

Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737 30 January 2020

Pro Sci Inc. 12170 Flint Place Poway, CA 92064 Registration No.: 93-R-0521

License # 93-B-0247 Customer No. : 43309

Dear Dr. Geng:

Your January 20, 2020 appeal of citations on the USDA inspection reports dated January 02, 2020 was thoroughly reviewed by an Animal Care appeal panel consisting of a Supervisory Animal Care Specialist, an Assistant Director, the Animal Care Research Program Manager, and me. The appeal is addressed below.

- 2.126(b) on inspection report # 2016082569690466 for license # 93-B-0247 will be upheld.
  - As stated in your appeal letter, your B dealer license is still active, because you have not sold this part of your business and have therefore not cancelled this license. APHIS inspectors attempted to inspect your B dealer facility and records on January 02, 2020. They called your office when they could not gain access to the property located at (b) (7)(F)After learning from your office by phone that you had sold that property, the APHIS inspectors asked if they could come to your other property at 12170 Flint Place, Poway, CA to inspect the records associated with your B dealer license. Your office informed the APHIS inspectors that the records were at the property in Ramona and your office said they could not grant the inspectors access to the records. The APHIS inspectors offered to come back the next day to inspect the records, but your office said they would not be able to grant access to the records on that day either. This noncompliance is consistent with regulation section 2.126(b) which states that each dealer shall, during business hours, allow APHIS officials to enter its place of business to examine records required to be kept by the Animal Welfare Act and the regulations.
  - Your appeal letter states that from now on your records will be made available at your Poway property. We appreciate your efforts to make those records available during future inspections.
- 2.38(b) on inspection report # 2016082569690511 for registration #93-R-0521 will be rescinded.
  - As stated in your appeal letter, on January 01, 2020, you sold the part of your business associated with your research registration. As of January 02, 2020 you had not notified APHIS of this change, and APHIS inspectors tried to inspect the research facility thinking your company still owned it. However, according to regulation section 2.30(c)(1), a research facility shall notify APHIS by mail of any change in ownership within 10 days after making such change. The date the APHIS inspectors tried to inspect was within the 10

- days after change in ownership. Therefore, you were within the available timeframe to notify APHIS and not subject to inspection of the research facility since you were not responsible for the regulated research activity at that facility.
- APHIS recognizes that you sent our office a letter on January 06, 2020 informing us of the change in ownership and requesting cancellation of your research registration.

The inspection report for registration #93-R-0521 will be rescinded. There will be no replacement inspection report for the R registration since you no longer owned that facility at the time of the inspection.

All decisions made by the appeal panel are final and represent Animal Care's final determination for this appeal.

Sincerely,

Dana Cole, DVM, PhD Acting Director, Animal Welfare Operations USDA, APHIS, Animal Care

USDA Animal Care. Ensuring humane treatment. Serving people. Doing right.





ProSci Incorporated 12170 Flint Place Poway, CA 92064

Your Antibody Experts

Toll Free: +1 (888) 513 9525 Local: +1 (858) 513 2638 Fax: +1 (858) 513 2692

info@prosci-inc.com prosci-inc.com

20 January 2020

USDA APHIS Animal Care 2150 Centre Avenue, Bldg. B Mailstop 3W11 Fort Collins, CO 80526-8117

RE: Inspection Appeal, 93-B-0247 and 93-R-0521, Inspection dated January 2, 2020

To Whom It May Concern:

ProSci would like to appeal the inspection reports of January 2, 2020, for license 93-B-0247 and registration 93-R-0521. The citations for these inspection reports are as follows:

The inspection report for 93-R-0521 states:

### 2.38(b)

### MISCELLANEOUS.

A responsible adult was not available to accompany APHIS Officials during the inspection process at 12:01PM on 02-JAN-2020.

Upon contacting the facility representative, inspectors were informed that the property and all animals have been sold, with new ownership effective 01-JAN-2020. The Animal Care office had not been notified in advance of the site cancellation, and the facility is unavailable for inspection at this time.

The inspection report for 93-B-0247 states:

### 2.126(b)

#### ACCESS AND INSPECTION OF RECORDS AND PROPERTY; SUBMISSION OF ITINERARIES.

A responsible adult was not available to accompany APHIS Officials during the inspection process at 12:01PM on 02-JAN-2020.

Upon contacting the facility representative, inspectors were informed that the property and all animals have been sold, with new ownership effective 01-JAN-2020. The Animal Care office had not been notified in advance of the site cancellation, and the facility is unavailable for inspection at this time.

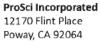
Note: 2.126(b) was probably supposed to reference to 2.126(a).

#### Basis for the Appeal:

Per section 2.38(b)(1)(i), "Each research facility shall, during business hours, allow APHIS officials: (i) To enter its place of business;" and per 2.126(a)(1), "Each dealer, exhibitor, intermediate handler, or carrier, shall, during business hours, allow APHIS officials: (1) To enter its place of business."









Toll Free: +1 (888) 513 9525 Local: +1 (858) 513 2638 Fax: +1 (858) 513 2692

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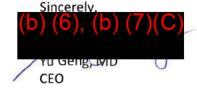
As the reports state, ProSci was unable to grant access to the animal facilities in question on January 2, 2020 since they were no longer owned by ProSci. These facilities, and the animals housed therein, were transferred to a new owner effective January 1, 2020. (Enclosed for your reference is Bill of Sale and Assignment and Assumption Agreement showing January 1, 2020, as the effective date of this transaction.) Hence, ProSci had no legal authority or responsibility at the time of the attempted inspections with regard to these animals and animal facilities. The inspectors, Drs. Amanda White and Katharine Frank, went directly to these animal facilities located in Ramona, CA, as opposed to the ProSci corporate offices in Poway, CA. The relevant Class B Dealer acquisition and disposition records are maintained at ProSci's corporate office in Poway, CA. These records will remain available at this location for any future inspections.

The two inspection reports also state that, "The Animal Care office had not been notified in advance of the site cancellation..." Section 2.8 of the Animal Welfare Act (AWA) regulations states, "A licensee shall promptly notify the AC Regional Director by certified mail of any change in the name, address, management, or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of any change." In fact, such written notification was made via FedEx received in your office on January 7, 2020. This notification was within the 10 days of the effective date of the change, i.e., January 1, 2020. A copy of this letter is attached for your reference.

Based on the information above, ProSci requests that the citations listed on these two inspection reports be rescinded. As such, we would like to request that the USDA reconsiders issuing the reports.

To ensure there is clarity on ProSci's current status relative to the Animal Welfare Act, a written request has been submitted asking that Animal Care cancel ProSci's research registration (93-R-0521). Effective January 1, 2020, ProSci will no longer be conducting any research activities covered by the AWA. Even though ProSci no longer maintains any animals regulated under the AWA, ProSci will maintain its Class B Dealer license (93-B-0247) since it still has in its inventory antibody and serum products for sale that were produced using animals previously owned by ProSci. ProSci will request termination of its Class B Dealer license when those inventories are depleted.

I look forward to your decision regarding the appeal of the inspection citations. Please let me know if you have any questions or need additional information.



### **Enclosures:**

Bill of Sale and Assignment and Assumption Agreement showing sale of animals/animal facilities ProSci letter to AC Western Regional Office dated January 6, 2020

### BILL OF SALE AND ASSIGNMENT AND ASSUMPTION AGREEMENT

This Bill Of Sale And Assignment And Assumption Agreement (this "Bill of Sale and Assignment and Assumption Agreement"), effective as of January 1, 2020, is made and entered into by and between ProSci Incorporation, a California corporation (the "Seller") and (the "Buyer"). Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Asset Purchase Agreement (the "Asset Purchase Agreement"), dated as of the date hereof, by and between the Seller and the Buyer.

WHEREAS, pursuant to the Asset Purchase Agreement, the Seller have agreed to sell to the Buyer, and the Buyer has agreed to purchase from the Seller, substantially all of the assets used or held for use by the Seller in the conduct of the Animal Business as a going concern, and the Buyer has agreed to assume certain of the liabilities and obligations of the Seller, in each case on the terms and subject to the conditions set forth in the Asset Purchase Agreement.

**NOW THEREFORE**, in consideration of the premises and the respective representations, warranties, covenants, agreements and conditions set forth herein and in the Asset Purchase Agreement, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

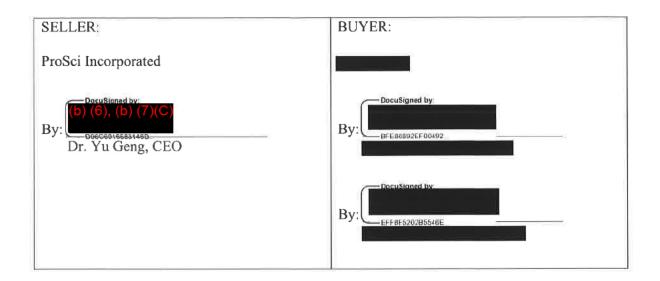
- Section 1. Sale of Assets. The Seller hereby grants, sells, assigns, transfers, conveys and delivers to the Buyer, and the Buyer hereby purchases and acquires from the Seller, all of the Seller's right, title and interest in and to the Assets, free and clear of any and all Liens (other than Permitted Liens), and by way of example and not as an exhaustive or exclusive list, such Assets include all tangible personal property, furnishings, equipment, machinery, vehicles, parts, accessories, inventory, materials, and animals (including but not limited to mice, chickens, rabbits, goats, and llamas) and all work in process being conducted, all of which being located on the Premises.
- Section 2. <u>Excluded Assets.</u> For the avoidance of doubt, the Assets to be transferred and assigned by the Seller to Buyer hereunder shall not include the Excluded Assets.
- Section 3. <u>Assignment</u>. The Seller hereby assigns to the Buyer, in accordance with and subject to the terms of the Asset Purchase Agreement, all existing and future right, title and interest of the Seller in, to and under the Assets, and the Buyer hereby accepts the assignment.
- Section 4. <u>Assumption</u>. The Buyer hereby assumes the Assumed Obligations, in accordance with and subject to the terms of the Asset Purchase Agreement. For the avoidance of doubt, the Buyer does not, and will not by assumption of the Assumed Obligations or the execution of this Bill of Sale and Assignment and Assumption Agreement or otherwise, be liable for or assume any excluded liabilities, and the parties hereto agree that all such excluded liabilities will remain the sole responsibility of the Seller, as set forth in the Asset Purchase Agreement.
- Section 5. <u>Purchase Price</u>. The purchase price to be paid by Buyer to Seller for the Assets (the "Purchase Price") shall be

- Section 6. <u>Further Assurances</u>. The Seller shall from time to time after the date hereof at the request of the Buyer and without further consideration execute and deliver to the Buyer such additional instruments of conveyance in addition to this Bill of Sale and Assignment and Assumption Agreement as the Buyer shall reasonably request to consummate or evidence the transactions provided for herein, to accomplish the purpose hereof or to assure to the Seller the benefits hereof.
- Section 7. <u>Terms of the Asset Purchase Agreement</u>. The terms of the Asset Purchase Agreement are incorporated herein by this reference. In the event of any conflict or inconsistency between the terms of the Asset Purchase Agreement and the terms hereof, the terms of the Asset Purchase Agreement will govern.
- Section 8. <u>Binding Effect</u>. This Bill of Sale and Assignment and Assumption Agreement will be binding upon and will inure to the benefit of the parties hereto and their respective successors and permitted assigns, and any reference to a party shall also be a reference to the successors and permitted assigns thereof.
- Section 9. Third Party Beneficiary. Nothing expressed or implied in this Bill of Sale and Assignment and Assumption Agreement is intended, or will be construed, to confer upon or give any Person other than the parties hereto, and their successors or permitted assigns, any right, remedy, obligation or liability under or by reason of this Bill of Sale and Assignment and Assumption Agreement, or result in such Person being deemed a third party beneficiary of this Agreement.
- Section 10. <u>Captions</u>. The titles, captions and table of contents contained in this Bill of Sale and Assignment and Assumption Agreement are inserted in this Bill of Sale and Assignment and Assumption Agreement only as a matter of convenience and for reference and in no way define, limit, extend or describe the scope of this Bill of Sale and Assignment and Assumption Agreement or the intent of any provision of this Bill of Sale and Assignment and Assumption Agreement.
- Section 11. <u>Governing Law</u>. This Bill of Sale and Assignment and Assumption Agreement will be governed by and construed and enforced in accordance with the internal laws of the State of California without reference to its choice of law rules.
- Section 12. <u>Expenses</u>. Except as otherwise expressly provided in the Asset Purchase Agreement, each party hereto shall pay its own fees, costs and expenses incurred in connection herewith and the transactions contemplated hereby, including the fees, costs and expenses of its financial advisors, accountants and counsel.
- Section 13. <u>Severability</u>. Any provision hereof that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by law, each party hereby waives any provision of law that renders any such provision prohibited or unenforceable in any respect.

Section 14. Counterparts; Copies. This Bill of Sale and Assignment and Assumption Agreement may be executed in two or more counterparts, each of which shall be deemed an original, and it shall not be necessary in making proof of this Bill of Sale and Assignment and Assumption Agreement or the terms hereof to produce or account for more than one of such counterparts. Delivery of an executed signature page to this Bill of Sale and Assignment and Assumption Agreement by facsimile or other electronic imaging means, including email transmission by PDF, will be as effective as delivery of a manually executed signature page to this Bill of Sale and Assignment and Assumption Agreement.

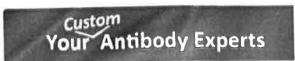
[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Bill of Sale and Assignment and Assumption Agreement as of the date first written above.









USDA Animal and Plant Health Inspection Service Attention: Program Support 2150 Centre Avenue, Bldg. B 3W11 Fort Collins, CO 80526

06 January 2020

ProSci

To Whom It May Concern:

This letter is to request the removal of the following sites for ProSci Incorporated, customer number 43309:



As of January 1, 2020, ProSci Incorporated is no longer in ownership of the above Animal Facilities. As such, we would like to cancel our Research Registration, 93-R-0521.

Please let us know if you have any questions or need additional information.





2016082569690511 Insp\_id

## Inspection Report

Pro Sci Inc.

12170 Flint Place

Poway, CA 92064

Customer ID:

43309

93-R-0521 Certificate:

> 002 Site

PRO SCI INC

ROUTINE INSPECTION Type:

Date: 02-JAN-2020

#### 2.38(b)

#### MISCELLANEOUS.

A responsible adult was not available to accompany APHIS Officials during the inspection process at 12:01PM on 02-JAN-2020.

Upon contacting the facility representative, inspectors were informed that the property and all animals have been sold, with new ownership effective 01-JAN-2020. The Animal Care office had not been notified in advance of the site cancellation, and the facility is unavailable for inspection at this time.

#### **Additional Inspectors**

Frank Katharine, Veterinary Medical Officer

AMANDA WHITE Digitally signed by AMANDA WHITE Date: 2020.01.08 10:50:12 -08'00'

WHITE AMANDA, D V M

USDA, APHIS, Animal Care

Date:

08-JAN-2020

Title:

Title:

VETERINARY MEDICAL OFFICER 6131

Received By:

Prepared By:

VALENTINA SAVICH

**FACILITY REPRESENTATIVE** 

Date:

08-JAN-2020

20-02527\_000010

Page 1 of 1



Customer: Inspection Date: 02-JAN-20

43309

# **Species Inspected**

Inspection Site Name Site Cert No Cust No 02-JAN-20 PRO SCI INC 002 43309 93-R-0521

No Animals were Inspected.

Count 000000 Scientific Name

NONE

000000

Total

Common Name

NONE





2016082569690466 Insp\_id

### Inspection Report

Pro Sci Inc.

Customer ID: 43309

12170 Flint Place

Certificate: 93-B-0247

Poway, CA 92064

Site: 001

PRO SCI, INC.

Type:

ROUTINE INSPECTION

Date: 02-JAN-2020

### 2.126(b)

# ACCESS AND INSPECTION OF RECORDS AND PROPERTY; SUBMISSION OF ITINERARIES.

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#### Additional Inspectors

Frank Katharine, Veterinary Medical Officer

AMANDA WHITE Digitally signed by AMANDA WHITE Date: 2020.01.08 10:46:48 -08'00'

WHITE AMANDA, D V M

USDA, APHIS, Animal Care

Date: 08-JAN-2020

Title:

VETERINARY MEDICAL OFFICER 6131

Received By:

Prepared By:

VALENTINA SAVICH

Date:

20-02527\_000012

Title:

**FACILITY REPRESENTATIVE** 

08-JAN-2020



Customer:

43309

Inspection Date: 02-JAN-20

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
43309	93-B-0247	001	PRO SCI, INC.	02-JAN-20

No Animals were Inspected.

Scientific Name Count 000000

NONE

000000 Total Common Name

NONE

#### 2016082569690466 Insp\_id

# **Inspection Report**

Pro Sci Inc. Customer ID: 43309

12170 Flint Place Certificate: 93-B-0247

Poway, CA 92064 Site: 001

PRO SCI, INC.

Type: ROUTINE INSPECTION

Date: 02-JAN-2020

2.126(b)

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Frank Katharine, Veterinary Medical Officer

Prepared By:			
	WHITE AMANDA, D V M	USDA, APHIS, Animal Care	<b>Date:</b> 08-JAN-2020

Title: VETERINARY MEDICAL OFFICER 6131

Received By: Obtained by Rise for Animals. Uploaded 07/10/2020

VALENTINA SAVICH

**Date:** 08-JAN-2020



Customer: 43309 Inspection Date: 02-JAN-20

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
43309	93-B-0247	001	PRO SCI, INC.	02-JAN-20

No Animals were Inspected.

 Count
 Scientific Name
 Common Name

 000000
 NONE
 NONE

000000 Total

2016082569690511 Insp\_id

# **Inspection Report**

Pro Sci Inc. Customer ID: 43309

12170 Flint Place Certificate: 93-R-0521

Poway, CA 92064 Site: 002

PRO SCI INC

Type: ROUTINE INSPECTION

Date: 02-JAN-2020

# 2.38(b)

### MISCELLANEOUS.

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Prepared By:			
	WHITE AMANDA, D V M	USDA, APHIS, Animal Care	<b>Date:</b> 08-JAN-2020

Title: VETERINARY MEDICAL OFFICER 6131

Received By:

Obtained by Rise for Animals. Uploaded 07/10/2020

VALENTINA SAVICH

**Date:** 08-JAN-2020



Customer: 43309 Inspection Date: 02-JAN-20

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
43309	93-R-0521	002	PRO SCI INC	02-JAN-20

No Animals were Inspected.

 Count
 Scientific Name
 Common Name

 000000
 NONE
 NONE

000000 Total