

Committee
Blood Products Advisory Committee
National Center for Toxicological

Research:

Science Board to the National Center
for Toxicological Research
Center for Drug Evaluation and
Research:

Joint Meetings of the Anesthetic and
Analgesic Drug Products Advisory
Committee and the Drug Safety and
Risk Management Advisory
Committee

Drug Safety and Risk Management
Advisory Committee

Annual Reports are available for public
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Monday through Friday, at:

(1) The Library of Congress, Madison
Building, Newspaper and Current
Periodical Reading Room, 101
Independence Ave. SE, Rm. 133,
Washington, DC 20540; and

(2) Dockets Management Staff (HFA-
305), Food and Drug Administration,
5630 Fishers Lane, Rm. 1061, Rockville,
MD 20852.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1203]

Pilot Meetings Program for Model- Informed Drug Development Approaches

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The sixth iteration of the Prescription Drug User Fee Act (PDUFA VI), incorporated as part of the FDA Reauthorization Act of 2017 (FDARA), highlights the goal of advancing model-informed drug development (MIDD). The Food and Drug Administration (FDA or Agency) is announcing a pilot program that affords sponsors or applicants who are selected for participation the opportunity to meet with Agency staff to discuss MIDD approaches in medical product development. Meetings under the pilot 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 2018 to 2022. This pilot program is being conducted to fulfill

FDA's performance commitment under PDUFA VI. For this pilot program, MIDD is defined as the application of exposure-based, biological, and/or statistical models derived from preclinical 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 pilot program consists of two meetings between sponsors or applicants and the relevant center and will 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 April 17, 2018 through June 15, 2022. See section III of this notice for instructions about how to request participation in the pilot 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 the first week of the new quarter.

The pilot program meetings will begin in Q4 of FY 2018 (July 1–September 30, 2018), and run through Q4 of FY 2022 (September 30, 2022). Proposals not selected for a given quarter will be so notified by the Agency. Sponsors who are not chosen to participate in the pilot program may seek Agency interaction through existing channels (e.g., Type C meeting requests, critical path innovation meetings).

ADDRESSES: Comments about this pilot program can be submitted until May 17, 2018. You may submit comments about the MIDD pilot 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 "Pilot 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.

- **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.gpo.gov/fdsys/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.

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 20993-0002, 301-796-2133, Yvonne.Knight@fda.hhs.gov, with the subject line "MIDD Pilot Meetings Program for CDER."

CBER: Jason Claeys, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1223, Silver Spring, MD 20993-0002, 240-402-8589, jason.claeys@fda.hhs.gov, with the subject line "MIDD Pilot Meetings Program for CBER."

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA FDA agreed, in accordance with the "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022: I. Ensuring the Effectiveness of the Human Drug Review Program, Part J. Enhancing Regulatory Decision Tools to Support Drug Development and Review" to provide information on how a sponsor can apply to participate in a pilot meetings program with FDA to discuss MIDD approaches (<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>).

FDA is announcing this pilot meetings program to satisfy the above-mentioned commitment and to facilitate MIDD approaches. This excludes 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 pilot program is to provide advice on how specific, proposed MIDD approaches can be used in a specific drug development program. FDA has committed to accepting two to four meeting requests quarterly each fiscal year. The meetings granted will include an initial and followup meeting on the same drug development issues within the span of approximately 120 days.

The listed eligibility factors 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 pilot program evolves. The most current pilot program eligibility factors and procedures may be found on the MIDD Pilot Program website: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm600311.htm>.

II. Eligibility and Selection for Participation in the MIDD Pilot Program

The requester 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. Recognizing that FDA will learn both from the number and types of submissions received for consideration into the pilot program, FDA welcomes submissions related to any relevant MIDD topics. However, given that the Agency expects to grant two to four meeting requests per quarter as part of the pilot program, the Agency will initially prioritize selecting requests that focus on:

- 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).
- 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 pilot 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 Epidemiology, 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 Pilot Program Meeting Request for CDER" (CDER applications) or "MIDD Pilot 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/DevelopmentApprovalProcess/FormsSubmissionRequirements/%20ElectronicSubmissions/ucm153574.htm>.

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. 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. 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 or applicants whose meeting requests are granted as part of the pilot program should submit a meeting information package electronically with "MIDD Pilot Program Meeting Package for CDER" (CDER applications) or "MIDD Pilot Program Meeting Package for CBER" (CBER applications) in the subject line no later than 30 days before each (initial and followup) meeting. This meeting package should include the following information:

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indication(s) 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, and the status of product development.
6. Proposed agenda, including estimated times needed for discussion of each agenda item.
7. List of questions for discussion with a brief summary for each question to explain the need or context for the question.
8. Drug development issue (e.g., dosing, clinical trial design, safety prediction), including the proposed MIDD approach to the solution, information to support discussion (e.g., a description of the data used for developing the models, model development, simulation plan, results), and how the Agency can help guide any next steps relative to the regulatory decision making process, which 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 60 days of each meeting.

IV. Paperwork Reduction Act of 1995

This notice refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information resulting from formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0429. The collection of information in 21 CFR part 312 (INDs) has been approved under OMB control number 0910–0014.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6931]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and “Lookback”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and “Lookback”

OMB Control Number 0910–0116—Extension

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health

Service Act (PHS Act) (42 U.S.C. 262(a)). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacturing into products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic Act (FD&C Act) also applies to biological products. Blood and blood components for transfusion or for further manufacturing into products are drugs, as that term is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the FD&C Act, blood and plasma establishments must comply with the provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351), drugs are deemed “adulterated” if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (CGMP) and related regulations.

The CGMP regulations (part 606) (21 CFR part 606) and related regulations implement FDA’s statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donations for evidence of relevant transfusion-transmitted infections and in notifying donors is to prevent the transmission of relevant transfusion-transmitted infections. For example, the “lookback” requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to consignees of blood and blood components and appropriate notification of recipients of blood components that are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donation testing, donor notification, and “lookback” regulations provide FDA