Annual Report to OLAW

Institution: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition
Assurance Number: D16-00650 (A4294-01)
Reporting Period: January 1, 2018 through December 31, 2018

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
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- [] 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.]
- [x] B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. (FAQ 6)

Select all that apply:

[]	This in	stitution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).
		[]	AAALAC Accredited - Category 1

- [] Non-Accredited Category 2
- [x] 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.]
- [x] 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: April 17, 2018	Date 2: October 16, 2018
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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: April 18, 2018	Date 2: October 16 & 17, 2018

III. Minority Views [Select A or B]

- [x] A. There were **no minority** views during this reporting cycle.
- [] B. Any minority views submitted by members of the IACUC regarding reports filed under <u>PHS</u> <u>Policy IV.F.</u> for this reporting cycle are attached.

IV. Signatures

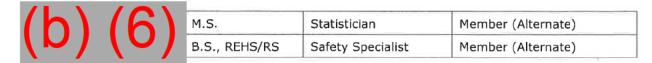
IACUC Chairperson	Institutional Official
Name: (b) (6)	Name: Mary E. Torrence, D.V.M., Ph.D., DACVPM
Signature: (b) (6) Date: 2/6/1	Signature: 7 orrence Date: 2/6/2019

V. Change in Institutional Official

Name: Mary E. Torrence, D.V.M., Ph.D., DACV	ame: Mary E. Torrence, D.V.M., Ph.D., DACVPM		
Title: Director, Office of Applied Research and Safety Assessment (OARSA)	Degree/Credential: D.V.M., Ph.D., DACVPM		
Name of Institution: U.S. Food and Drug Administration	stration, Center for Food Safety and Applied		
Address: [street, city, state, zip code]			
Center for Food Safety and Applied Nutrition Food and Drug Administration MOD-1 (b) (4)			
E-mail: mary.torrence@fda.hhs.gov			
Phone: (b) (6)	_{Fax} (b) (6)		

VI. Change in IACUC Membership [Current roster]

Institution: U.S. Food	d and Drug Adminis	stration	, Center for Food Safe	ety and Applied Nutrition
IACUC Contact Info	rmation			
Address: [street, city,	state, zip code]			
Center for Food Safety Food and Drug Admini MOD-1 (b) (4)		ion		
E-mail: : mary.torrenc	e@fda.hhs.gov			
Phone: (b) (6)			Fax: (b) (6)	
IACUC Chairperson				
Name:(b) (6)	M.S.			
Title: Research Pharm	acologist		Degree/Credentials:	M.S.
PHS Policy Membershi	p Requirements***:			
IACUC Roster [Providence]	de below or attach]			
Name of Member/	Degree/ Credential	00	sition Title/ cupational ckground**	PHS Policy Membership Requirements***
(h) (R	D.V.M.	Attending Veterinarian		Attending Veterinarian
(D) (O	Ph.D ₆		search crobiologist	Vice Chairperson
	B.S.	Retired Microbiologist		Nonaffiliated Member
	R.N., M.S.		rse/Informatics	Nonaffiliated Member
B.S. LATG			cilities/Animal ogram Manager	Member
	R.N.	Biosafety Officer		Member
	Ph.D.	Sta	atistician	Member
	B.S.	Bio	ologist	Scientist Member representing GCSL
	B.A.	Mi	crobiologist	Scientist Member representing Moffett Center
	B.S.		pervisory Facilities ecialist	Nonscientist Member
	Ph.D.	Research Biologist		Scientist Member
	Ph.D.	Research Microbiologist		Scientist (Alternate)
	LATG	Ex	ecutive Secretary	Non-voting Member
	M.S.	Po	st Approval Monitor	Non-voting Member
	B.S.	Bio	ologist	Scientist (Alternate)
	B.S.	Bio	ologist	Scientist (Alternate)



^{*} Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report 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.

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.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (for example,

ethicist, lawyer, member of the clergy).

Nonaffiliated 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.]

^{**} 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. 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 May 24, 2018, Mary Torrence, D.V.M., Ph.D., DACVPM, Director of the Office of Applied Research and Safety Assessment (OARSA) replaced Steven Musser, Ph.D., Deputy Director for Scientific Operations, as the Institutional Official (IO) of the CFSAN Animal Research Program. The Director of OARSA reports directly to the Deputy Director for Scientific Operations. The IO has authority over all three CFSAN animal research facilities located at MOD-1(b) (4)

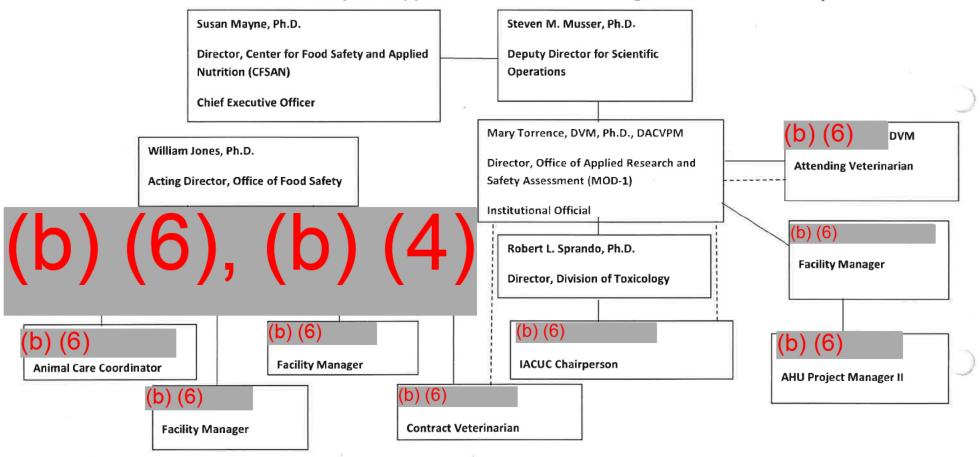
Changes in Membership of this Institution's IACUC:

(b) (6)
are no longer on the IACUC.
(b) (6)
afety Specialist has been added as an alternate member.

B. Facility Inspections

The main CFSAN animal facility (MOD-1) inspections were done April 18, 2018 and October 16 and 17, 2018. The (b) (4) inspection was conducted April 12, 2018 and October 11, 2018. The (b) (4) inspections were done April 19, 2018 and October 12, 2018. There has been no animal activity at (b) (4) since March 2010.

Center for Food Safety and Applied Nutrition Animal Program Lines of Authority



Changes indicated in red. The IACUC Chair and Attending Veterinarian have direct lines of communication with the IO: