Name: Contrafect Corporation [A248]

FOR OF	FICE USE ONLY
Recd Code	A248

NEW YORK STATE DEPARTMENT OF HEALTH WADSWORTH CENTER LABORATORY ANIMAL WELFARE PROGRAM **EMPIRE STATE PLAZA, P.O. BOX 509 ALBANY, NEW YORK 12201-0509**

2019 RENEWAL APPLICATION FOR APPROVAL FOR USE OF LIVING ANIMALS

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Laboratory/Institution Name:	
Contrafect Corporation	
Address 1:	
28 Wells Avenue	
Address 2:	
3rd Flr	
City, State, Zipcode:	
Yonkers, NY 10701	·
County:	
Westchester	
Telephone Number:	
914-207-2300	· · · · · · · · · · · · · · · · · · ·
Fax Number:	
914-207-2399	
E-mail Address:	
ksauve@contrafect.com	

AW-APP01(10/2007)

FECENCED HOW 19 2018 HOW 19 2018 **Uploaded to Animal Research Laboratory Overv** w (ARLO) on 07/13/2021

Rise for Animals

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

Ownership:				
Ø Corporation □ Other:	□ Government	🗆 Individual	Not For Profit	□ Partnership
Facility Type:				
□ 2 Year College □ Hospital □ Public Health L □ Other:		4 Year College Medical School Research & Develo		or Environmental Lab Testing Lab ry School

SECTION II - PROGRAM INFORMATION

Animals (Check all that app	oly):		
□ Mice (wild or other) □ C ⊠ Rats (genus rattus) □ F	lamsters Guinea Pigs Rabbits Small Birds	□ Fish □ Cats □ Dogs □ Non-Human Pr	□ Sheep/Goats □ Cattle □ Swine imates □ Poultry
Are you currently housing liv	e animals at your	institution?	⊠ No
If you are not currently h having live animals in yo	ousing live animal ur facility during th	s, do you anticipate ne next 12 months?*	🛚 Yes 🗆 No
*LAWP permits are issued to th animals for teaching and/or rea and facilities to properly and h	search and have the a	ppropriate programs	
Does your laboratory/institut (If Yes, attach a copy of the Committee n	ion have an Anima ^{nembers})	al Care Committee?	🖾 Yes 🗆 No
Since your last application, l animal care and use proced control, environmental mana (If Yes, please explain)	ures (i.e. feeding	programs, disease	□ Yes ⊠ No
Note: Any procedures that r water or exposing the conditions should be protocols and approve	animals to advers documented in yo	se or unusual ur animal use	
Living animals are used for	or (Check all that	apply):	
 Diagnostic Procedures Experimentation Public Display Other: 		🗆 🗆 Farm Producti	iching Demonstrations on Disease Survellience
Are animals used in studies (If Yes, attach a copy of your procedure	with human infec	tious agents?	es 🗆 No
Registration/Accreditation	п Туре:		
□ AAALAC Accredited □ Other:		-	⊠ None
AW-APP01(10/2007)			

SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE		
Laboratory/Institution Person In Charge (Name):			
Gilman, Steven C.			
Title:			
Chairman & CEO			
Telephone Number:			
914-207-2301			
317-201-2001			
Work Hours:	Work Hours:		
work hours.			
MON: 9:00 am to 6:00 pm	Mon: to		
TUE: 9:00 am to 6:00 pm	Tue: to		
WED: 9:00 am to 6:00 pm	Wed: to		
THU: 9:00 am to 6:00 pm	Thu: to		
FRI: 9:00 am to 6:00 pm	Fri: to		
to	Sat: to		
to	Sun: to		
CURRENT DATA	INDICATE CHANGES HERE		
Veterinarian in Charge (Name):			
Rasmussen, Skye			
Title:			
DVM	•		
Telephone Number:			
212-327-8553			
Work Name/Address (if different from laboratory/institution):			
Rockefeller University			
1230 York Avenue	· · ·		
Box 2			
New York, NY 10065			
Work Hours:	Work Hours:		
MON: 9:00 am to 5:00 pm	Mon: to		
TUE: 9:00 am to 5:00 pm	Tue: to		
WED: 9:00 am to 5:00 pm	Wed: to		
THU: 9:00 am to 5:00 pm	Thu: to		
FRI: 9:00 am to 5:00 pm	Fri: to		
to	Sat: to		
to	Sun: to		

SECTION III - PERSONNEL INFORMATION

CURRENT DATA			URRENT DATA	IN	DICATE CHANGES HERE
Contac	t Person (N				
	Karen L.				
Title:					
Researc	ch Scientist	Microl	biology/Lab Mgr.		
Teleph	one Numbe	r:			
914-207	7-2326				
Work H	lours:			Work Hours:	
MON:	9:00 am	to	6:00 pm	Mon:	to
TUE:	9:00 am	to	6:00 pm	Tue:	to
WED:	9:00 am	to	6:00 pm	Wed:	to
THU:	9:00 am	to	6:00 pm	Thu:	to
FRI:	9:00 am	to	6:00 pm	Fri:	to
		to	-	Sat:	to
		to		Sun:	to

Attach a list of all full-time and part-time animal care staff which includes the following information: Name, Full-Time or Part-Time, Title and Education Level (Highest).

□ No additional staff.

SECTION IV - ATTESTATION

I have read the Administrative Rules and Regulations concerning the use of living animals and understand that I am fully responsible for all work involving the use of living animals. I understand that the Certificate of Approval is not transferable and the New York State Department of Health (the Department) shall be advised promptly if the individual, in whose name approval has been granted, ceases to be in charge. The facility(ies) will be operated according to all applicable laws, rules and regulations.

I understand that by signing this application form I agree to cooperate with any investigations conducted by the Department to verify or confirm information given or any other investigation conducted in connection with animal welfare in any facility identified in this application. If additional information is requested, I will provide it.

In signing this application, I hereby certify that the information I have given the Department as a basis for obtaining or retaining a certificate of approval is true and correct. As information changes, I will promptly notify the Department. Further, I understand that filing a false instrument constitutes a crime under the Penal Law of the State of New York.

Chairman & Chief Executive Officer09 Nov 2018TitleDate

Signature, Laboratory/Institutional Officer

SECTION V - ADDITIONAL SITES WHERE LIVING ANIMALS ARE LOCATED

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

FIELDS		NEW SITE DATA	
Site Name:			
Address 1:			
Address 2:			
City, State, Zipcode:			
Site Telephone Number:			
Site Fax Number:			
Site E-mail Address:		•	
Contact Person (Name):			

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	· · · ·

Attachment – Renewal Application (A248) Nov. 2018

List of IACUC Members

Name	Employment	Title	Education
Karen Sauve	Full	Research Scientist Micro.	BS
Skye Rasmussen	Consultant	Veterinarian	DVM,DACLAM
Steve Sansone	NA	Non Affiliated Member	BS
Steven Jones	Full	IACUC Chair/Senior Director, Pharmacology	PhD
Ray Schuch	Full	VP Research	PhD
	· · · · · · · · · · · · · · · · · · ·	······································	
	<u></u>		

Attachment – Renewal Application (A248)

List of Animal Care Staff

Name	Employment	Title	Education
Ray Schuch	Full	Vice President of Research	PhD
Karen Sauve	Full	Research Scientist – Microbiology/Lab Manager	BS
Steven Jones	Full	Senior Director, Pharmacology	PhD
Aubrey Watson	Full	Associate Scientist	MS
<u> </u>		· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·

MEDICAL WASTE MANAGEMENT

I. DEFINITIONS:

- A. <u>Biohazardous waste</u> is waste that may contain pathogens capable of replication and capable of causing disease in humans, animals or plants.
- B. <u>Medical waste</u> is biohazardous waste and/or sharps waste that may contain agents infectious to humans. Medical waste includes biohazardous waste capable of causing disease in humans.

Medical waste **does not** include the following:

- 1. Waste generated in food processing or biotechnology that does not contain an agent infectious to humans.
- 2. Sharps waste that is not contaminated with medical waste.
- 3. Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with agents infectious to humans.
- 4. Urine, feces, saliva, sputum, nasal secretions, sweat, tears, and vomitus, <u>unless</u> it contains fluid blood from humans or animals known or suspected to have agents that are infectious to humans.
- 5. Waste that is not biohazardous, including items such as paper towels, surgical gowns or bandages that contain <u>non-fluid</u> blood.
- 6. Hazardous chemical waste, radioactive waste, and household waste.
- 7. Waste generated from normal and legal veterinary, agricultural, and livestock- management practices.
- C. <u>Medical Sharps waste</u> is discarded material that has acute rigid corners, edges or protuberances capable of cutting or piercing as described below:
 - 1. All discarded hypodermic needles attached to syringes or tubing, blades and syringes contaminated with <u>medical</u> waste.
 - 2. Discarded medical appliances, sharp devices, broken glass laboratory equipment, pasteur pipettes, vacutainer tubes, etc. that are contaminated with <u>medical</u> waste.

D. <u>Agents infectious to humans</u> are microbial agents including viruses, bacteria, rickettsia, protozoa, spores, mold, and funguses that are indicated by scientific evidence to cause disease in humans.

- E. <u>Off-site hauler/treatment facility</u> will collect, transport and treat medical waste from ContraFect animal site. The transportation and treatment of medical waste will be documented and a copy provided to the department operating the storage/accumulation site. Only approved outside vendors will be allowed to treat medical waste.
- F. <u>Biohazard bags</u> are disposable orange bags of sufficient strength to preclude ripping, tearing or bursting under normal conditions of usage and handling of a filled bag. The bag must meet the standards prescribed by American Society for Testing and Materials (ASTM) Standard D 1709-85 and must be certified by the bag manufacturer. Bags must be conspicuously labeled with the words "Biohazardous Waste" or with the international biohazard symbol and the word "BIOHAZARD."

- G. <u>Sharps containers</u> are rigid, puncture-resistant containers that, when sealed, are leak resistant and cannot be reopened without great difficulty. Medical waste sharps containers must be labeled with the international biohazard symbol and the word "BIOHAZARD".
- H. <u>Mixed hazardous or radioactive wastes</u> are wastes that contain a mixture of two or more of the following: medical waste, radiological waste, and hazardous chemical waste.

II. TYPE OF MEDICAL WASTE GENERATED and/or TREATED (Check all that apply):

✓ Laboratory bagged waste ✓ Sharps ✓ Animal carcasses ✓ Manure/Bedding

Other (list below)

III. SEGREGATION, CONTAINMENT, LABELING & COLLECTION OF MEDICAL WASTE

- a. Medical waste will be segregated at the point of generation in each laboratory work area. Waste will be placed in **orange** biohazard bags labeled with the words "Biohazardous waste" or with the biohazard symbol and the word "Biohazard." Biohazard bags will be sealed at the point of origin to prevent leakage or expulsion of contents when they are ready for transport, treatment and disposal.
- b. Biohazard bags will be labeled with the building and room number where the waste is generated. Bags will be placed in labeled, leakproof secondary containers with tightfitting covers. Medical waste bags will not be removed from the secondary container except for transfer to another secondary container or to the secondary storage container at the storage/accumulation site. Bags should not weigh more than 40 pounds.
- c. Bagged medical waste will be transport in secondary containers to the designated storage/accumulation site and removed only when transferred into other secondary containers.
- 2. Disposal of Sharps: Medical waste sharps will be placed in approved medical waste sharps containers prior to disposal. Medical waste sharps containers will be labeled with the generator's building, and room number. Transport sharps containers to the designated storage/accumulation site and place in labeled medical waste containers.

^{1.} Segregation of medical waste:

Note: Non-medical sharps will be placed in sharps containers or other rigid puncture resistant, leak resistant container with a tight fitting lid that are not labeled as medical waste. These containers must not have biohazard symbols or any wording indicating medical waste, biohazard waste, or biohazard and should not be orange or red in color.

- 3. Disposal of Fluids: Liquid blood and body fluids not known to contain agents infectious to humans may be discharged with copious amounts of water to the local sewage system. Mixing liquids with a 1:10 final volume of chlorine bleach is recommended for a minimum of 30 minutes contact time. If liquid medical waste cannot be disposed of through the drains of the local sewage system, contact EH&S for alternative disposal methods.
- 4. Disposal of Animal Waste and Bedding:
 - a. Animal waste and bedding known or suspected of containing agents infectious to humans will be placed in biohazard bags and autoclaved by trained personnel.
 - b. Animal carcasses: Animal carcasses will be handled, treated and disposed of as medical waste.
- 5. Mixed Hazardous or Radioactive Waste Handling:
 - a. Medical waste containing hazardous chemicals require special handling, transporting, treating, and/or disposal methods. This waste is handled on a case by case basis.
 - b. Medical waste containing radioactive materials is considered radioactive waste and require special handling, transportation, and disposal and is handled following radioactive materials procedures in accordance with our license for use of radioactive materials.

IV. MEDICAL WASTE STORAGE/ACCUMULATION SITE

- A. Containment: Medical waste will be placed in orange biohazard bags within an approved secondary container, or in approved sharps containers, at the point of generation. Medical waste may be stored at room temperature up to seven (7) days after generation prior to autoclaving and longer term storage.
- B. Site security: Approved storage enclosures and accumulation areas will be secured by locking access doors or receptacle lids to prevent unauthorized entry and posted with warning signs containing the wording, "CAUTION--BIOHAZARDOUS WASTE STORAGE AREA--UNAUTHORIZED PERSONS KEEP OUT" and "CUIDADO--ZONA DE RESIDUOS--BIOLOGICOS PELIGROSOS--PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS." Medical waste in secondary containers must not be stored in unsecured, common use autoclave rooms.

V. DISINFECTION PROCEDURES FOR TREATMENT OR CLEANING OF MEDICAL WASTE SPILLS & DECONTAMINATION OF REUSABLE RIGID CONTAINERS:

A. Secondary-container Disinfection: Secondary containers for biohazard bags will be disinfected on a monthly basis and whenever leakage occurs from the bags. Obtained by Rise for Animals.

- 1. One of the following chemical sanitizers must be used (indicate solution(s) used with an 'X' below):
 - Hypochlorite (chlorine bleach) solution (500 ppm available chlorine)
 - Iodophorm solution (100 ppm available iodine)
 - Quaternary ammonium solution (400 ppm active agent)
 - Other disinfectant that is effective against the specific organism(s) used. Indicate disinfectant and concentration to be used.
- 2. The container will be rinsed, sprayed or immersed in the sanitizer. The sanitizer will remain in contact with container surfaces for a minimum of **three minutes** before washing.
- B. Procedures for Using Chemical Disinfectants for Spills:
 - 1. Use appropriate commercial disinfectants. Label directions must be followed.
 - 2. The minimum required contact time for decontamination is thirty (30) minutes.
 - 3. Spill Cleanup Materials must be treated as Laboratory Medical Waste. Chemical disinfectants are not approved as substitutes for an approved treatment process. Note: Use disinfectant that is compatible with the treatment process.

VI. EMERGENCY ACTION PLAN:

A. Equipment Failure:

- 1. Non-sharps medical waste can be held up to seven days prior to treatment. This should be adequate time to restore equipment to service.
- 2. If medical waste is disposed of frequently (daily), adequate time should be available to secure an alternate treatment facility or equipment.
- 3. Primary and alternate medical waste hauling and treatment vendors are listed below.
- B. Natural disasters:
 - 1. In the event of a natural disaster that may interfere with treatment and disposal of medical waste, all non-essential medical waste generating activities will be suspended immediately.
 - 2. Spills and releases of biohazardous agents will be handled by trained personnel in conjunction with EH&S. In the event of a major spill or issue, call 911 and our first response support team (Clean Harbors) will handle the incident.