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/starthere.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/starthere.jsp?ei=1093259.* On September 13, 2016, the live Webcast will be available at: *https://event.webcasts.com/starthere.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.*

[FR Doc. 2016–14230 Filed 6–15–16; 8:45 am]

**BILLING CODE 4164–01–P**

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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

Management, 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–2016–D–1495 for the draft guidance entitled ''Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ann M. Ferriter, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3680, Silver Spring, MD 20993, 301–796–5530.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The draft guidance, when finalized, is intended to provide a shared benefit-risk framework for FDA and stakeholders and to set forth overarching principles. FDA may consider the types of benefit-risk factors described in the draft guidance—including reliable patient preference information from a representative sample—on a case-by-case basis when determining the appropriate regulatory action to take and to help ensure that informed and science-based decisions are made to the greatest extent practicable. Factors may be weighted differently for different types of decisions.

In addition, the draft guidance, when finalized, is intended to harmonize FDA's approach to weighing benefits and risks for medical device product availability, compliance, and enforcement decisions with FDA's benefit-risk framework for evaluating medical device marketing and investigational device exemption (IDE) applications. The benefit-risk factors in the draft guidance also support evaluation of medical devices with real world evidence.

The principles described in the draft guidance may be applicable to industry and FDA decisions. The benefit-risk factors may be considered when device manufacturers evaluate appropriate responses to nonconforming product or regulatory compliance issues, such as determining whether to limit the availability of a medical device (*e.g.,* a voluntary recall or market withdrawal). FDA may evaluate the benefit-risk factors during, for example, assessments of device shortage situations, selection of the appropriate regulatory engagement mechanism following an inspection during which regulatory non-compliance was observed, evaluation of recalls and consideration of petitions for variance from those sections of the Quality System regulation (21 CFR part 820) for which there were inspectional observations during a premarket approval (PMA) preapproval inspection. Premarket review decisions, such as premarket notification (510(k)) substantial equivalence determinations, de novo classification, and PMA, humanitarian device exemption (HDE) or IDE application approval decisions, are beyond the scope of this draft guidance.

The draft guidance applies to both diagnostic and therapeutic medical devices subject to, and exempt from, premarket review. The scope of the draft guidance excludes medical devices regulated by FDA's Center for Biologics Evaluation and Research (CBER); combination products, as defined in 21 CFR 3.2(e), for which the Center for Devices and Radiological Health (CDRH) is not the lead Center; and electronic products that are not devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321) as regulated by CDRH under the Electronic Product Radiation Control (ERPC) provisions in the FD&C Act and implementing regulations (21 CFR Subchapter J—Radiological Health). This draft guidance does not apply to products (*e.g.,* drugs, biologics, dietary supplements, foods, tobacco products, or cosmetics) regulated by other FDA Centers.

## II. Significant of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions.'' 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 draft guidance may do so by using the Internet. A search capability for all CDRH 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 ''Factors to Consider regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500065 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft 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 7, subpart C, have been approved under OMB control number 0910–0249. The collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485. The collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control numbers 0910–0291, 0910–0437, and 0910–0471. The collections of information in 21 CFR part 806 have been approved under OMB control number 0910–0359. 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 810, regarding medical device recall authority, have been approved under OMB control number 0910–0432. 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 B and E, have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 820, regarding the Quality System regulation, have been approved under OMB control number 0910–0073. The collections of information in 21 CFR part 822, regarding postmarket surveillance of medical devices, have been approved under OMB control number 0910–0449.

Dated: June 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–14200 Filed 6–15–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0001]**

### Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on June 28, 2016, from 8 a.m. to 3:15 p.m., and June 29, 2016, from 8 a.m. to 4:15 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

**FOR FURTHER INFORMATION CONTACT:** Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On June 28, 2016, information will be presented to gauge investigator interest in exploring potential pediatric development plans for four products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) VENETOCLAX, application sponsored by AbbVie, Inc.; (2) TAZEMETOSTAT, application sponsored by Epizyme, Inc.; and (3) ATEZOLIZUMAB, application sponsored by Roche/Genentech.

On June 29, 2016, during the morning session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) LOXO–101, application sponsored by Loxo Oncology, Inc.; and (2) ENTRECTINIB, application sponsored by Ignyta, Inc.

During the afternoon session, information will be presented on the current unmet clinical need in the nearly uniformly fatal brain tumor, diffuse intrinsic pontine glioma (DIPG), which occurs predominantly in the pediatric age group. The diagnosis of DIPG is typically based on characteristic radiographic and clinical features in lieu of brain biopsy, and histological confirmation. Recent data has demonstrated that the biology and pathophysiology of these tumors differ. There are no approved drugs for this disease. Clinical investigators seek to exploit precision medicine approaches to DIPG and use potentially predictive information from the genomic signature of tumors at either diagnosis or relapse. This information can be used to select specific molecularly targeted drugs based on the genetic aberrations of an individual patient's tumor. The Agency will seek the input of the subcommittee, including an assessment of benefit/risk given the potential for an adverse event associated with a surgical intervention in the brainstem.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views,