Dated: June 14, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–13103 Filed 6–20–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2275]

Oncology Drug Products Used With Certain In Vitro Diagnostic Tests: Pilot Program; Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff; 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, clinical laboratories, and FDA staff entitled ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program.'' FDA is issuing this guidance to announce and describe FDA's voluntary pilot program for certain oncology drug products regulated by FDA's Center for Drug Evaluation and Research (CDER) used with certain in vitro diagnostic tests. FDA intends to pilot a new approach to provide greater transparency regarding performance characteristics that certain tests for oncology biomarkers should meet. Through this transparency FDA seeks to support better and more consistent performance of certain laboratory-developed tests (LDTs) used to identify patients for treatment with certain oncology drug products, resulting in better drug selection and improved care for patients with cancer. The guidance has been implemented without prior comment, but remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on June 21, 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–2022–D–2275 for ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies of the 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 to the Office of Policy, 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.

FOR FURTHER INFORMATION CONTACT: Brittany Schuck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993–0002, 301–796–5199 or Reena Philip, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6179.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry, clinical laboratories, and FDA staff entitled ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The pilot is intended to provide greater transparency regarding performance characteristics that certain tests for oncology biomarkers should meet. Although this guidance document is being implemented without prior public comment, it remains subject to comment in accordance with FDA's GGP regulation.

An in vitro companion diagnostic test (also known as an in vitro companion diagnostic device) provides information that is essential for the safe and effective use of a corresponding therapeutic product. FDA is issuing this guidance to announce and describe FDA's voluntary pilot program for drug product sponsors with regard to certain CDER-regulated oncology drug products for which FDA determines that use of an in vitro diagnostic test is needed to identify the intended patient population, and corresponding clinical trial assay(s) that use the same technology as a previously FDA-authorized companion diagnostic test for any indication for which there is a well-validated reference method, well-validated comparator method, and/or well-characterized materials that can be used to support test accuracy. This pilot is intended for tests for which FDA believes it is appropriate to extrapolate clinical validity of the test(s) used to select patients in a drug trial to other tests of the same type with similar analytical performance. In this pilot, FDA will evaluate no more than nine sponsors for possible acceptance into the pilot based on evaluation of the factors described in the guidance. Sponsors who are interested in being considered for the voluntary pilot program and who affirm their commitment to provide information set forth in the guidance if FDA subsequently requests that they do so should submit correspondence titled ''Statement of interest in participation in the Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program'' to their Investigational New Drug (IND) applications, New Drug Applications (NDA), or Biologic License Applications (BLA), as appropriate.

Under this pilot, if FDA concludes that the drug product meets the applicable standards for its approval, FDA intends to rely on the same pivotal clinical trial(s) that support approval of the drug product to establish the clinical validity for the clinical trial assays (CTAs) used in those trial(s). Further, FDA intends to recommend minimum analytical performance characteristics for other tests that, when established through properly conducted validation studies, FDA believes would support extrapolation of the clinical validity of the CTA(s) to additional tests of the same type. If FDA approves an oncology drug product enrolled in this pilot program, FDA intends to recommend minimum performance characteristics for in vitro diagnostic tests to identify patients for treatment with those drug products, and make this information publicly available on FDA's website.

The guidance represents the current thinking of FDA on ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program.'' 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. 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 *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.* Persons unable to download an electronic copy of ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 22001 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

For this pilot, FDA will request information from no more than 9 sponsors. Initial statements of interest from sponsors interested in being evaluated for participation in the pilot, as described in the guidance, are not ''information'' in accordance with 5 CFR 1320.3(h)(1). Thus, this guidance contains no new collection of information.

While this guidance contains no new collection of information, to the extent the guidance does refer to previously approved FDA collections of information, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
860, subpart D	De Novo classification process	0910–0844
312	Investigational new drug applications	0910–0014
314	New drug applications	0910–0001
601	Biologic license applications	0910–0338

Dated: June 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13134 Filed 6–20–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2687]

Daylen Diaz: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Daylen Diaz from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Daylen Diaz was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Daylen Diaz was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of February 26, 2023 (30 days after receipt of the notice), Ms. Diaz had not responded. Ms. Diaz' failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable June 21, 2023.

ADDRESSES: Any application by Daylen Diaz for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted as follows:

Electronic Submissions

■ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov*.

■ If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

■ *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–2687. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On October 18, 2022, Ms. Diaz was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Southern District of Florida, Miami Division, when the court accepted her plea of guilty and entered judgment against her for one count of conspiracy to commit mail fraud and wire fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: As contained in the Information, entered into the docket on March 16, 2021, and the Factual Proffer in support of Ms. Diaz' guilty plea, entered into the docket on August 8, 2022, both from her case, Ms. Diaz was a research assistant and assistant study coordinator employed at Tellus Clinical Research, Inc. (Tellus). Tellus was a medical research clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. Sponsor 1 was a drug manufacturer that developed drugs for commercial distribution in the United States. Contract Research Organization 1 (CRO 1) was an organization that hired clinical investigators and managed clinical trials for sponsors. On or about December 23, 2013, CRO 1 entered into a contract with Tellus and one of Ms.