IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR parts 1002, 1010, and 1040 are approved under OMB control number 0910–0025.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–21079 Filed 9–29–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2017–N–5442]

Leveraging Quantitative Methods and Modeling To Modernize Generic Drug Development and Review; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of public workshop; request for comments.
SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review.” The purpose of the public workshop is to engage stakeholders in a discussion of current and emerging scientific approaches and applications for the conduct of quantitative modeling and simulations in generic drug development, especially for complex and locally acting products, and to gain input regarding opportunities and knowledge gaps related to the use of quantitative modeling and simulation to inform regulatory decision making through the product lifecycle. FDA will use the information gained through the workshop to support product-specific guidance development, improve pre-abbreviated new drug applications (ANDA) interactions with applicants, increase the quality and efficiency of regulatory reviews, and identify a next generation modeling and simulation toolset for complex and locally acting products.
DATES: The public workshop will be held on October 2 and 3, 2017, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by November 3, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADRESSES: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Great Room, Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 3, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 3, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 comment 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–2017–N–5442 for “Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review.” 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.

• 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 docket, 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
and generic drugs. Given the broad applications of modeling and simulation through the entire lifecycle of a product, there is a need to identify best practices to improve the routine use and acceptance of modeling and simulation for regulatory decision making.

The purposes of the workshop are to:
(1) Engage global stakeholders and share experience and vision on using quantitative approaches in regulatory decision making for generic drug development and product lifecycle management;
(2) Identify and prioritize potential areas for global harmonization to inform regulatory decision making;
(3) Share the current state of knowledge and practice in utilizing quantitative methods and modeling for generic drug development and review by case demonstrations and by integrating experience and lessons learned from new drug product development and review;
(4) Identify opportunities for complex and locally acting product development and discuss approaches and principles in using quantitative methods and modeling to aid product-specific guidance development, pre-ANDA interactions between FDA and prospective applicants, ANDA reviews, and postmarket performance monitoring; and
(5) Discuss next generation quantitative method and modeling toolsets, future directions, and application areas beyond currently available tools.

There is a paradigm shift to a risk-based product-specific regulatory approach for generic drugs. Examples of this transition include recommendations for partial AUC (area under the concentration-time curve) for some modified release drugs and replicate study bioequivalence (BE) recommendations for narrow therapeutic index (NTI) drugs. These product-specific guidance is driven by the therapeutic significance of either the exposure-response relationships for safety and efficacy (NTI drugs) or the difference in the shape of PK profiles. Modeling and simulation toolsets help design and evaluation of PK or comparative clinical endpoint (CPK) or absorption models, systems pharmacology, quantitative risk modeling, and emergent machine learning tools. These application areas can leverage the large pharmaceutical data sets available to FDA and other organizations. Quantitative approaches have been used by all stakeholders to address significant scientific and regulatory issues in all phases of the product lifecycle: from pre-investigational new drug (NDA) and post-approval evaluation of new and generic drugs. Given the broad applications of modeling and simulation through the entire lifecycle of a product, there is a need to identify best practices to improve the routine use and acceptance of modeling and simulation for regulatory decision making.

The purposes of the workshop are to:
(1) Engage global stakeholders and share experience and vision on using quantitative approaches in regulatory decision making for generic drug development and product lifecycle management;
(2) Identify and prioritize potential areas for global harmonization to inform regulatory decision making;
(3) Share the current state of knowledge and practice in utilizing quantitative methods and modeling for generic drug development and review by case demonstrations and by integrating experience and lessons learned from new drug product development and review;
(4) Identify opportunities for complex and locally acting product development and discuss approaches and principles in using quantitative methods and modeling to aid product-specific guidance development, pre-ANDA interactions between FDA and prospective applicants, ANDA reviews, and postmarket performance monitoring; and
(5) Discuss next generation quantitative method and modeling toolsets, future directions, and application areas beyond currently available tools.

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the corresponding reference listed drugs
or reference standards:
a. How to effectively integrate systems
pharmacology, PBPK, and the exposure-
clinical response relationship to
evaluate product risk and assist BE
evaluation?
b. What will be the next generation
methodologies in postmarket signal
detection to evaluate product
substitution or compare product
performance using the Sentinel database
or complementary tools?
III. Participating in the Public
Workshop
Registration: Persons interested in
attending this public workshop must
register online at https://survey.co1.
qualtrics.com/jfe/form/SV_3eilOCSnr
PdTTZU9. Please provide complete
contact information for each attendee,
including name, title, affiliation,
address, email, and telephone.
Registration is free and based on
space availability, with priority given to
early registrants. Persons interested in
attending this public workshop must
register by September 25, 2017,
midnight, Eastern Standard Time. Early
registration is recommended because
seating is limited; therefore, FDA may
limit the number of participants from
each organization.
If you need special accommodations
due to a disability, please contact
Lanyan (Lucy) Fang (see FOR FURTHER
INFORMATION CONTACT) no later than 7
days before the workshop.
Requests for Oral Presentations:
During online registration you may
indicate if you wish to present during a
public comment session, and which
topic(s) you wish to address. We will
do our best to accommodate requests to
make public comments. Individuals and
organizations with common interests are
urged to consolidate or coordinate their
presentations, and to request time for a
joint presentation, or to submit requests
for designated representatives to
participate in the focused sessions.
Following the close of registration, we
will determine the amount of time
allotted to each presenter and the
approximate time each oral presentation
is to begin, and will select and notify
participants by September 27, 2017. All
requests to make oral presentations
must be received by the close of
registration on September 25, 2017. If
selected for presentation, any
presentation materials must be emailed
to Lanyan (Lucy) Fang (see FOR FURTHER
INFORMATION CONTACT) no later than
September 28, 2017. No commercial or
promotional material will be permitted
to be presented or distributed at the
public workshop.

**Streaming Webcast of the Public
Workshop:** This public workshop will
also be webcast. A live webcast of this
workshop will be viewable at https://
collaboration.fda.gov/dqpm1017/on
the day of the workshop.
If you have never attended a Connect
Pro event before, test your connection at
https://collaboration.fda.gov/common/
help/en/support/meeting_test.htm. To
get a quick overview of the Connect Pro
program, visit https://www.adobe.com/
go/connectpro_overview. FDA has
verified the Web site addresses in this
document, as of the date this document
publishes in the Federal Register, but
Web sites are subject to change over

**Transcripts:** Please be advised that as
soon as a transcript of the public
workshop is available, it will be
accessible at https://
www.regulations.gov. It may be viewed
at the Dockets Management Staff (see
**ADDRESSES**). A link to the transcript
will also be available on the internet at
http://www.fda.gov/Drugs/NewsEvents/
ucm554182.htm.
Dated: September 26, 2017.
Anna K. Abram,
Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.

**BILLING CODE** 4164–01–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES
National Institutes of Health**

**Prospective Modification of Exclusive
Patent License Potent and Selective
Analogues of: Monamine Transporters;
Methods of Making; and Uses Thereof**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Drug
Abuse, an institute of the National
Institutes of Health, Department of
Health and Human Services is
contemplating the modification of grant
of an Exclusive Patent License to
EncepHeal Therapeutics, Inc., located in
Winston-Salem, North Carolina, to
practice the inventions embodied in the
patent applications listed in the
Supplementary Information section of
this notice.

**DATES:** Only written comments and/or
applications for a license which are
received by the National Institute on
Drug Abuse’s Technology Transfer
Office on or before October 17, 2017
will be considered.

**ADDRESS:** Requests for copies of the
patent application, inquiries, and
comments relating to the contemplated
modification of the Exclusive Patent
License should be directed to Martha
Lubet, Ph.D., Technology Transfer
Manager, NCI TTC, 9609 Medical Center
Drive, Room IE350, MSC 9702,
Rockville, MD 20850. Telephone: 240
Email: lubetm@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:**
The following represents the intellectual
property to be licensed under the
prospective agreement:
U.S. provisional application 61/
774,878, filed March 8, 2013 entitled
“Potent and Selective Inhibitors of
Monamine Transporters; Methods of
Making; and Uses Thereof” [HHS Ref.
No. E–073–2013/0–US–01];
PCT application PCT/US2014/021514,
filed March 7, 2014 entitled “Potent and
Selective Analogues of: Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–PCT–02];
U.S. application 14/772,486, filed
September 3, 2015 entitled “Potent and
Selective Analogues of Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–US–06];
EPO application 14714043.8, filed
September 1, 2015 entitled “Potent and
Selective Analogues of Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–EP–05];
Australian application 2014225550,
filed September 8, 2015 entitled “Potent
and Selective Analogues of Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–AU–03];
Australian application 201720849,
filed April 28, 2017 entitled Potent and
Selective Analogues of Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–AU–07];
Canadian application 2903746, filed
September 2, 2015 entitled “Potent
and Selective Analogues of Monamine
Transporters; Methods of Making; and
Uses Thereof” [HHS Ref. No. E–073–
2013/0–CA–04];
The patent rights to these inventions
have been assigned to and/or
exclusively licensed to the Government
of the United States of America.
The Government previously
announced its intention to grant an
exclusive license to EncepHeal at FR
80:245 (December 22, 2015), pp. 79595–
79596.
The Notice of Intent to Grant (NOITG)
specified a Field of Use as “Use of