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Cover Letter

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Not for Submission



BIO2022P1

OMB No. 2070-0038 Expires 12/31/2025

**EPA Biotech Form****Biotech Form Report Number**Mark (X) if anything is CBI ☒

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

**I. SUBMITTER IDENTIFICATION INFORMATION**CBI ☒

|                                      |                                |           |                                  |             |       |
|--------------------------------------|--------------------------------|-----------|----------------------------------|-------------|-------|
| First Name                           | William                        | Last Name | Brigman                          |             |       |
| Position                             | Not Applicable                 | Company   | CDX Test Org                     |             |       |
| Mailing Address<br>(Number & Street) | 123 Main St                    |           |                                  |             |       |
| City                                 | Virginia Beach                 | State     | VA                               | Postal Code | 23462 |
| e-mail                               | william.brigman@cgifederal.com |           | Telephone<br>(include area code) | 8289191634  |       |

Ia. JOINT SUBMITTER -- If you are submitting this notice as part of a joint submission, mark (X) ☐ CBI ☐

|                                      |  |           |                                  |             |  |
|--------------------------------------|--|-----------|----------------------------------|-------------|--|
| First Name                           |  | Last Name |                                  |             |  |
| Position                             |  | Company   |                                  |             |  |
| Mailing Address<br>(Number & Street) |  |           |                                  |             |  |
| City                                 |  | State     |                                  | Postal Code |  |
| e-mail                               |  |           | Telephone<br>(include area code) |             |  |

**II. TECHNICAL CONTACT IDENTIFICATION INFORMATION**CBI ☒

|                                      |                                |           |                                  |             |       |
|--------------------------------------|--------------------------------|-----------|----------------------------------|-------------|-------|
| First Name                           | William                        | Last Name | Brigman                          |             |       |
| Position                             |                                | Company   | CDX Test Org                     |             |       |
| Mailing Address<br>(Number & Street) | 123 Main St                    |           |                                  |             |       |
| City                                 | Virginia Beach                 | State     | VA                               | Postal Code | 23462 |
| e-mail                               | william.brigman@cgifederal.com |           | Telephone<br>(include area code) | 8289191634  |       |



BIO2022P2

CBI SUBMISSION

## III. TYPE OF SUBMISSION (Check One)

- ☒ MCAN (Microbial Commercial Activity Notice)  
☐ TERA (TSCA Experimental Release Application)  
☐ Tier I Exemption  
☐ Tier II Exemption  
☐ Biotech TME (Test Market Exemption)

## IIIa. TS Number

214513

## IV. TEXT / COMMENTS

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Not for Submission

**V. FEES CERTIFICATION**

If you are submitting a MCAN, Tier II Exemption, TERA, or Biotechnology TME, check the following Fees Certification statement that applies:

- ☐ The Company named in Part I is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee as specified in 40 CFR 700.45(c).
- ☒ The Company named in Part I will remit the fee as specified in 40 CFR 700.45(c).
- ☐ This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).
- ☐ The company named in Part I is submitting a sustainable futures TME. The company has graduated from EPA's Sustainable Futures program and is therefore exempt from fees for this sustainable futures TME.

**I certify that to the best of my knowledge and belief:**

**The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.**

Confidential

Signature and title of  
the Authorized Official  
(Original Signature  
Required)

ES/William K Brigman

Date

12/19/2022

☒



## LIST OF ATTACHMENTS

[illegible]

Mark (X) this box if the data continues on the next page.

|  |  |
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BIO2022P5

## Continuation Sheet

| ID                        |  | Field |  |
|---------------------------|--|-------|--|
| <p>Not for Submission</p> |  |       |  |



## CBI Substantiation

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

1. Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be substantial? Why is the substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information rather than just possible? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

2. Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

Yes/No: Yes

Cbi: Yes

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

3A. Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

Yes/No: Yes

Cbi: Yes

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

3B. Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential. If this chemical is patented and the patent reveals the information you are claiming confidential, please explain your reasons for believing the information is nonetheless still confidential.

Yes/No: Yes

Cbi: No

test





**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

4. Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1 and 10 years) or the specific date after which the claim is withdrawn.

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

5. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this microorganism? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

1. Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported into US commerce? If not, explain why the microorganism identity should still be afforded confidential status (e.g., the microorganism is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the microorganism in the United States is publicly available).

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Chemical ID

2. Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? If yes, please explain what measures have been taken to guard against the discovery of its identity. Further, what is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

Yes/No: Yes

Cbi: No

test



## CBI Substantiation

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Submitting Official Information

1. Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be substantial? Why is the substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information rather than just possible? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A **Selected Chemical**

**Claim:** Submitting Official Information

2. Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

Yes/No: Yes

Cbi: Yes

test

**Selected Chemical Identifier:** N/A **Selected**

**Chemical Claim:** Submitting Official Information

3A. Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

Yes/No: Yes

Cbi: Yes

test

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim:** Submitting Official Information

3B. Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential. If this chemical is patented and the patent reveals the information you are claiming confidential, please explain your reasons for believing the information is nonetheless still confidential.

Yes/No: Yes

Cbi: No

test



BIO2022P5

CBI SUBMISSION

**Selected Chemical Identifier:** N/A

**Selected Chemical Claim: Submitting Official Information**

4. Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1 and 10 years) or the specific date after which the claim is withdrawn.

Yes/No: Yes

Cbi: No

test

**Selected Chemical Identifier:** N/A **Selected**

**Chemical Claim: Submitting Official Information**

5. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this microorganism? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

Yes/No: Yes

Cbi: No

test