

Annual Report to OLAW

Institution:	U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition
Assurance Number:	A4294-01
Reporting Period:	October 1, 2020, through September 30, 2021

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes *[Select A or B]*

- ☐ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. *[Skip to Item II.]*
- ☒ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period.

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed ([PHS Policy IV.A.2.](#)).
- ☐ [AAALAC Accredited](#) – Category 1
- ☐ Non-Accredited – Category 2
- ☒ This institution's program for animal care and use has changed ([PHS Policy IV.A.1.a-i.](#)). *[Attach a full description of the changes.]*
- ☒ The individual designated by this institution as the Institutional Official has changed. *[Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]*
- ☒ The membership of this institution's IACUC has changed. *[Provide current roster of members in Item VI.]*

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. *[Do not provide semiannual reports unless they include a minority view.]*

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6-month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.]

Date 1:	October 6, 2021	Date 2:	
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There was a delay in between the establishment of a new committee due to delay in authority transfer to appoint new members. Therefore, only one program inspection was conducted. There were no live animal or protocols in place during this period.

B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6-month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]

Date 1: See waiver	Date 2: See waiver
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A facility waiver has been granted due to facility access restrictions (see attachment).

III. Minority Views *[Select A or B]*

- ☒ A. There were **no minority** views during this reporting cycle.
- ☐ B. Any minority views submitted by members of the IACUC regarding reports filed under [PHS Policy IV.F.](#) for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	Institutional Official
Name: (b) (6)	Name: (b) (6)
Signature: (b) (6) <small>Date: 2021.11.04 09:11:57 -05'00'</small>	Signature: (b) (6) <small>Date: 2021.11.04 09:18:23 -05'00'</small>
Date: 11/14/2021	Date: 11/14/2021

V. Change in Institutional Official

Name: (b) (6)	
Title: Director, Division of Seafood Science and Technology	Degree/Credentials: Ph.D.
Name of Institution: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition	
Address: (b) (6)	
Phone: (b) (6)	Fax: (b) (6)
E-mail: (b) (6)	

IX. Membership of the IACUC

Date: April 26, 2022			
Name of Institution: FDA Center for Food Safety and Applied Nutrition			
Assurance Number: A4294-01			
IACUC Chairperson			
Name*: (b) (6)			
Title*: Research Microbiologist		Degree/Credentials*: Ph.D.	
Address*: (street, city, state, zip code) (b) (6)			
E-mail*: (b) (6)			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)	D.V.M., Ph.D.	Attending Veterinarian	Attending Veterinarian
	M.S.	Research Pharmacologist	Vice Chairperson, Scientist
	B.S.	Facilities Manager	Facility Manager, Nonscientist
	M.S.	Safety Officer	Safety Officer, Scientist
	M.S.	Mathematical Statistician	Statistician, Scientist
	M.S.	Quality Assurance Specialist	IACUC Administrator, nonvoting member
	B.A., MBA	Director at Mobile Bay National Estuary Program	Alternate Nonaffiliated Member, Nonscientist
	B.S.	Biologist	Scientist Member, Scientist
	D.V.M., M.S.	Veterinary Medical Officer at National Oceanic and Atmospheric Administration (NOAA)	Alternate Veterinarian
Ph.D. (Integrated Ecology)	Assistant Extension Professor (Oil Spill Extension Specialist)	Nonaffiliated Member, Scientist	

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must

be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** [PHS Policy](#) Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

Annual report to OLAW 2021

U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition

Assurance Number: D16-00650 (A4294-01)

Reporting Period: October 1, 2020, through September 30, 2021

I. Program Changes

Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period.

On January 1, 2021, (b) (6) Ph.D., Research Microbiologist, replaced (b) (6) (b) (6) as the Chairperson for the CFSAN. Additionally, (b) (6), Ph.D. was appointed Institutional Official, replacing (b) (6) DVM, Ph.D., DACVPM. The CFSAN Animal Care and Use program and research facility is now located at the Gulf Coast Seafood Laboratory (GCSL) (Dauphin Island, AL).

The animal facility at (b) (6) is no longer being used to conduct live animal research and therefore all research under the CFSAN Animal Care and Use program and IACUC will be performed at the (b) (6). To reflect these changes, a new committee was formed on August 3, 2021. Major changes to the animal research program include a focus of research on aquatic animals and a discontinuation of radioactive materials in research. A semi-annual program review was performed as soon as this newly formed committee met on October 6, 2021.

Changes in Membership of this Institution's IACUC:

(b) (6) is now the Chairperson of the CFSAN IACUC, (b) (6) is the Vice-chairperson, (b) (6) is the Institutional Official. Additional new committee members are: (b) (6) (Attending Veterinarian), (b) (6) (Facility Manager), CAPT (b) (6) (Safety Officer), (b) (6) (Statistician), (b) (6) (IACUC Administrator), (b) (6) (Community Member), (b) (6) (Scientist Member), and (b) (6) (Alternative Community Member).

B. Facility Inspections

Due to COVID, access to facility was restricted in 2021. A facility inspection waiver was granted to the CFSAN Animal Care and Use program on February 11, 2021 and until access to facility has been restored. Semi-annual facilities inspection for (b) (6) will be conducted once personnel are able to safely return to the laboratory

IX. Membership of the IACUC

Date: April 26, 2022			
Name of Institution: FDA Center for Food Safety and Applied Nutrition			
Assurance Number: A4294-01			
IACUC Chairperson			
Name*: (b) (6)			
Title*: Research Microbiologist		Degree/Credentials*: Ph.D.	
Address*: (street, city, state, zip code) (b) (6)			
E-mail*: (b) (6)			
Phone*: (b) (6)		Fax*: (b) (6)	
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Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
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	M.S.	Mathematical Statistician	Statistician, Scientist
	M.S.	Quality Assurance Specialist	IACUC Administrator, nonvoting member
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XI. Facility and Species Inventory

Date: April 4, 2022			
Name of Institution: CFSAN			
Assurance Number: A4294-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [<i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i>]	Approximate Average Daily Inventory
(b) (6)	150	NA**	0

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

** Only fieldwork is performed under this assurance and no live species are housed in the facility.