



SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

October 26, 2016

Larry Badiner
Badiner Urban Planning, Inc.
95 Brady Street
San Francisco, CA 94103

Name:	Driver Group, LLC
Site Address:	No Address Specified
Staff Contact:	Corey Teague, (415) 575-9183 or corey.teague@sfgov.org
Record No.:	2016-011029ZAD

Dear Mr. Badiner:

This letter is in response to your request for a Letter of Determination regarding the proper use classification for Driver Group, LLC ("Driver"). The request seeks a confirmation that the subject use is a "non-life science laboratory use" and does not seek a determination about whether the use would be allowed at a specific property.

Background

As noted in your letter (dated August 23, 2016), Driver "is a patient-oriented company that performs molecular diagnostic testing and other analytics, connecting these patients to clinical trials." Additionally, Driver "is also working to use the information obtained from these samples to build a cancer genomics map. The map will be used to characterize the mutations present in certain cancers that could be acted upon using existing treatment compounds." Based upon your letter, while Driver uses a combination of a typical biochemistry wet lab and an analytical dry lab, it does not use advanced biological techniques. The biological techniques employed will be conducted in a laboratory with Biosafety level 2 controls. Driver does not manufacture products, but through its analytical services it will "aggregate all of the individual patient analyses to identify patient subsets whom would benefit from new clinical trials. In identifying these new subsets, Driver will collaborate with biotech and pharmaceutical companies to launch new clinical trials."

Planning Code Definitions

As noted in your letters, the Planning Code contains similar definitions for Laboratory and Life Science uses, and both were added to the Planning Code by Ordinance No. 298-08 to implement the Eastern Neighborhoods Area Plan.

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Planning Code Section 890.52 defines Laboratory as follows:

Laboratory shall mean space within any structure intended or primarily suitable for scientific research. The space requirements of uses within this category include specialized facilities and/or built accommodations that distinguish the space from office uses (as defined in Section 890.70), light manufacturing (as defined in Section 890.54(a)), or heavy manufacturing (including uses listed in 226(g) through 226(w)). Examples of laboratories include the following:

- (a) *Chemistry, biochemistry, or analytical laboratory;*
- (b) *Engineering laboratory;*
- (c) *Development laboratory;*
- (d) *Biological laboratories including those classified by the Centers for Disease Control (CDC) and National Institutes of Health (NIH) as Biosafety level 1, Biosafety level 2, or Biosafety level 3;*
- (e) *Animal facility or vivarium, including laboratories classified by the CDC/NIH as Animal Biosafety level 1, Animal Biosafety level 2, or Animal Biosafety level 3;*
- (f) *Support laboratory;*
- (g) *Quality assurance/Quality control laboratory;*
- (h) *Core laboratory.*

Planning Code Section 890.53 defines Life Science use as follows:

Life Science is an industry that involves the integration of natural and engineering sciences and advanced biological techniques using organisms, cells, and parts thereof for products and services. This includes the creation of products and services used to analyze and detect various illnesses, the design of products that cure illnesses, and/or the provision of capital goods and services, machinery, instruments, software, and reagents related to research and production. Life Science uses may utilize office, laboratory, light manufacturing, or other types of space. As a subset of Life Science uses, Life Science laboratories typically include biological laboratories and animal facilities or vivaria, as described in Section 890.52(d) and (e).

Determination

Based upon the information provided in your request letters, it is my determination that Driver is a Laboratory use, and more specifically, an analytical/biochemistry/biological laboratory (with Biosafety level 2) use as defined in Planning Code Sections 102 and 890.52. This is due to the focus on analytical work and the means and methods of research as described in your request. The subject use, as described in your request letters, is not consistent with the definition of Life Science Use in Planning Code Sections 102 and 890.53.

Please note that a Letter of Determination is a determination regarding the classification of uses and interpretation and applicability of the provisions of the Planning Code. This Letter of Determination

Larry Badiner
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95 Brady Street
San Francisco, CA 94103

October 26, 2016
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Driver Group, LLC.

is not a permit to commence any work or change occupancy. Permits from appropriate Departments must be secured before work is started or occupancy is changed.

APPEAL: If you believe this determination represents an error in interpretation of the Planning Code or abuse in discretion by the Zoning Administrator, an appeal may be filed with the Board of Appeals within 15 days of the date of this letter. For information regarding the appeals process, please contact the Board of Appeals located at 1650 Mission Street, Room 304, San Francisco, or call (415) 575-6880.

Sincerely,



Scott F. Sanchez
Zoning Administrator

cc: Citywide Mailing List



Lawrence Badiner
Urban Planner

Badiner Urban Planning, Inc.
95 Brady Street
San Francisco, CA 94103
Phone: (415) 865-9985

E-Mail: larry@badinerurbanplanning.com
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August 23, 2016

Mr. Scott Sanchez
Zoning Administrator
San Francisco Planning Department
1650 Mission Street, Suite 400
San Francisco, CA 94103

R# 2016-011029 ZAD
CK# 1272 \$ 645 -
C. TEAGUE

RE: Request for Zoning Administrator Determination that Driver Group, LLC is a Laboratory Use.

Dear Mr. Sanchez:

We are writing on behalf of Driver Group, LLC ("Driver") to request a Letter of Determination confirming that Driver is a Laboratory use under the Planning Code.

Driver is growing rapidly, is searching for new laboratory space of approximately 20,000 square feet and hopes to grow its company here in San Francisco. Driver has engaged Badiner Urban Planning, Inc. and Reuben, Junius & Rose, LLP to advise and aid the company in its search for new space in San Francisco. We are seeking this Letter of Determination to affirm that Driver is a Laboratory use under Planning Code Sections 102 and 890.52.

Background:

Driver is a patient-oriented company that performs molecular diagnostic testing and other analytics, connecting these patients to clinical trials. Specifically, the company uses information gleaned from a tissue analysis in a laboratory, together with other clinical information, to match patients with on-going cancer trials. Driver is also working to use the information obtained from these samples to build a cancer genomics map. The map will be used to characterize the mutations present in certain cancers that could be acted upon using existing treatment compounds. In identifying new therapeutic opportunities, Driver will collaborate with other companies to launch new clinical trials.

As demonstrated below, Driver is directly comparable to Invitae, which you determined was a laboratory use in a Letter of Determination dated July 28, 2015 (attached).

Driver's Operations and Facility

1. Driver's Operations

To perform tests for patients, Driver obtains a sample of the patient's tumor and a sample of non-tumor/normal tissue in the form of a blood sample. Driver then sequences both samples in

its laboratory. Note, this sequencing process is functionally the same as the process used by Invitae. When testing is complete, Driver provides a clinical analysis that summarizes the therapies available to the patient by informing him or her of clinical trials associated with the results. Furthermore, Driver will facilitate the connection of patients into relevant clinical trials. Lastly, Driver will aggregate all of the individual patient analyses to identify patient subsets whom would benefit from new clinical trials. In identifying these new subsets, Driver will collaborate with biotech and pharmaceutical companies to launch new clinical trials.

2. *Driver's Facility*

Driver's facility consists of a laboratory space with approximately 30 percent administrative support space. The laboratory is subdivided into wet and dry sections—(1) a typical biochemistry wet lab area with largely off-the-shelf equipment, including genomic sequencing machines and immunohistochemical staining equipment to analyze and sequence the blood and tumor samples of the individual patients; and (2) an analytical dry lab in which Driver analyzes the data obtained from the wet lab and matches the patient with clinical trials. More specifically, the dry lab is used to create and manage an extensive database of clinical trials, including the requirements for inclusion in each trial, and any exclusionary factors that make a particular individual ineligible for a particular trial. A front-end web portal makes this information easily accessible to the patient. Scientists in the dry lab also study the data gathered in the wet lab in an effort to identify actionable genetic targets related to cancer.

Planning Code Analysis

1. *Planning Code Definitions*

Planning Code Sections 102 and Section 890.52 define a laboratory as follows (the definitions are largely the same, with only the first sentences varying):

Laboratory. A Non-Retail Sales and Services Use intended or primarily suitable for scientific research. The space requirements of uses within this category include specialized facilities and/or built accommodations that distinguish the space from Office uses, Light Manufacturing, or Heavy Manufacturing. Examples of laboratories include the following:

- (a) Chemistry, biochemistry, or analytical laboratory;
- (b) Engineering laboratory;
- (c) Development laboratory;
- (d) Biological laboratories including those classified by the Centers for Disease Control (CDC) and National Institutes of Health (NIH) as Biosafety level 1, Biosafety level 2, or Biosafety level 3;
- (e) Animal facility or vivarium, including laboratories classified by the CDC/NIH as Animal Biosafety level 1, Animal Biosafety level 2, or Animal Biosafety level 3;
- (f) Support laboratory;



- (g) Quality assurance/Quality control laboratory; and
- (h) Core laboratory.

Planning Code Sections 102 and 890.53 define a Life Science use as follows (again, the definitions are largely the same, with only the first sentences varying):

Life Science. A Non-Retail Sales and Service Use that involves the integration of natural and engineering sciences and advanced biological techniques using organisms, cells, and parts thereof for products and services. This includes the creation of products and services used to analyze and detect various illnesses, the design of products that cure illnesses, and/or the provision of capital goods and services, machinery, instruments, software, and reagents related to research and production. Life Science uses may utilize office, laboratory, light manufacturing, or other types of space. As a subset of Life Science uses, Life Science laboratories typically include biological laboratories and animal facilities or vivaria, as described in the Laboratory definition Subsections (d) and (e). [Emphasis Added.]

2. *Driver's Use of Wet and Dry Lab Spaces*

Driver's laboratory has wet and dry laboratory components. In accordance with Planning Code Sections 102 and 890.52, the laboratory areas are arranged to be primarily suitable for scientific testing, analysis and research and include "specialized facilities and/or built accommodations that distinguish the space from Office uses, Light Manufacturing, or Heavy Manufacturing."

The wet laboratory area is a typical biochemical laboratory, in which Driver analyzes small tumor and blood samples. The company follows standard sanitary procedures and utilizes direct ventilation through hoods, genetic analytics equipment and specialized piped utilities. The laboratory contains the following types of equipment to conduct testing: sequencers, centrifuges, and liquid handlers, as is typical for a CLIA licensed laboratory. Driver complies with the standards of a Biosafety Level 2 lab. The Biosafety Level 2 controls are a requirement for handling blood samples, and are employed to prevent outside contamination of the samples. According to the Invitae Letter of Determination request, Invitae also employs Biosafety Level 2 controls in its San Francisco laboratory facility. (See attachment A for wet and dry lab photos.)

The dry laboratory section of the space is an analytical laboratory, where computational and applied mathematical analyses are performed on a computer. Scientists in the dry laboratory area analyze the genomic information obtained from the wet laboratory area using bioinformatics and computational biology techniques via supportive proprietary software. A typical dry lab scientist will have a degree or advanced degree in bioinformatics, molecular biology and/or biochemistry. Some dry lab scientists may also have a degree in computer science.



Lawrence Badiner
Urban Planner

Badiner Urban Planning, Inc.

Driver Group, LLC

August 23, 2016

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The two sides of Driver's laboratory go hand in hand. Recent advances in DNA sequencing technologies have resulted in dramatic increases in the amount of data produced by sample analyses. This has made it infeasible for a single person to both perform the tests and analyze the resulting data. Most modern tests are performed by two groups of people: wet lab scientists and dry lab scientists. Wet lab scientists handle the biological specimens and perform the tests and dry lab scientists analyze the resulting data. It is important that these two groups work together when designing tests because some scientific questions can be most effectively answered by modifying the techniques for testing the samples in the laboratory, while others are best answered by developing new analytical methods. Furthermore, wet lab scientists may not know that a test has failed until a dry lab scientist performs the requisite analysis, and so identifying and troubleshooting tests requires close collaboration. Accordingly, the wet and dry lab functions of the company are interdependent, and as such must be located adjacent to one another. The two groups of scientists communicate constantly and often move back and forth between the two lab areas in order to provide feedback and inform the work that each is performing—in other words, the wet and dry labs are the left and right hand of the same operation. And, of course, the ultimate purpose of the analysis is creating real patient impact by connecting them to a clinical trial, which is Driver's mission.

3. *Driver is a Biochemical and Analytic Laboratory and is not a Life Science Use*

Driver conducts a laboratory analysis of tumor tissues and blood samples and provides a clinical analysis to patients and physicians, and is using the information obtained from the patient samples to connect patients to clinical trials. These categories fall within the definition of a laboratory pursuant to Planning Code Sections 102 and 890.52(a).

Driver performs genetic testing and other analyses on blood samples and tumors, and this does not depend upon the "...integration of natural and engineering sciences and advanced biological techniques using organisms, cells and parts thereof for products and services..."—which is the prerequisite for a Life Science use. Rather, Driver employs biological laboratory techniques to analyze samples and obtain molecular information with off-the-shelf equipment that is found in biochemical, core, and analytical labs industry-wide. Furthermore, Driver does not use organisms, cells and parts thereof as part of their testing and analytic service, as described above.

Driver is similar to Invitae in that it analyzes human tissue and blood samples in order to acquire genetic data. Also, like Invitae, Driver does not use "...organisms, cells and parts thereof for products and services..." In Driver's case, functionally, it does the same analysis as Invitae, and this information is actionable in the sense that it allows Driver to provide patients with information about appropriate clinical trials.



Finally, the Life Science definition states that "as a subset of Life Science uses, Life Science laboratories typically include biological laboratories and animal facilities or vivaria, as described in the Laboratory definition Subsections (d) and (3)." (Planning Code Section 102 and 890.53; emphasis added.) While Driver does use basic analytical techniques commonly used in biological or biochemical laboratories, its laboratory does not include animal facilities or vivaria. Because Planning Code Sections 102 and 890.53 refer to specific kinds of laboratories that qualify as Life Science laboratories, it can logically be inferred that not all laboratories are life science laboratories.

Conclusion:

Driver is a biochemical and analytical laboratory. It does not fall under the Life Science definition because in providing this service to patients, it does not require "... integrating natural and engineering sciences and advanced biological techniques using organisms, cells or parts thereof for products or services." Rather, Driver analyzes the blood and tumor samples of cancer patients with the ultimate goal of using this information to connect them to potentially life-prolonging clinical trials.

We therefore respectfully request a Letter of Determination confirming that Driver is properly classified as Laboratory under Planning Code Section 102 and Section 890.52 to further its search for space to remain in San Francisco.

Please feel free to have you or your staff contact me at (415) 865-9985 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Lawrence Badiner". The signature is fluid and cursive, written over the printed name.

Lawrence Badiner
Principal

cc: Pete Wild, Driver
Chloe Angelis, RJR

Attachments:

- Attachment A – Photos
- Attachment B – Invitae Letter of Determination

Attachment A - Photos



Wet Lab



Wet Lab



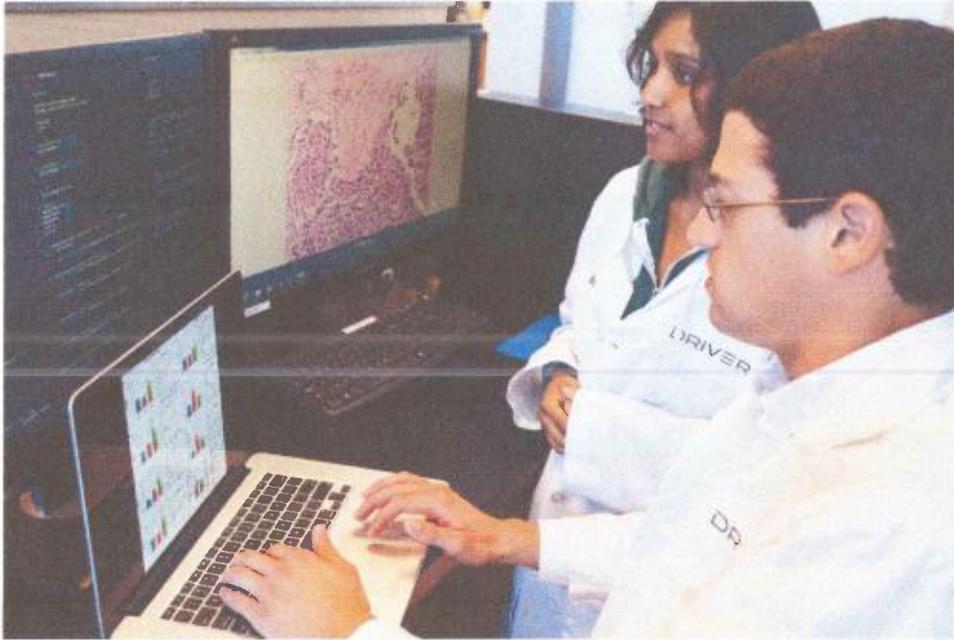
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Driver Group, LLC

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Dry Lab



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Urban Planner

Badiner Urban Planning, Inc.

Driver Group, LLC

August 23, 2016

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Attachment B – Invitae Letter of Determination



SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

July 28, 2015

Lawrence Badiner
Badiner Urban Planning, Inc.
95 Brady Street
San Francisco, CA 94103

Site Address: 1400 16th Street
Assessor's Block/Lot: 3938/001
Zoning District: PDR-1-D (Production Distribution & Repair-Design)
Staff Contact: Kimberly Durandet (415) 575-6816
kimberly.durandet@sfgov.org

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Dear Mr Badiner:

This letter is in response to your request for a Letter of Determination regarding the property at 1400 16th Street. This parcel is located in the PDR-1-D (Production Distribution & Repair-Design) Zoning District, 58-X and 68-X Height and Bulk Districts, and Showplace Square/Potrero Plan Area. You have requested a determination of the proper land use classification for a proposed tenant (dba "Invitae") and have suggested that the proposed use is a Laboratory and not a Life Science use.

Based upon the description in your request, Invitae provides medical information using genetic data beginning with a blood draw at a remote location by a doctor or a service such as LabTech. The blood sample is sent to Invitae where DNA is extracted from the blood sample and the requested genetic information is processed using genetic sequencing technology. The information is shared with the medical professional or patient to identify a client's predisposition to disorders such as cancer, cardiology, hematology, neurology, and pediatrics.

Laboratory is defined in Planning Code Section 102 as follows:

A Non-Retail Sales and Services Use intended or primarily suitable for scientific research. The space requirements of uses within this category include specialized facilities and/or built accommodations that distinguish the space from Office uses, Light Manufacturing, or Heavy Manufacturing. Examples of laboratories include the following:

- (a) Chemistry, biochemistry, or analytical laboratory;
- (b) Engineering laboratory;
- (c) Development laboratory;
- (d) Biological laboratories including those classified by the Centers for Disease Control (CDC) and National Institutes of Health (NIH) as Biosafety level 1, Biosafety level 2, or Biosafety level 3;
- (e) Animal facility or vivarium, including laboratories classified by the CDC/NIH as Animal Biosafety level 1, Animal Biosafety level 2, or Animal Biosafety level 3;
- (f) Support laboratory;
- (g) Quality assurance/Quality control laboratory; and
- (h) Core laboratory.

Lawrence Badiner
Badiner Urban Planning, Inc.
95 Brady Street
San Francisco, CA 94103

July 28, 2015
Letter of Determination
1400 16th Street

Life Science is defined in Planning Code Section 102 as follows:

A Non-Retail Sales and Service Use that involves the integration of natural and engineering sciences and advanced biological techniques using organisms, cells, and parts thereof for products and services. This includes the creation of products and services used to analyze and detect various illnesses, the design of products that cure illnesses, and/or the provision of capital goods and services, machinery, instruments, software, and reagents related to research and production. Life Science uses may utilize office, laboratory, light manufacturing, or other types of space. As a subset of Life Science uses, Life Science laboratories typically include biological laboratories and animal facilities or vivaria, as described in the Laboratory definition Subsections (d) and (e).

Your letter states that "While Invitae performs genetic testing on blood samples, it does not use '...organisms, cells and parts thereof for products and services...' which is the prerequisite for being a Life Science use."

Based upon your description of the proposed use, I would concur that Invitae operates consistent with the definition of a Laboratory use and would not be considered a Life Science use. Planning Code Section 210.3 lists Laboratory as a Permitted Use under Non-Retail Sales and Services in the PDR-1-D District.

APPEAL: If you believe this determination represents an error in interpretation of the Planning Code or abuse in discretion by the Zoning Administrator, an appeal may be filed with the Board of Appeals within 15 days of the date of this letter. For information regarding the appeals process, please contact the Board of Appeals located at 1650 Mission Street, Room 304, San Francisco, or call (415) 575-6880.

Sincerely,



Scott F. Sanchez
Zoning Administrator

cc: Kimberly Durandet, Planner
Property Owner
Neighborhood Groups