



# USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT			
Complaint No. AC19-194	Date Entered: 4-Apr-19	Processed By: LBA	
Referred To: KINGSTON/ WHITE		Reply Due: 6-May-19	
Facility or Person Complaint Filed Against			
Name: NOVUS BIOLOGICALS		Customer No.: 331569	License No.: 84-R-0089
Address: 1649 GRIFFITH RD		Email Address:	
City: RAMONA	State: CA	Phone No.: 3037301950	
Complainant Information			
Name: (b) (6), (b) (7)(C), (b) (7)(D)		Organization: (b) (6), (b) (7)(C), (b) (7)(D)	
Address:		Email Address: (b) (6), (b) (7)(C), (b) (7)(D)	
City:	State:	Phone No.:	
How was the Complaint received? Email			
Details of Complaint: SEE ATTACHED			
Results: <p>This complaint refers to citations on a prior inspection report.</p> <p>Animal Care inspectors conduct unannounced inspections for all USDA registered and licensed facilities. Our authority is to ensure that they meet the standards required by Federal regulations. We also perform inspections in response to valid concerns and complaints received from the public to ensure the well-being of the animals and compliance with Federal law.</p> <p>When non-compliant items are found, these noncompliances are cited on the inspection report under the most accurate regulation based on the circumstances of the issue. Multiple noncompliances for the same issue are only cited when appropriate. With the exception of focused inspections, our inspectors evaluate the facility for compliance with all applicable regulations. Although all regulatory requirements are assessed, only noncompliant items are listed on the inspection report.</p> <p>We will continue to inspect this facility to make sure that past noncompliances are corrected and that AWA-regulated animals are protected to the fullest extent of Federal law.</p>			
Application Kit Provided: Yes: <input type="checkbox"/> No: <input type="checkbox"/>			
Inspector: Program Support		Date:	
Reviewed By: Dr. Petervary		Date:	



# USDA-APHIS-Animal Care





Animal and Plant  
Health Inspection  
Service

April 4, 2019

Animal Care  
4700 River Road  
Riverdale, MD 20737

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

Dear Complainant,

Thank you for your correspondence dated 12-Feb-19. We are reviewing your concerns and assigned tracking number AC19-194. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publically available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: <https://efoia-pal.usda.gov/App/Home.aspx>
2. Fax: 301-734-5941
3. US Mail:  
USDA- APHIS- FOIA  
4700 River Road, Unit 50  
Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102.**

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Betty Goldentyer  
Associate Deputy Administrator  
Animal Care

**From:** (b) (6), (b) (7)(C), (b) (7)(D)  
**To:** [Gibbens, Robert - APHIS](#)  
**Cc:** [AC West](#)  
**Subject:** Official Complaint -- Novus Biologicals  
**Date:** Tuesday, February 12, 2019 11:54:31 AM

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(b) (6), (b) (7)(C), (b) (7)(D)



Dr. Robert  
Gibbens

2/12/19

Director, Western Region, USDA/APHIS/AC,  
2150 Center Ave.  
Building B, Mailstop 3W11  
Fort Collins, CO 80526-8117

Dr. Gibbens,

I am writing to you today to file an Official Complaint against Novus Biologicals (84-R-0089), for clear violations of the Animal Welfare Act. Novus Biologicals (84-R-0089) has now amassed a total of four non-compliances in just over a year, 1 of which was considered to be CRITICAL. During this time period Novus Biologicals negligence has killed two animals, and seriously impacted at least 13 others. There are multiple incidents where animals were denied veterinary treatment.

As you know, Novus Biologicals was recently inspected on 3/21/18. This inspection report documents multiple violations of Sec. 2.33 Attending Veterinarian and Adequate Veterinary Care. The lack of veterinary care documented in this inspection has ranged from failure to cut excessively long nails, which can become tangled in cage flooring and be ripped out, to animals who were found dead without receiving any veterinary evaluations or prescribed treatment:

***"In further review of the records, Rabbit 515 and Rabbit 454 (weighed at 5 kg only once on 11/27/17) were found dead on 6 March 2018. The communication within the facility identified several rabbits as having had diarrhea on that day and common treatments were started without direction or consultation from the veterinarian."***

The internal email which discusses the animal deaths clearly demonstrates that these animals had not received treatment from a veterinarian. And the photos taken by the USDA illustrate disturbing conditions.

In an earlier 3/27/17 inspection, Novus Biologicals is cited for removing too much blood from rabbits during an antibody production protocol:

***"During inspection, rabbits were observed during bleed procedures, and 50 mls of blood were being taken from each animal, which exceeds the amount approved in the protocol."***

As you know, many laboratories within the antibody production industry, such as Novus Biologicals, have demonstrated a long-term pattern of serious Animal Welfare Act violations, with the largest fine ever levied by USDA/APHIS/AC \$3.5 million against Santa Cruz Biotechnology, a one-time leader in the antibody production industry.

It is clear that this industry as a whole, and this facility in particular, treats animals as nothing more than a means to an end. They are seen as nothing more than a tool of production, and are utterly exploited.

(b) (6), (b) (7)(C), (b) (7)(D)

As other labs in this industry, and Novus Biologicals have demonstrated, the abuse will not stop until this facility is compelled to do so. Therefore, I am calling upon your office to take the most severe action allowable under the Animal Welfare Act against Novus Biologicals.

I hereby file an Official Complaint against Novus Biologicals relevant to the deaths and injuries of multiple animals. I must insist that your office institute an immediate investigation.

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations kill, abuse, or seriously injure animals. Since the Novus Biologicals has a history of animal abuse which has led to multiple animal deaths and abuses, I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately begin the process of issuing the maximum fine allowable against Novus Biologicals at the completion of your investigation -- \$10,000 per infraction, per animal. As I am sure you are aware, this could result in a maximum penalty well over \$100,000.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

Attachments: Multiple USDA Inspection Reports, internal email, photos



### Inspection Report

Novus Biologicals  
8100 Southpark Way Unit A8  
Littleton, CO 80120

Customer ID: 331569  
Certificate: 84-R-0089  
Site: 001  
NOVUS BIOLOGICALS

Type: ROUTINE INSPECTION  
Date: 21-MAR-2018

#### 2.33(b)(2)

##### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

During inspection there were several rabbits noted with long toenails, which indicated a lack of appropriate methods to prevent and treat diseases and injuries. The rabbits are regularly handled for weights as documented below, and should be monitored for husbandry and health concerns under the guidance of the attending veterinarian.

- \*Rabbit 671, first weight recorded on 12/18/17, handled in January and February for weight.
- \*Rabbit 464, first weight recorded on 10/23/17, handled in November, December and February for weight.
- \*Rabbit 412, no weights recorded in records.
- \*Rabbit 290, only weight recorded on 9/4/17.
- \*Rabbit 111, first weight recorded on 9/4/17, handled in October, November, December and January for weight.
- \*Rabbit 21, first weight recorded on 9/18/17, handled in October, November, January and February for weight.

Animals with long toenails can catch their nails in the enclosure wire and can result in injury to the animals. At the time of inspection there was no written guidance from the attending veterinarian to prevent, identify and treat common injuries or diseases as well as routine animal husbandry issues. Appropriate methods to control and prevent disease include a system in place to prevent, control, diagnose and treat diseases and injuries, including animal husbandry issues, such as regular nail trimming.

Correct by 20 April, 2018.

#### 2.33(b)(3) CRITICAL

##### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The rabbits have been weighed regularly in order to ensure that the protocol is followed, but individual rabbit weights were not tracked to ensure an animal has not lost weight too quickly or communicated weight loss or other

Prepared By:

FRANK KATHARINE, D V M

FRANK KATHARINE, D V M USDA, APHIS, Animal Care

Date:

10-APR-2018

Title: VETERINARY MEDICAL OFFICER 6091

Received By:

Title:

Date:

10-APR-2018





## Inspection Report

health concerns to the veterinarian. Upon reviewing the records, there were several rabbits with weight loss of greater than 10% in approximately a month (between recorded weights) and the facility did not have a system in place to identify weight loss in an individual animal or communicate health concerns with the veterinarian. At the time of inspection, there was no standard operating procedure in place with guidance from the veterinarian for treating common ailments on site and the veterinarian had not been contacted when animals were losing weight or found dead.

\*Rabbit 224 dropped from 4.9 kgs on 12/11/17 to 4.1 kgs on 1/8/18  
\*Rabbit 289 dropped from 4.5 kgs on 9/4/17 to 3.8 kgs on 10/30/17  
\*Rabbit 335 dropped from 4.3 kgs on 10/9/17 to 3.6 kgs on 10/23/17  
\*Rabbit 443 dropped from 5.3 kgs on 11/20/17 to 4.7 kgs on 1/1/18 and 3.7 kgs on 2/12/18  
\*Rabbit 499 dropped from 4.6 kgs on 1/8/18 to 3.7 kgs on 2/5/18  
\*Rabbit 515 dropped from 4.8 kgs on 10/9/17 to 3.6 kgs on 12/4/17 and 3.4 kgs on 1/1/18  
\*Rabbit 587 dropped from 4.3 kgs on 12/18/17 to 3.4 kgs on 1/1/18  
\*Rabbit 687 dropped from 4.9 kgs on 1/1/18 to 3.9 kgs on 2/12/18

In further review of the records, Rabbit 515 and Rabbit 454 (weighed at 5 kg only once on 11/27/17) were found dead on 6 March 2018. The communication within the facility identified several rabbits as having had diarrhea on that day and common treatments were started without direction or consultation from the veterinarian.

Monitoring weight of individual animals helps identify abnormal trends in order to ensure that animals with significant weight loss are identified. Daily observation of all animals to assess their well-being, appropriate documentation of those observations, and direct and frequent communication with the attending veterinarian regarding health issues are necessary to ensure that the animals at the facility receive timely and adequate veterinary care. A system should be in place to ensure that all animals are observed daily, any health problems are documented and addressed, and the attending veterinarian is notified with timely and accurate information.

Correct by 20 April, 2018.

This inspection and exit interview were conducted with facility representatives on site and over the telephone.

Prepared By:

**FRANK KATHARINE, D V M**

FRANK KATHARINE, D V M USDA, APHIS, Animal Care

Date:

10-APR-2018

Title: VETERINARY MEDICAL OFFICER 6091

Received By:

Title:

Date:

10-APR-2018



Health

Inbox



me

to (b) (6), (b) (7)(C)

Mar 6 - \*\*\*

Hi (b) (6), (b) (7)(C)

I have a few rabbits with diarrhea.  
2 have died. Numbers 515 and 454. I am giving  
them timothy hay cubes and keeping fresh  
water bowls in the cages.



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

to me

Mar 6 - \*\*\*

Thank you.

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

Antibody Product Manager

Office: +1 303 730 1950 x5812

CFR : 2.33(b)(3)

Photographer: SENT TO K. FRANK

Date and Time: 28-MAR-18 8:30 AM

Inspection No: 2016082569097882

Description:

Followup on rabbit records after looking at weight records, specifically asked  
about Rabbit 515 and any notes/information.

Certificate: 84-R-0089

Legal Name:

Novus Biologicals

18-03420\_000000





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Photographer: K. FRANK  
Date and Time: 21-MAR-18 12:00  
Inspection No: 2016082569097882  
Description:

Certificate: 84-R-0089  
Legal Name:  
Novus Biologicals

18-03420\_000073



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Photographer: K. FRANK  
Date and Time: 21-MAR-18 12:00  
Inspection No: 2016082569097882  
Description:

Certificate: 84-R-0089  
Legal Name:  
Novus Biologicals

18-03420\_000072



## Inspection Report

Novus Biologicals  
8100 Southpark Way, Unit #A8  
Littleton, CO 80120

Customer ID: 331569  
Certificate: 84-R-0089  
Site: 001  
Novus Biologicals

Type: ROUTINE INSPECTION  
Date: 27-MAR-2017

### 2.31(d)(2)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The umbrella rabbit antibody production protocol was submitted to the IACUC by the principal investigator and the same individual (PI) approved the protocol as the current IACUC chair on 9/22/2014 and 4/13/2016.

With respect to activities involving animals, the IACUC, as an agent of the research facility, shall review protocols and amendments to protocols prior to approval. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity).

Correct by 30 April, 2017.

### 2.31(d)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC approved umbrella rabbit antibody production protocol states that "Rabbit bleeds will consist of 30-40 mls of whole blood...No more than 1% body weight will be taken during any 2 week period and if bleeds are done more than 4 times the hematocrit will be checked at least monthly or before each bleed."

During inspection, rabbits were observed during bleed procedures, and 50 mls of blood were being taken from each animal, which exceeds the amount approved in the protocol. There are no weight records for the animals to confirm the amount of blood drawn does not exceed 1% body weight. There are no records of hematocrit available and no way to measure hematocrit onsite before each bleed.

Two representative animals were weighed at 9.8 & 9.9 lbs, which is 4.45 kgs and 4.5 kgs. 1% of body weight for these animals is 44-45 mls, so the amount drawn (50 mls) still exceeds the approved protocol.

The IACUC has not sufficiently reviewed the activities involving animals and departures from the protocol have occurred without approval. The activity is not being conducted in accordance with the description of that activity

Prepared By:

FRANK KATHARINE, D V M

FRANK KATHARINE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6091

Date:  
03-APR-2017

Received By:

Title:

Date:  
03-APR-2017



## Inspection Report

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provided by the principal investigator and approved by the Committee. The IACUC has the responsibility to ensure evaluation of procedures that may cause more than momentary pain or distress. The increase in blood volume taken could result in a serious impact on the health of the animals. After approving a protocol, the IACUC should determine that procedures involving animals are conducted in accordance with the protocol and will avoid or minimize discomfort, distress, and pain to the animals unless acceptable justification for the departure is provided in writing.

Correct by 30 April, 2017.

Exit interview conducted with facility representative by phone on 3 April, 2017

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Prepared By:

**FRANK KATHARINE, D V M**

FRANK KATHARINE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6091

Date:  
03-APR-2017

Received By:

Title:

Date:  
03-APR-2017