4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-0944]

Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination; 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 final guidance for industry entitled "Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination." This guidance, developed by the Oncology Center of Excellence at FDA, describes an optional streamlined submission process to determine whether use of an investigational in vitro diagnostic in an oncology clinical trial is considered significant risk, nonsignificant risk, or exempt from investigational device exemption requirements. In the streamlined process, the sponsor submits all information about the oncology trial (including information about the investigational in vitro diagnostic) to the investigational new drug application (IND). As part of IND review, the Center for Biologics Evaluation and Research (CBER) works with the Center for Drug Evaluation and Research (CDER), or CDER or CBER works with the Center for Devices and Radiological Health (CDRH), as appropriate, to determine if the investigational in vitro diagnostic is significant risk, nonsignificant risk, or exempt.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2018-D-0944 for "Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination." 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.

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.

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; the Office of Communication and Education, CDRH-Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Julie Schneider, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2208, Silver Spring, MD 20993, 240-402-4658; Yun-Fu Hu, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5676, Silver

Spring, MD 20993-0002, 301-796-6170; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination." This guidance describes an optional streamlined submission process for determining whether use of an investigational in vitro diagnostic in an oncology clinical trial under an IND (an oncology codevelopment program) is significant risk, nonsignificant risk, or exempt from investigational device exemption requirements.

In the traditional submission process, many sponsors submitted a study risk determination Q-submission to the appropriate center (CDRH or CBER) and an IND to the appropriate center (CBER or CDER). In the streamlined process, all information regarding the oncology codevelopment program (including investigational in vitro diagnostic information) is initially submitted to the IND. CBER or CDER works with CDRH or CDER works with CBER, as appropriate, to determine whether the investigational in vitro diagnostic is significant risk, nonsignificant risk, or exempt. If the investigational in vitro diagnostic in the trial is determined to be significant risk in the streamlined process, the sponsor may need to submit an investigational device exemption to CDRH in addition to submitting an IND to CDER.

This guidance finalizes the draft guidance of the same name issued on April 16, 2018 (83 FR 16366). All public comments received on the draft guidance have been considered, and the guidance has been revised as appropriate along with a few editorial changes. Major changes

from the draft to the final version included adding language to clarify that sponsors will receive significant risk determinations within the 30-day review period for the IND and to clarify that the streamlined submission process only applies to new INDs (not additional protocols added to an existing IND, or IND amendments) and adding the definition of *noninvasive* in 21 CFR 812.3(k) to the glossary.

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 "Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination." 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.

II. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information. 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 809 have been approved under OMB control number 0910-0485. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755. The collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130. The collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586. 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 820 have been approved under OMB control number 0910-0073. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the

collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in the guidance document entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (available at https://www.fda.gov/media/114034/download) have been approved under OMB control number 0910-0756.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, or https://www.regulations.gov.

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-22117 Filed: 10/9/2019 8:45 am; Publication Date: 10/10/2019]