

April 23, 2013, and the comment period closed on July 22, 2013. The final guidance was revised in response to the comments to emphasize use of risk assessment and leveraging of prior information within a submission to potentially reduce the need for new biocompatibility testing.

Commenters also requested additional details regarding biocompatibility testing of devices in contact with gas pathways and color additives used in medical devices. FDA has determined that these concepts would be appropriately addressed in separate guidance documents and have therefore been removed from this final guidance.

## 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 International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process." 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.

## 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process'" 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 1811 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. 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 58 have been approved under OMB control number 0910-0119;

the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; 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 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff 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: June 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

### Pediatric Clinical Investigator Training; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development are announcing a 2-day public workshop entitled "Pediatric Clinical Investigator Training." The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. Although we have learned a lot about conducting pediatric trials over the past two decades, there are still challenges that need to be addressed. The training

course is intended to provide investigators with: (1) A clear understanding of some of the challenges of studying products in the pediatric population, including: Pediatric study design, neonates, biomarkers, endpoints, orphan drugs and rare disease trial design, formulations; (2) an overview of extrapolation as it relates to the pediatric population; and (3) an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

**DATES:** The public workshop will be held on September 12 and 13, 2016, from 8 a.m. to 4 p.m. Registration to attend the workshop should be completed by September 6, 2016. (See the **SUPPLEMENTARY INFORMATION** section for instructions).

**ADDRESSES:** This public workshop will be held at the DoubleTree Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

### FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, [terrie.crescenzi@fda.hhs.gov](mailto:terrie.crescenzi@fda.hhs.gov); or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, [elizabeth.sanford@fda.hhs.gov](mailto:elizabeth.sanford@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act, which have stimulated pediatric research over the past two decades. The National Institutes of Health section of BPCA legislation, however, is due for reauthorization in 2017. Though much progress has been made, pediatric trials for the purpose of developing product use information are still performed less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have both scientific challenges and unique attributes and requirements which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric

researchers recognize and understand the challenges and differences between the standards for adult trials and pediatric trials. Researchers are responsible for ensuring the safe and ethical treatment of pediatric patients and obtaining adequate and reliable data to support regulatory decisions. There is a critical need for further pediatric research on medical products to obtain additional data which will help ensure that these products are safe and effective in the pediatric population. Much of the progress which has been made in obtaining proper therapeutic information in pediatrics has occurred in the older and more populous pediatric populations. The challenge of obtaining data from non-verbal children, neonates, and for conditions existing in limited populations is much more difficult. This need reinforces our responsibility to educate clinical investigators to assure that children are only enrolled in research that is scientifically necessary, ethically sound, and designed to meet the challenges of review by FDA.

## II. Workshop Attendance and Participation

If you wish to attend this workshop, visit <http://pedsinvesttrain.eventbrite.com>. Please register by September 6, 2016. Those who are unable to attend the workshop in person can register to view a live Webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration will also require your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the workshop will be based on space availability. Persons attending the workshop are advised that FDA is not responsible for providing access to electrical outlets.

Registration information, the agenda, and additional background materials can be found at <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm>.

**Webcast:** The workshop will be Webcast live and available on the Internet.

The live Webcast on September 12, 2016, will be available at: <https://event.webcasts.com/start/here.jsp?ei=1093258>. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon

session (note that it is different from the morning's session): <https://event.webcasts.com/start/here.jsp?ei=1093259>. On September 13, 2016, the live Webcast will be available at: <https://event.webcasts.com/start/here.jsp?ei=1093263>. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): <https://event.webcasts.com/starthere.jsp?ei=1093265>. The Webcast will only be for listening and there will not be an opportunity for Webcast participants to speak. The Webcast will be posted after the workshop at: <http://wcms.fda.gov/FDAgov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm?ssSourceSiteId=null&SSContributor=true>, approximately 30 days after the workshop.

If you need special accommodations due to a disability, please contact Betsy Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: June 10, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-1495]

#### Factors To Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions." This draft guidance, when finalized, is intended to provide clarity for FDA staff and industry regarding the benefit and risk factors FDA may consider in prioritizing resources for compliance and enforcement efforts to maximize medical device quality and patient safety. Although product

availability and other medical device compliance and enforcement decisions are generally fact-specific, FDA believes that consideration of the factors listed in the draft guidance, when relevant, will improve the consistency and transparency of those decisions and that a shared understanding of benefit and risk will better align industry's and FDA's focus on actions that maximize benefit to patients, improve medical device quality, and reduce risk to patients. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets