Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ian Hendricks, Center for Veterinary Medicine (HFV–172), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5661, *Ian.Hendricks@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 2023 (88 FR 37551), FDA published a notice announcing the availability of draft GFI #279 entitled ''Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.'' Interested persons were originally given until August 7, 2023, to comment on the draft guidance.

The Agency received a request for a 60-day extension of the comment period for the draft guidance. The requestor indicated they needed more time to complete development of comments to submit in response to the draft guidance. FDA has considered the request and is reopening the comment period for the draft guidance for 60 days, until October 16, 2023. The Agency believes that a 60-day reopening of the comment period allows adequate time for interested persons to submit comments to ensure that the Agency can consider the comments on this draft guidance before it begins work on the final version of the guidance.

Dated: August 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17507 Filed 8–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0031]

Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors.'' The guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in carrying out their responsibilities related to informed consent. The guidance provides the Agency's recommendations regarding informed consent and describes FDA regulatory requirements to help assure the protection of the rights and welfare of human subjects in clinical investigations. This guidance finalizes the draft guidance entitled, ''Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors,'' issued on July 15, 2014, and supersedes FDA's guidance entitled ''A Guide to Informed Consent,'' issued in September 1998.

DATES: The announcement of the guidance is published in the **Federal Register** on August 16, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2006–D–0031 for the final guidance entitled ''Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kevin A. Prohaska, Office of Clinical Policy, Office of Clinical Practice and Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5110, Silver Spring, MD 20993–0002, 301–796–3707, *kevin.prohaska@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors.'' The guidance announced in this notice is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in carrying out their responsibilities related to informed consent. The guidance provides the Agency's recommendations regarding informed consent and describes FDA regulatory requirements to help assure the protection of the rights and welfare of human subjects in clinical investigations.

This guidance supersedes FDA's guidance entitled ''A Guide to Informed Consent,'' issued in September 1998, and finalizes the draft guidance entitled, ''Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors,'' issued on July 15, 2014 (79 FR 41291). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include references and links to other relevant guidance issued since 2014. Additionally, the document was reorganized to first present general guidance on FDA's regulatory requirements for informed consent and a discussion of roles of IRBs, clinical investigators, sponsors, and FDA related to informed consent, followed by a series of frequently asked questions. Editorial changes were also made to improve clarity.

FDA notes that, since 2014 when we issued the draft informed consent guidance, HHS and a number of other Federal Departments and Agencies issued revisions to the Federal Policy for the Protection of Human Subjects (codified for HHS at 45 CFR 46, subpart A; ''the 2018 Common Rule''). The 2018 Common Rule sets forth requirements for the protection of human subjects involved in research that is conducted or supported by HHS and these Federal Departments and Agencies.[1]

FDA is currently engaged in notice and comment rulemaking to harmonize with the 2018 Common Rule to the extent practicable and consistent with other statutory provisions.[2] This guidance does not address possible future changes to FDA's informed consent regulations that may be developed as part of these harmonization efforts. FDA may amend this guidance to reflect such changes or to address new questions related to informed consent.

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, ''Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors.'' 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. The use of the word ''should'' in Agency guidance means that something is suggested or recommended, but not required.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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. 3501–3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control

[1] A final rule to revise the Federal Policy for the Protection of Human Subjects was issued on January 19, 2017 (82 FR 7149; *https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf*). That final rule was modified by an interim final rule that delayed the effective date and general compliance date (83 FR 2885, January 22, 2018; *https://www.govinfo.gov/content/pkg/FR-2018-01-22/pdf/2018-00997.pdf*) and a final rule that delayed the general compliance date, while allowing use of three burden-reducing provisions for certain research during the delay period (83 FR 28497, June 19, 2018; *https://www.govinfo.gov/content/pkg/FR-2018-06-19/pdf/2018-13187.pdf*).

[2] On September 28, 2022, FDA issued proposed rules to harmonize certain provisions of 21 CFR parts 50 and 56 with the 2018 Common Rule to the extent practicable and consistent with other statutory provisions (see 87 FR 58733 at *https://www.federalregister.gov/documents/2022/09/28/2022-21088/protection-of-human-subjects-and-institutional-review-boards,* and 87 FR 58752 at *https://www.federalregister.gov/documents/2022/09/28/2022-21089/institutional-review-boards-cooperative-research*).

number 0910–0014, and the collections of information under 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17594 Filed 8–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3329]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 4, 2023, from 9:30 a.m. to 3 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–3329. The docket will close on October 3, 2023. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 3, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 20, 2023, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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.*
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- 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–2023–N–3329 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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, 240–402–7500.

- 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.'' FDA 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 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 the 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–