

Inspection Report

Ricerca Biosciences LLC	Customer ID:	254
7528 Auburn Road	Certificate:	31-R-0091
Concord Twp, OH 44077	Site:	001
	RICERC	CA BIOSCIENCES LLC
	Type:	ROUTINE INSPECTION
	Date:	26-APR-2017

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility representatives.

Prepared By:				Deter
	NEAFSEY MICHAEL	USDA, APHIS, Anima	al Care	Date: 26-APR-2017
Title:	VETERINARY MEDICAL	OFFICER 6094		
Received By:				
	(b) (6), (b) (7)	(C)		Date:
Title: 19-04394	IACUC CHAIR			26-APR-2017
		Page 1 of 1	Obtained by Rise for	Animals. Uploaded 07/09/2020



United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 254 Inspection Date: 26-APR-17

Animal Inspected at Last Inspection

Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENCES LLC	26-APR-17

Count	Species
000022	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
000124	DOG ADULT
000146	Total



Inspection Report

Customer ID:	254
Certificate:	31-R-0091
Site:	001
CONCC	ORD BIOSCIENCES LLC
Туре:	ROUTINE INSPECTION
Date:	18-SEP-2018
	Certificate: Site: conco Type:

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility representatives.

Prepared By:	CROWLEY LACY, D V M	USDA, APHIS, A	nimal Care	Date:
Title:	VETERINARY MEDICAL OF			18-SEP-2018
Received By:				
Titler	(b) (6), (b) (7)(C) IACUC CHAIR			Date: 18-SEP-2018
Title: 19-04394	_000003	Page 1 of 1	Obtained by Rise fo	r Animals. Uploaded 07/09/2020



United States Department of Agriculture Animal and Plant Health Inspection Service Customer: 254 Inspection Date: 18-SEP-18

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENCES LLC	18-SEP-18
Count	Scientific Name		Common Name	
000235	Canis lupus familia	aris	DOG ADULT	
000021	Macaca fascicular	is	CRAB-EATING MACAQUE	/ CYNOMOLGUS MONKEY
000003	Sus scrofa domes	tica	DOMESTIC PIG / POTBELL	Y PIG / MICRO PIG

000259 Total



Inspection Report

Frontage Labs	Customer ID:	254
10845 Wellness Way	Certificate:	31-R-0091
Concord Twp, OH 44077	Site:	001
	CONCC	ORD BIOSCIENSES LLC
	Туре:	FOCUSED INSPECTION
	Date:	29-MAY-2019

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility staff including the attending veterinarian and IACUC Chair.

Prepared By:				
	CROWLEY LACY, D V M	USDA, APHIS, A	Animal Care	Date: 29-MAY-2019
Title:	VETERINARY MEDICAL OF	FICER 6122		
Received By:				
	(b) (6), (b) (7)(C)			Date:
Title: 19-04394				29-MAY-2019
19-04394	_000003	Page 1 of 1	Obtained by Rise fo	r Animals. Uploaded 07/09/2020



United States Department of Agriculture Animal and Plant Health Inspection Service Customer: 254 Inspection Date: 29-MAY-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENSES LLC	29-MAY-19
Count	Scientific Name		Common Name	
000164	Canis lupus familia	aris	DOG ADULT	
000061	Macaca fascicular	is	CRAB-EATING MACAQUE	/ CYNOMOLGUS MONKEY
000029	Sus scrofa domes	tica	DOMESTIC PIG / POTBELI	LY PIG / MICRO PIG
000054	T - 4 - 1			

000254 Total

Research Facility Protocol Selection Worksheet

Legal Name Ricerca Biosciences, LLC

Customer	Number	254	
customer.	Number:		

Certificate Number: 31-R-0091

Inspection Date: 04/26/2017

Site Number:_____001

Inspector: Michael Neafsey

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols (select all)	0
 Protocols with IACUC-approved exemptions/exceptions (select all) 	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
 5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance): 	3
Total Protocols Selected and Reviewed	3

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Research Facility Protocol Selection Worksheet

Legal Name:	Frontage Labs
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Customer Number: ²⁵⁴	Certificate Number: ^{31-R-0091}	Site Number: ¹

Inspection Date: 5/29/19

Inspection Type: Routine

Animals

Inspector: Lacy Crowley DVM

Reasor	s Protocols Were Selected for Review :	How Many Protocols Were Selected
1.	Protocols identified during inspection of concern (select all)	0
2.	Column E protocols (select all)	0
3.	Protocols with IACUC-approved exemptions/exceptions (select all)	0
4.	Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5.	 Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: Protocol for each regulated species and/or, Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance): 	0
Тс	otal Protocols Selected and Reviewed	0

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Version 2/11/19



April 21, 2017

Elizabeth Goldentyer, DVM Director – Animal Care, Eastern Region United States Department of Agriculture Animal and Plant Inspection Service 920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: Appointment of Temporary Attending Veterinarian (31-R-0091)

Please be advised that Dr. (b) (6), (b) (7)(C) has left employment at Ricerca Biosciences. We have instituted a search for a new full time veterinarian and will notify you when we have filled the position. In the interim, Dr. (b) (6), (b) (7)(C) DVM, Ph.D., an existing member of the IACUC Committee, has been appointed by (b) (6), (b) (7)(C) IO, as temporary Attending Veterinarian.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,





JUN 27 2017

Concord Biosciences 10845 Wellness Way Concord, OH 44077

June 22, 2017

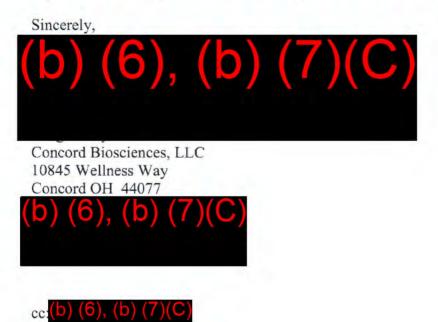
Elizabeth Goldentyer, DVM Director – Animal Care, Eastern Region United States Department of Agriculture Animal and Plant Inspection Service 920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: New name and address - 31-R-0091

Please be advised Ricerca Biosciences, LLC has changed its name to Concord Biosciences, LLC. Although our physical location has not changed the address has changed to 10845 Wellness Way, Concord, OH 44077. The main telephone number has changed to 440-357-3200. These changes were made due to a split of our Chemical and Drug Safety Divisions.

If you have further questions or concerns, please don't hesitate to contact me.

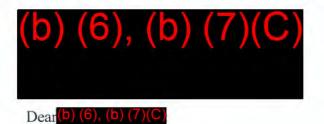


*Please note email address has not changed yet.

JUN 27 2017

Concord Biosciences 10845 Wellness Way Concord, OH 44077

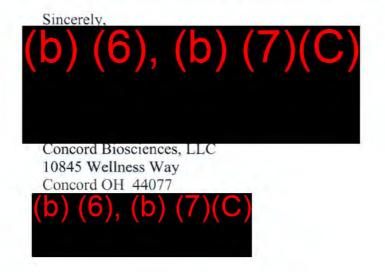
June 22, 2017



SUBJECT: New name and address - 000850

Please be advised Ricerca Biosciences, LLC has changed its name to Concord Biosciences, LLC. Although our physical location has not changed the address has changed to 10845 Wellness Way, Concord, OH 44077. The main telephone number has changed to 440-357-3200. These changes were made due to a split of our Chemical and Drug Safety Divisions.

If you have further questions or concerns, please don't hesitate to contact me.



cc: Clifford Croley, IO.

*Please note that email address has not changed yet.



United States Department of Agriculture

Marketing & Regulatory Programs Business Services

Animal and Plant Health Inspection Service

Animal Care

920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213 Tel. 919-855-7100 Fax: 919-855-7123 RE: ACKNOWLEDGE REMOVAL OF SITE Certificate Number: 31-R-0091 Anniversary Date: 07/17/2017

> July 12, 2017 Customer ID Number: 254

Concord Biosciences Llc 10845 Wellness Way Concord Twp, OH 44077

Dear Registrant:

As you requested, site(s) number 001 has been removed from your Animal Welfare Act (AWA) registration. We understand that this site is no longer being used for activities covered under the AWA.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (919) 855-7100 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Elizabeth Goldentyer, D. V. M. Director, Animal Welfare Operations USDA, APHIS, Animal Care

cc: Diane R Forbes cc: Lacy Crowley



Safeguarding American Agriculture APHIS is an agency of USDA's Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration. U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE APPLICATION FOR REGISTRATION (TYPE OR PRINT) REGISTRATION UPDATE		5	OMB No. 0579-0036 FORM APPROVED	
		USDA USE ONLY Applicant should send completed form to this address. USDA APHIS ANIMAL CARE EASTERN 920 Main Campus Drive Suite 200 Raleigh, NC 27606-5210 (919) 855-7100 JUL 1 2017		
		CERTIFICATE NO./CUST No 31-R-0091 254	0: RENEWAL DATE 17-Jul-2017	
REGISTRANT (Name and permanent mailing add	Iress including Zin Code)	2. LOCATION (S) OF BUSINESS, EXHIBITION		
oncord Biosciences LLC 0845 Wellness Way oncord, OH 44077 OUNTY: LAKE TELEPHONE (440) 357 - (A) PREVIOUS USDA REGISTRATION NUMBER (3200 IF ANY)	(Use additional sheets if necessary) Concord Biosciences LLC 7528-Auburn Road 6843 Concord, OH 44077 County: Lake 4. (B) ACTIVE USDA CERTIFICATE NUMBER 31-R-0091	R(S) IN WHICH YOU HAVE AN INTEREST:	
ARE YOU USING FEDERAL FUNDS TO CARRY C RESEARCH, TESTS, OR EXPERIMENTS				
X Yes No	1		Intermediate Handler	
	Class R	- Research Facility Class I -	Carrier	
EDERAL FUND TYPES:	8. TYPE OF OR	- Research Facility Class T - GANIZATION:	Carrier	
🛇 Award 🚿 Contract 🛇 Gran	t 🗘 Loan 🔅 Other (GANIZATION: ship 🎉 Corporation Specify)	♦ Individual	
Award St Contract Gran	t 🗘 Loan 🔅 Other (GANIZATION: ship	♦ Individual	
Award Contract Gran	8. TYPE OF OR 8. TYPE OF OR Partner Other (WNER, IF PARTNERSHIP IDENTIFY EACH PA	GANIZATION: ship	Individual PRINCIPAL	
Award Contract Gran	8. TYPE OF OR 8. TYPE OF OR 9 Partner Other (WNER, IF PARTNERSHIP IDENTIFY EACH PA TIES INCLUDE THE INSTITUTIONAL OFFICIAL	GANIZATION: ship <i>K</i> Corporation Specify) RTNER OR OFFICER, IF CORPORATION, IDENTIFY . (Use separate sheet if needed)	Individual PRINCIPAL	
9. IF INDIVIDUAL IDENTIFY EACH OF	8. TYPE OF OR 8. TYPE OF OR 9 Partner Other (WNER, IF PARTNERSHIP IDENTIFY EACH PA TIES INCLUDE THE INSTITUTIONAL OFFICIAL	GANIZATION: ship <i>K</i> Corporation Specify) RTNER OR OFFICER, IF CORPORATION, IDENTIFY . (Use separate sheet if needed)	Individual PRINCIPAL	
Award Contract Gran	8. TYPE OF OR 8. TYPE OF OR Partner Other (WNER, IF PARTNERSHIP IDENTIFY EACH PA TIES INCLUDE THE INSTITUTIONAL OFFICIAL B. TITLE	SANIZATION: ship Corporation Specify TRINER OR OFFICER, IF CORPORATION, IDENTIFY (Use separate sheet if needed) C. ADDRESS (full addres) C. ADDRESS (full addres)	PRINCIPAL	
Award Contract Gran	B. TYPE OF OR S. TYPE OF OR Other (Other (WNER, IF PARTNERSHIP IDENTIFY EACH PA Inss INCLUDE THE INSTITUTIONAL OFFICIAT B. TITLE D. TITLE CERTIFIC ier, or Intermediate Handler under the Animal We pt of and agree to comply with all the regulations	SANIZATION: ship Corporation Specify TNNER OR OFFICER, IF CORPORATION, IDENTIFY (Use separate sheet if needed) C. ADDRESS (full addres) C. ADDRESS (full addres)	Individual PRINCIPAL ss, including ZIP Code) formation provided herein is true and correct t	

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(FEB 2009)	

ACKNOWLEDGEMENT OF RECEIPT OF REGULATIONS AND STANDARDS



United States Department of Agriculture

Marketing & Regulatory Programs Business Services

Animal and Plant Health Inspection Service

Animal Care

920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213 Tel. 919-855-7100 Fax: 919-855-7123 (b) (6), (b) (7)(C) Concord Biosciences Llc

10845 Wellness Way Concord Twp, OH 44077

Dear Registrant:

Thank you for notifying us of your need for an additional site under your Animal Welfare Act (AWA) registration. The new Site(s) numbered 001 has been added to your current registration.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (919) 855-7100 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Elizabeth Goldentyer, D. V. M. Director, Animal Welfare Operations USDA, APHIS, Animal Care

cc: Diane R Forbes cc: Lacy Crowley

Enclosures



Safeguarding American Agriculture APHIS is an agency of USDA's Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer

RE: ACKNOWLEDGE NEW SITE Certificate Number: 31-R-0091 Renewal Date: 07/17/2017

> July 12, 2017 Customer ID Number: 254

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration. U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE APPLICATION FOR REGISTRATION (TYPE OR PRINT) REGISTRATION UPDATE				lo. 0579-0036 APPROVED
		USDA USE ONLY Applicant should send completed form to this address. USDA APHIS ANIMAL CARE EASTERN 920 Main Campus Drive Suite 200 Raleigh, NC 27606-5210 (919) 855-7100 JUL 11 2017		
		CERTIFICATE NO./CUS 31-R-0091 254	17-Jul-2017	20208
I. REGISTRANT (Name and permanent mailing address, including Zip Code))	2. LOCATION (S) OF BUSINESS, EXHIB		-
Concord Biosciences LLC 10845 Wellness Way Concord, OH 44077 COUNTY: LAKE TELEPHONE (440) 357 - 3200 3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)		(Use additional sheets if necessary) Concord Biosciences LLC 7528 AUBUM ROAD Concord, OH 44077 County: Lake 4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST: 31-R-0091		
5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT	6. TYPE OF REGIS			
RESEARCH, TESTS, OR EXPERIMENTS	Class E -	Exhibitor 🔷 Class	s H – Intermediate Han s T - Carrier	dler
7. FEDERAL FUND TYPES:	8. TYPE OF ORGA			
Award 🕅 Contract 🛇 Grant 🛇 Loan	 Partnersh Other (Sp 		Individual	
9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTIT	IDENTIFY EACH PART	NER OR OFFICER, IF CORPORATION, IDE	NTIFY PRINCIPAL	
	ITLE		II address, including ZIP Code)	

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C.. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older,

DATE SIGNED

-Joly -2017





August 1, 2017

Elizabeth Goldentyer, DVM Director – Animal Care, Eastern Region United States Department of Agriculture Animal and Plant Inspection Service 920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213

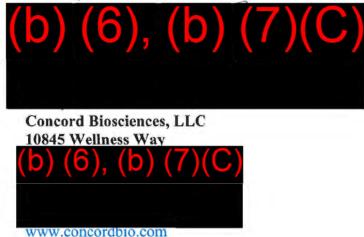
Dear Dr. Goldentyer:

SUBJECT: Appointment of New Attending Veterinarian (31-R-0091)

Please be advised that Dr.(b)(6), (b)(7)(C) has been appointed Attending Veterinarian of Concord Biosciences effective August 1st, 2017. Dr.(b)(6), (b)(7)(C) DVM, Ph.D., will step down as temporary AV but remain an existing member of the IACUC Committee.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,





Thank you

William (Dan) Austin Inspection & Licensing Assistant

USDA-APHIS-AC 2150 Centre Ave Building B, Mailstop 3W11 Fort Collins, CO 80526-8117 970-494-7463

From: Crowley, Lacy A - APHISSent: Wednesday, September 19, 2018 7:06 AMTo: ACEAST <ACEAST@aphis.usda.gov>Subject:

Dear ACEast, Registrant 254 Concord Bioscience has had some changes to their IO and other contact personnel. The new IO is: (b) (6), (b) (7)(C)

Executive VP 10845 Wellness Way Concord, OH (b) (6), (b) (7)(

Also (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) are no longer with the company and should be removed. Please let me know if there are any questions or concerns. Sincerely, Lacy Crowley DVM 984-209-9464

Get Outlook for iOS



Elizabeth Goldentyer, DVM Director – Animal Care, Eastern Region United States Department of Agriculture Animal and Plant Inspection Service 920 Main Campus Drive, Suite 200 Raleigh, NC 27606-5213

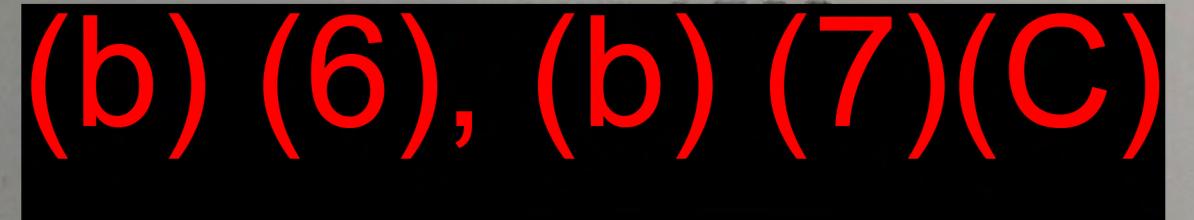
Dear Dr. Goldentyer:

SUBJECT: New name – 31-R-0091

Please be advised Concord Biosciences, LLC has been purchased by Frontage Laboratories in Exton, PA. and are changing our name to Frontage Labs effective with this communication. Our physical location and address remain the same. The main telephone number is still 440-357-3200. If you have further questions or concerns, please don't hesitate to contact me.

Sincerely, (b) (6), (b) (7)(C)

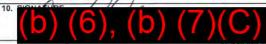
Frontage Laboratories 10845 Wellness Way Concord OH 44077



cc: Abdul Mutlib, IO.

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provide information for such registration.	s OMB No. 0579-0036 FORM APPROVED		
U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE APPLICATION FOR REGISTRATION (TYPE OR PRINT)	USDA USE ONLY Applicant should send completed form to this address. USDA APHIS ANIMAL CARE EASTERN 920 Main Campus Drive Suite 200 Raleigh, NC 27606-5210 (919) 855-7100 JUL 1 1 2017		
REGISTRATION UPDATE	CERTIFICATE NO./CUST NO: RENEWAL DATE 31-R-0091 17-Jul-2017 254 17 Jul-20208		
REGISTRANT (Name and permanent mailing address, including Zip Code) oncord Biosciences LLC 0845 Wellness Way oncord, OH 44077 DUNTY: LAKE TELEPHONE (440) 357 - 3200 (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)	2. LOCATION (S) OF BUSINESS, EXHIBITION SITE(S), OR RESEARCH FACILITIES (Use additional sheets if necessary) Concord Biosciences LLC 7528 AUDUM ROAD 6845 WLCMASS WAY Concord, OH 44077 County: Lake 4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST: 31 - R = 0091		
FEDERAL FUND TYPES: 8. TYPE OF ORC Award Award Contract Federal Function Federation	- Exhibitor Class H - Intermediate Handler - Research Facility Class T - Carrier SANIZATION: ship Corporation Individual		
Other (S IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PAR OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL			
NAME B. TITLE	C. ADDRESS (full address, including ZIP Code)		

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq, and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older.



12. DATE SIGNED 5-Joly-2017

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United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Animal Care

EXPIRATION DATE: JULY 17, 2020

This is to certify that

CONCORD BIOSCIENCES LLC

is a registered under the

CLASS R RESEARCH FACILITY

Animal Welfare Act

(7 U.S.C. 2131 et seq.)

Certificate No.

31-R-0091

Customer No. 254

254

Deputy Administrator

000020

APHIS FORM 7021 (NOV 99)

Previous editions are obsolate.