U.S. FOOD & DRUG ADMINISTRATION

March 17, 2022

Dr. Florian Vogel
Chief Process Officer
CENTOGENE GmbH
Am Strande 7
18055 Rostock
Germany

Re: Revocation of EUA202546

Dear Dr. Vogel:

This letter is in response to the request from CENTOGENE US, LLC. ("Centogene"), received on March 14, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CentoSure SARS-CoV-2 RT-PCR Assay issued on September 29, 2020, and amended on August 13, 2021, and September 23, 2021. Centogene indicated that it does not offer this test anymore. FDA understands Centogene and has notified associated laboratories to also stop using this test.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Centogene has notified FDA that it does not offer the CentoSure SARS-CoV-2 RT-PCR Assay anymore and requested FDA revoke the EUA for the CentoSure SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202546 for the CentoSure SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CentoSure SARS-CoV-2 RT-PCR Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Justin Bingham, CENTOGENE US, LLC.

Dated: April 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08230 Filed 4–15–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0430]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and

to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection entitled ''Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.''

DATES: Submit either electronic or written comments on the collection of information by June 17, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 17, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 2022. 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.

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–2019–N–0430 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.'' 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.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control Number 0910–0876—Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role consumers and stakeholders play in ensuring the safety of the food supply,

which helps ensure that suppliers produce food that meets U.S. safety standards.

Occasionally, FDA will need to communicate with consumers and other stakeholders about immediate health issues which could affect public health and safety. This collection of information allows the use of fast-track methods of communication such as quick turnaround surveys, focus groups, and in-depth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health significance. We plan on using these methods of communication to collect vital public health and safety information.

For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information provided by this collection of information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers of FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation will be voluntary.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-depth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
In-depth Interviews, Cognitive Interviews	9	1	9	1	9
In-depth Interviews Screener	900	1	900	0.083 (5 minutes)	75
In-depth Interviews	180	1	180	1	180
Survey Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Survey Cognitive Interviews	9	1	9	1	9
Pretest survey screener	750	1	750	0.083 (5 minutes)	62
Pretest survey	150	1	150	0.25 (15 minutes)	38
Self-Administered Surveys—Study Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys	15,000	1	15,000	0.25 (15 minutes)	3,750
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes)	15
Focus Group/Small Group, Cognitive Groups	60	1	60	1.5 (90 minutes)	90
Focus Group/Small Group Participant Screening	720	1	720	0.083 (5 minutes)	60
Focus Group/Small Group Discussion	240	1	240	1.5 (90 minutes)	360
Total					10,881

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08189 Filed 4–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Ending the HIV/HCV Epidemics in Indian Country: A Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: New.

Funding Announcement Number: HHS–2022–IHS–ETHIC–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: June 17, 2022.

Earliest Anticipated Start Date: August 1, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the Ending the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) Epidemics in Indian Country (ETHIC) program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1621q, 1660e. This program is described in the Assistance Listings located at *https://sam.gov/content/home* (formerly known as the CFDA) under 93.933.

Background

In February 2019, the White House announced a new initiative, Ending the HIV Epidemic in the U.S. (EHE). This 10-year initiative beginning with fiscal year (FY) 2020, seeks to achieve the critical goal of reducing new HIV infections in the United States (U.S.) to less than 3,000 per year by 2030. The first phase of the initiative focuses on 48 counties, Washington, DC, San Juan, Puerto Rico, and seven states with a substantial rural HIV burden. By focusing on these geographic focus areas (see *https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf*) in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within five years. To reduce new HIV infections in the U.S. by 75 percent by 2025 and 90 percent by 2030, EHE focuses on four key strategies that together can end the HIV epidemic in the U.S.: Diagnose, Treat, Prevent, and Respond. In this cooperative agreement, the IHS directs applicants to implement activities specific to strategies one, two, and three: Diagnose, Treat, and Prevent.

EHE is a collaboration of HHS agencies, primarily the Health Resources and Services Administration, the Centers for Disease Control and