

2017–D–2165 for “Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations; Draft Guidance for Industry; Availability.” 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 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 <https://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: <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 “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. Send one self-addressed adhesive label to assist that office in processing

your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–0750; or Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993–0002, 301–796–0750.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.” This guidance presents FDA’s current approach to assessing potential risks to embryo-fetal development associated with oncology pharmaceutical use in male and female patients. The term *pharmaceutical* in this guidance refers to small molecules, therapeutic proteins, antibodies, and related products such as conjugated products. The guidance describes when embryo-fetal developmental studies for oncology pharmaceuticals may be warranted for different types of pharmaceuticals, such as cytotoxic, biological, and conjugated pharmaceuticals, or pharmaceuticals used in combinations. The guidance also discusses other aspects of a nonclinical reproductive toxicity evaluation, such as fertility and pre- and postnatal evaluation. The guidance addresses the need for a reproductive toxicity evaluation when pharmaceuticals are used in specific populations (e.g., pediatric, males-only, or postmenopausal women).

Although current regulatory guidances exist regarding the need to assess the embryo-fetal developmental toxicity potential of pharmaceuticals and the overall design of the studies, this guidance provides additional recommendations on specific types of products and for specific populations, which are not covered under other guidances. In addition, this guidance provides recommendations on the use of contraception and the duration of its use to minimize the potential risks associated with the use of oncology pharmaceuticals.

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 reproductive toxicity testing and

labeling recommendations for oncology pharmaceuticals. 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 is not a significant regulatory action subject to Executive Order 12866.

##### **II. The Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information that 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 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR 201.56, 201.57, and the final rule “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling” have been approved under OMB control numbers 0910–0572 and 0910–0624.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov/>.

Dated: September 22, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–20906 Filed 9–28–17; 8:45 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

**[Docket No. FDA–2015–D–4644]**

##### **Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization; Guidance for Industry; 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 guidance for industry entitled “Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization.” This guidance finalizes the draft guidance

issued December 23, 2015, which provides recommendations to pharmaceutical companies interested in participating in a program involving the submission of emerging manufacturing technology. The program is open to companies that intend to include the technology as part of a regulatory submission including an investigational new drug application (IND), original or supplemental new drug application (NDA), abbreviated new drug application (ANDa) or biologic license application (BLA), or application-associated Drug Master File (DMF) reviewed by the Center for Drug Evaluation and Research (CDER), and where that technology meets other criteria described in this guidance.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** 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>.

- 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-2015-D-4644 for "Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization." 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.

- **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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Saul L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 2128, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-506-9136; or for further information or to submit requests to participate in the program, please use [CDER-ETT@fda.hhs.gov](mailto:CDER-ETT@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization." FDA is committed to supporting and enabling pharmaceutical innovation and modernization as part of the Agency's mission to protect and promote the public health. While the implementation of emerging technology is critical to advancing product design, modernizing pharmaceutical manufacturing, and improving quality, FDA also recognizes that the adoption of innovative approaches may represent challenges to industry and the Agency.

Issues in pharmaceutical manufacturing have the potential to significantly impact patient care as failures in quality may result in product recalls and harm to patients. Additionally, product failures or facility, equipment, or manufacturing problems are a major factor leading to disruptions in drug supply. Modernizing manufacturing technology may lead to a more robust manufacturing process with fewer interruptions in production, fewer product failures (before or after distribution), and greater assurance that the drug products manufactured in any given period of time will provide the expected clinical performance. Encouraging development of emerging technology may lead to pharmaceutical innovation and modernization, such as a more robust drug product design and improved manufacturing with better process control, thereby leading to improved product quality and availability throughout a product's lifecycle.

In this program, pharmaceutical companies can, prior to the regulatory submission, submit questions and proposals about the use of specific emerging technology to a group within

the FDA Emerging Technology Team (ETT), which includes relevant representation from all FDA pharmaceutical quality functions. The ETT works in partnership with relevant pharmaceutical quality offices and assumes a leadership or co-leadership role for the cross-functional quality assessment team (including review and on-site facility evaluation or inspection) for submissions involving emerging technology.

This guidance finalizes the draft guidance issued December 23, 2015 (80 FR 79907). It provides further clarification on the criteria that the proposed technology needs to meet for its acceptance into the Emerging Technology Program. It also clarifies types of novel technology (e.g., product technology, manufacturing process, and control strategy) that can be covered by the program.

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 advancement of emerging technology applications for pharmaceutical innovation and modernization. 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.

## II. The 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 information to be included in a meeting request for a product submitted in an IND, BLA, or NDA is approved by OMB control number 0910–0429 (“Guidance for Industry on Formal Meetings Between the FDA and Sponsors or Applicants”). Information to be included in a meeting request for a product submitted in an ANDA is approved by OMB control number 0910–0797 (“Guidance on Controlled Correspondence Related to Generic Drug Development”). The submission of INDs under 21 CFR 312.23 is approved by OMB control number 0910–0014; the submission of BLAs under 21 CFR 601.2 and 601.12 is approved by OMB control number 0910–0338; and the submission of NDAs and ANDAs under 21 CFR 314.50, 314.70, 314.71, 314.94, and 314.97 is approved by OMB control number 0910–0001.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 22, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–5315]

#### Antimicrobial 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 Antimicrobial Drugs Advisory 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 November 16, 2017, from 8:30 a.m. to 4 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: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5315. The docket will close on November 15, 2017. Submit either electronic or written comments on this public meeting by November 15, 2017. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or

before November 15, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 15, 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.

Comments received on or before November 1, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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>.

- 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”).

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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–2017–N–5315 for “Antimicrobial Drugs