the program. Meeting-granted and -denied decisions will be made the last 2 weeks of each quarter of the fiscal year based on submissions received to date. Requesters will receive a meeting-granted or -denied notification no later than the second week of the new quarter.

The program will proceed from October 1, 2022, through September 30, 2027. The Agency will notify sponsors of proposals not selected for a given quarter. Sponsors who do not participate in the program may seek Agency interaction through existing channels (*e.g.,* Type C meeting requests, critical path innovation meetings). The listed eligibility criteria and procedures outlined in this **Federal Register** notice reflect the current thinking at the time of publication. Processes may be revised and will be communicated as this program evolves. The most current program eligibility criteria and procedures may be found on the MIDD Program website: *https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program.*

ADDRESSES: Comments about this program can be submitted until February 10, 2023. You may submit comments about the MIDD meetings program 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–2018–N–1203 for ''Prescription Drug User Fee Act of 2023 VII Meetings Program for Model-Informed Drug Development Approaches.'' 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.

FOR FURTHER INFORMATION CONTACT:

CDER: 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.''

CBER: 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

Under the FDA User Fee Reauthorization Act of 2022, FDA agreed, in accordance with the ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027: I. Ensuring the Effectiveness of the Human Drug Review, Part L. Enhancing Regulatory Decision Tools to Support Drug Development and Review'' to provide information on how a sponsor can apply to participate in the MIDD Meetings Program (*https://www.fda.gov/media/151712/download*).

FDA will build on the success of the MIDD Paired Meeting Pilot under PDUFA VI by continuing to advance and integrate the development and application of exposure-based, biological, and statistical models derived from non-clinical and clinical data sources in drug development and regulatory review. FDA is announcing the continuation of this meeting program to satisfy the above-mentioned commitment and to facilitate the continued use of MIDD approaches. These approaches exclude statistical designs involving complex adaptations, Bayesian methods, or other features requiring computer simulations to determine the operating characteristics of a confirmatory clinical trial. MIDD approaches use a variety of quantitative methods to help balance the risks and benefits of drug products in development. When successfully applied, MIDD approaches can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials.

The goal of the early meeting discussions granted under this program is to provide advice on how specific, proposed MIDD approaches can be used in a particular drug development program. FDA has committed to accepting one to two appropriate meeting requests quarterly each fiscal year. The meetings granted will include an initial and followup meeting on the same drug development issues. The second meeting will occur within approximately 60 days of receiving the briefing package.

II. Eligibility and Selection for Participation in the MIDD Program

The sponsor should be a drug/biologics development company (interested consortia or software/device developer should come in partnership with a drug development company) and have an investigational new drug application (IND) or pre-IND (PIND) number for the relevant program. FDA welcomes submissions related to any relevant MIDD topics, such as:

- Dose selection or estimation (*e.g.,* for dose/dosing regimen selection or refinement)
- Clinical trial simulation (*e.g.,* based on drug-trial-disease models to inform the duration of a trial, select appropriate response measures, predict outcomes, etc.)
- Predictive or mechanistic safety evaluation (*e.g.,* use of systems pharmacology/mechanistic models for predicting safety or identifying critical biomarkers of interest)

III. Procedures and Submission Information

A. General Information

The MIDD program will be jointly administered by CDER's Office of Clinical Pharmacology, in the Office of Translational Sciences, which is the point of contact for all communications for CDER products, and CBER's Office of Biostatistics and Pharmacovigilance, which is the point of contact for all communications for CBER products.

B. How To Submit a Meeting Request and Meeting Package

Meeting requests should be submitted electronically to the relevant application (*i.e.,* PIND, IND) with ''MIDD Program Meeting Request for CDER'' (CDER applications) or ''MIDD Program Meeting Request for CBER'' (CBER applications) in the subject line. Information about providing regulatory submissions in electronic format is available at: *https://www.fda.gov/drugs/development-approval-process-drugs/forms-submission-requirements.*

C. Content and Format of the Meeting Request

Include the following information in the meeting request (no more than three to four pages):

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indication(s) or context of product development.
5. A brief statement of the purpose and objectives of the meeting. The statement should include a brief background of the MIDD issues underlying the agenda.
6. MIDD approach(es) considered for the product under development and how MIDD can assess uncertainties about issues (*e.g.,* dosing, duration, patient selection) in a way that can inform regulatory decision-making.
7. A list of issues for discussion with the Agency about the specific MIDD proposed approach for the applicable drug development program.

D. Content and Format of the Meeting Information Package

Sponsors whose meeting requests are granted as part of the program should submit a meeting information package electronically with ''MIDD Program Meeting Package for CDER'' (CDER applications) or ''MIDD Program Meeting Package for CBER'' (CBER applications) in the subject line no later than 47 days before the initial meeting and 60 days before the follow-up meeting. This meeting package should include the following information:

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indications or context of product development.
5. Background section that includes a brief history of the development program and the events leading up to the meeting as well as the status of product development.
6. Proposed agenda, including estimated times needed for discussion of each agenda item.
7. List of questions for discussion along with a brief summary explaining the question of interest and the context of use for each question. State whether the model will be used to inform future trials, to provide mechanistic insight, or in lieu of a clinical trial.
8. The drug development issue (*e.g.,* dosing, clinical trial design, safety prediction, etc.), the proposed MIDD approach to the solution, information to support discussion (*e.g.,* a description of the data utilized for developing the models, model development, simulation plan, results), assessment of model risk, and how the Agency can help guide any next steps relative to the regulatory decision-making process should be summarized and clearly articulated with any supporting data imperative to the discussion.

E. Meeting Summaries

A meeting summary will be sent to the requester within 30 days of each meeting.

IV. Paperwork Reduction Act of 1995

While this notice contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this notice. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to Prescription Drug User Fee Program have been approved under OMB control number 0910–0297. The collections of information for requesting meetings with FDA about drug development programs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 for INDs and clinical trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338.

Dated: January 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00389 Filed 1–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3091]

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal'' that appeared in the **Federal Register** of December 13, 2022. The document announced the renewal of the