DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	6/24/2019-6/28/2019 FEI NUMBER 3005138409

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Katie L. Misko, Laboratory Manager

FIRM NAME	STREET ADDRESS
Steiner Biotechnology, LLC	1051 Olsen St Ste 3611
CITY, STATE, ZIP CODE, COUNTRY Henderson, NV 89011-3161	TYPE ESTABLISHMENT INSPECTED Nonclinical Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Not all nonclinical laboratory studies were conducted in accordance with the protocol.

1. Specifically, Study Director GGS did not follow the protocol for **Study #1**, titled "The use of Steiner Biotechnology (b) (4) in the treatment of (b) (4)." From this point forward, this study will be referenced as **Study #1**.
   a. In lieu of a single surgery per (b) (4), GGS performed 2-3 surgeries on the same (b) (4) for 9 of the 19 (b) (4) operated on in the study. The protocol outlines one surgical procedure in which the (b) (4) each in order to (b) (4). The (b) (4) would be (b) (4) or adopted out depending on the version of the protocol.

Animal Number	Surgery Dates
3537	1. 02/14/2017 2. 03/28/2017
3557	1. 02/14/2017 2. 03/28/2017 3. 05/16/2017 4. 05/31/2018*
3563	1. 10/16/2016 2. 12/17/2016
3566	1. 02/14/2017 2. 03/28/2017

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE
Dustin P Tran, Investigator

X Dustin P Tran Investigator Signed by: 20012506S3 Date Signed: 07-10-2019 10:36:00

DATE ISSUED
7/10/2019

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	3. 05/16/2017 4. 05/31/2018*
3569	1. 02/14/2017 2. 03/28/2017 3. 05/16/2017 4. 05/31/2018*
5935	1. 06/27/2017 2. 08/08/2017
5936	1. 06/27/2017 2. 08/08/2017 3. 05/31/2018*
5938	1. 06/27/2017 2. 08/08/2017 3. 05/31/2018*
5939	1. 06/27/2017 2. 08/08/2017
***5 (b) (4) that were operated on 2-3 times for Study #1 were then operated on again for Study #2 on these dates**	

b. Study Director GGS performed surgery on (b) (4) #3132 on 05/31/2018 in which the (b) (4) in order to (b) (4) for **Study #1** and 2 grafts for **Study #2**, titled "Evaluation of (b) (4) ." From this point forward, this study will be referenced as **Study #2.** Neither study protocol specifically authorized that (b) (4) from a different study could be performed during the same surgical procedure.

c. Surgical Logs for all (b) (4) operated on 10/16/2016 only document that (b) (4) was given. Study #1 Protocol, dated 09/21/2016, states (b) (4) ", meaning that (b) (4) should have been given alongside (b) (4).

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d. There was a total of (b) (4) that had surgical procedures in Study #1 but the protocol specifies that there only (b) (4) are to be in the study.

OBSERVATION 2

Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.

Specifically, Study Director GGS performed the (b) (4) on all (b) (4) for Study #1. GGS performed the (b) (4) in all (b) (4) in Study #2. Furthermore, GGS harvested the tissue samples from the (b) (4) as specified in the respective protocols.

GGS is a periodontist who only received training on animal surgical procedures on (b) (6) GGS stated that he has no other specialized training in animal surgical procedures. GGS has no training or experience in surgical procedures involving the (b) (4) species; GGS has no training or experience in surgical procedures involving the (b) (4).

OBSERVATION 3

The quality assurance unit failed to inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection.

Specifically, the quality assurance unit has not inspected any phases of both nonclinical laboratory studies currently conducted at the firm.

- Study #1 was initiated on 09/06/2016 and the surgical procedure for the last (b) (4) occurred on 08/08/2017.

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- Study #2 was initiated on 05/04/2018 and the surgical procedure for the last (b) (4) occurred on 05/31/2018.

OBSERVATION 4

The quality assurance unit failed to maintain and make available for inspection required records regarding its responsibilities and procedures and the method of indexing such records.

Specifically, President RLS stated that the firm does not have any existing SOPs relating to the roles and responsibilities of the quality assurance unit.

OBSERVATION 5

The quality assurance unit failed to maintain a copy of a master schedule sheet that contained all required elements for all nonclinical laboratory studies conducted by the testing facility.

Specifically, on 06/24/2019, I was provided an incomplete copy of the master schedule sheet that contained required elements of only 1 of 2 nonclinical studies. Study #2 was not listed in the master schedule sheet. Firm SOP 290, No. 00, Data Handling, Storage and Retrieval, effective date 06/01/2017, states in 8.3 "The quality assurance unit will maintain the master schedule sheet, copies of protocols, and records of quality assurance inspection in separate folders in the file cabinet in (b) (6) office."

OBSERVATION 6

The testing facility does not provide separate areas, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases.

Specifically, on 06/25/2019, I observed that there was only one room in which (b) (4) for both studies were housed. There was no separate area or room for the quarantine of diseased or suspected diseased (b) (4)

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OBSERVATION 7

The testing facility failed to maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.

Specifically, [redacted] individuals engaged in the conduct of the firm's nonclinical laboratory studies but testing facility management was missing a complete and current summary of training and experience and job description for each individual. Refer to table below for the missing documents:

Name	Title	Role	Documents missing
(b) (6)	(b) (4	• (b) (4)	1. Summary of experience 2. Job Description
(b) (6)	(b) (4)	• (b) (4) • (b) (4)	1. Summary of experience 2. Job Description
(b) (6)	(b) (4)	• (b) (4)	1. Summary of training and experience 2. Job description
(b) (6)	(b) (4	• (b) (4)	1. Job Description
Greg G. Steiner, DDS	CEO	• Study Director • Responsible for firm and for GLP studies	1. Job description
(b) (6)	(b) (4)	• (b) (4)	1. Job description
(b) (6)	(b) (4)	• Researched and outlined	1. Job

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(b) (6)	(b) (4)	• (b) (4) • (b) (4)	description
Roslynn L. Steiner	President	• Oversee the staff, administrative management, regulations, SOPs, manufacturing and production • Organize administrative paperwork for animal surgeries	1. Job Description

OBSERVATION 8

Not all consulting laboratories, contractors, or grantees were notified that the study must be conducted in compliance with FDA GLP regulations.

Specifically, your firm contracts histology slide preparation to (b) (4) and contracts histopathological evaluation to (b) (4) but neither contracted laboratory was notified that the study must be conducted in compliance with FDA GLP regulations.

OBSERVATION 9

Not all specimens were identified by test system, study, nature, and date of collection. This information was not located on the specimen container or did not accompany the specimen in a manner that precluded error in the recording and storage of data.

Specifically, on 06/24/2019, I observed (b) (4) plastic containers with only the animal number written in black marker on the top container lids. Each container contained the (b) (4) which were (b) (4) to fill with the test article. Firm SOP 280, No. 00, Collection and Identification of Specimens, effective date 06/01/2017, states in 8.9: "Label container with test system (including (b) (4)

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(b) (4) test and control articles, etc.), study, nature, date of collection."

OBSERVATION 10

Archives failed to provide for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports.

Specifically, not all of the study documents for both Study #1 and Study #2 was provided in a timely manner. Both protocols state "(b) (4) will be monitored (b) (4) by personnel…and a (b) (4) report will be sent to the attending veterinarian…" The (b) (4) reports contain health monitoring data, such as evaluation of (b) (4) and miscellaneous notes. On the first day of the inspection on 06/24/2019, I requested to see all (b) (4) reports. The following day on 06/25/2019, I was only provided the (b) (4) reports from 10/19/2016 to 03/30/2017.

- Study #1 had the last (b) (4) surgeries on 08/08/2017 and Study #2 had the most recent surgeries on 05/31/2018; however, on 06/27/2019, approximately three days later from my initial request of obtaining the set of (b) (4) reports, President RLS stated that she found additional reports in her office cabinet. Although I did not have time to review the additional (b) (4) reports due to the close-out the following day, the reports may reflect the (b) (4) monitoring up to approximately 05/31/2018.
- Although I was provided (b) (4) reports up to 03/30/2017, seven (b) (4) had surgical procedures on 10/16/2016 and post-op (b) (4) reports was only available for one (b) (4). The post-op (b) (4) reports for the other six (b) (4) could have been in the additional (b) (4) reports discovered on 06/27/19, the day before close-out.

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