

of sufficient relevance and reliability to address the specific regulatory decision being considered.

This guidance does not affect any Federal, State or local laws or regulations or foreign laws or regulations that may otherwise be applicable to the use or collection of RWE and that provide protections for human subjects or patient privacy. This guidance should be used to complement, but not supersede, other device-specific and good clinical practice guidance documents. FDA considered comments received on the draft guidance that published in the **Federal Register** of July 27, 2016 (81 FR 49228). FDA revised the guidance as appropriate in response to the comments.

## II. Significance of Guidance

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 use of real-world evidence to support regulatory decision-making for medical devices. 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. This guidance is not subject to Executive Order 12866.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1500012 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E (premarket approval), have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption), have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 822 (postmarket surveillance) have been approved under OMB control number 0910–0449; the collections of information in 21 CFR 50.23 (exception from general requirements for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR part 54 (financial disclosure by clinical investigators) have been approved under OMB control number 0910–0396; the collections of information in 21 CFR 56.115 (institutional review boards records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR parts 50 subpart B (informed consent of human subjects) and 56 (institutional review boards) have been approved under OMB control number 0910–0755. The collections of information in the guidance "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910–0756.

Dated: August 25, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Peer Review of Draft NTP Approach to Genomic Dose-Response Modeling; Availability of Documents; Request for Comments; Notice of Expert Panel Meeting

**SUMMARY:** The National Toxicology Program (NTP) announces an expert panel meeting and is obtaining comment on a proposed approach to genomic dose-response modeling. Prior

to the expert panel meeting, NTP will host four webinars that present other approaches to genomic dose-response modeling. The expert panel meeting and four webinar presentations leading up to the meeting are open to the public. Registration is requested for both in-person meeting attendance and oral comment; registration is required to access the meeting webcast. URLs for live and archived pre-meeting webinars will be available at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

#### DATES:

*Pre-Meeting Webinars:* Dates are posted on the meeting Web site (<https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>). Registration is not required to view the pre-meeting webinars.

*Meeting:* October 23–25, 2017; expert panel meeting begins at 8:30 a.m. Eastern Daylight Time (EDT) each day and continues until adjournment.

*Document Availability:* Draft document should be available by August 23, 2017, at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

#### Written Public Comment

*Submissions:* Deadline is October 13, 2017.

*Registration for Oral Comments:* Deadline is October 13, 2017.

*Registration for Meeting and/or to View Webcast:* Deadline is October 25, 2017. Registration to view the meeting via webcast is required.

#### ADDRESSES:

*Meeting Location:* Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

*Meeting Web site:* The draft document, preliminary agenda, registration, pre-meeting webinars details, and other meeting materials will be available at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

*Webcast:* The URL for viewing the expert panel meeting webcast will be provided to those who register.

#### FOR FURTHER INFORMATION CONTACT:

Anna Stamatogiannakis, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1652, Fax: (919) 293–1645, Email: [anna.stamatogiannakis@icf.com](mailto:anna.stamatogiannakis@icf.com).

#### SUPPLEMENTARY INFORMATION:

*Background:* NTP proposes to use the approach embodied in the BMDEExpress software to perform gene and pathway-level genomic dose-response modeling as part of Tox21 Phase 3 and in vivo screening level studies. NTP seeks external scientific input on its proposed approach by an expert panel. NTP's goal

for implementing this approach considers a number of factors including methods accepted in the peer-review literature, ease of translation to risk assessment, and ease of understanding for the variety of potential end users that may not necessarily be experts in mathematical and systems modeling. A series of four pre-meeting webinars and the expert panel meeting aim to review current approaches and discuss best practices. The webinar series will provide an overview of various current approaches and NTP's proposed approach to genomic dose-response modeling. The expert panel will consider information presented in the webinars as well as other technical factors during its peer review of NTP's proposed approach.

**Pre-Meeting Webinars Registration:** There is no registration required to attend the webinars. The URLs for live and archived webinars will be available on the meeting Web site at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>; please refer to this page for the most current information about the webinars and the meeting.

**Expert Panel Meeting and Registration:** The meeting is open to the public with time set aside for oral public comment. Interested individuals can attend the meeting in person or view the webcast. Attendance at NIEHS is limited only by the space available. For planning purposes, registration to attend the meeting at NIEHS or view the webcast is requested. Registration to attend the meeting in person and/or view the webcast is by October 25, 2017, at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

**Attending the Meeting:** Visitor and security information for those attending in person is available at <https://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to participate in this event should contact Anna Stamatogiannakis by phone: (919) 293-1652 or email: [anna.stamatogiannakis@icf.com](mailto:anna.stamatogiannakis@icf.com). TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

**Meeting Materials:** The expert panel meeting agenda will be available on the meeting Web site at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>. The draft document should be available by August 23, 2017. Additional information will be posted when available or may be requested in hardcopy, see **FOR FURTHER INFORMATION CONTACT**.

Following the meeting, a report of the panel meeting will be prepared and

made available on the NTP Web site. Individuals are encouraged to access the meeting Web site to stay abreast of the most current information regarding the meeting.

**Request for Comments:** NTP invites written and oral public comments on the draft NTP approach. The deadline for submission of written comments is October 13, 2017, to enable review by the peer review panel and NTP staff prior to the meeting. Written public comments and any other correspondence on NTP's proposed approach should be sent to the **FOR FURTHER INFORMATION CONTACT**. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP Web site and the submitter identified by name, affiliation, and/or sponsoring organization (if any). Guidelines for public comments are at [https://ntp.niehs.nih.gov/ntp/about\\_ntp/guidelines\\_public\\_comments\\_508.pdf](https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf).

Oral public comment at this meeting is welcome, with time set aside on October 23 for the formal presentation of oral remarks on the draft document. In addition to in-person oral comments at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open from 8:30 a.m. each day until adjournment. Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one time slot. At least 7 minutes will be allotted to each time slot, and if time permits, the allotment may be extended to 10 minutes at the discretion of the chair. In addition to the formal public comment period, there will be several opportunities in the agenda for ad hoc comments.

Persons wishing to make oral comments during the formal comment period on October 23 are asked to register online at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/> by October 13, 2017, and indicate whether they will present comments in person or via the teleconference line. Oral public commenters are asked to send a copy of their slides and/or statement or talking points to the **FOR FURTHER INFORMATION CONTACT** by October 13, 2017. Written statements can supplement and may expand the oral presentation. Registration for in-person oral

comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site. Time is also being set aside in the agenda for ad hoc comments by both in-person attendees and webcast viewers. Information on how to make oral remarks during those ad hoc comment periods will be provided at the meeting.

**Background Information on Expert Panels:** NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods. NTP welcomes public comment for dose-response modeling.

Dated: August 15, 2017.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-HQ-R-2017-N102;  
FXRS12630900000-167-FF09R81000; OMB  
Control Number 1018-0140]

### Agency Information Collection Activities; Hunting and Fishing Application Forms and Activity Reports for National Wildlife Refuges

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of Information Collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service) are proposing to revise an information collection.

**DATES:** Interested persons are invited to submit comments on or before October 30, 2017.

**ADDRESSES:** Send your comments on the information collection request (ICR) by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041-