



SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

April 21, 2017

Chloe Angelis
Reuben, Junius & Rose, LLP
1 Bush Street, Suite 600
San Francisco, CA 94104

Name:	Notable Labs Group, LLC
Site Address:	No Address Specified
Staff Contact:	Corey Teague, (415) 575-9183 or corey.teague@sfgov.org
Record No.:	2017-002295ZAD

Dear Ms. Angelis:

This letter is in response to your request for a Letter of Determination regarding the proper use classification for Notable Labs. The request seeks a confirmation that the subject use is a Laboratory use, pursuant to Planning Code Sections 102 and 890.52, and does not seek a determination about whether the use would be allowed at a specific property.

Background

Your February 17, 2017 letter describes Notable Labs as follows: "Notable Labs is a medical testing company that provides medical professionals with analytic data demonstrating how existing drugs can be used in combination with one another to treat cancer. Bringing a new drug to market costs upwards of \$2.5 billion and can take at least 10 years [footnote removed]. Notable's mission is to provide personalized treatment options by analyzing how drugs that have already been approved and brought to market can be combined with one another to provide doctors with cancer treatment options that do not require any new regulatory approvals. The company is currently focused on identifying treatment options for patients with blood cancers.

The work begins with a blood draw or bone marrow aspiration performed off-site by a medical professional at a hospital. The patient sample is sent to Notable in a sealed tube via prepaid overnight shipping. Upon receipt, red blood cells are removed from the sample and the remaining components are analyzed using flow cytometry to assess the patient sample's physical and chemical characteristics [reference removed]. Similar flow cytometry techniques have been used routinely in clinical laboratory practice for over 60 years. Combinations of approved drugs are then applied to the patient sample in Notable's automated, robotic laboratory. The company operates under Biosafety Level 2 controls and the biological equipment and techniques that are used in Notable's testing process are basic and in-line with long accepted, traditional clinical lab industry standards.

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Notable's core value lies in its ability to rapidly screen therapeutic candidates on patient samples and observe previously unseen effects using cutting edge analytics tools. The company uses the information obtained from the samples it processes to build a proprietary database of treatment responses and correlated patient metadata. The database is used to map patient-specific omics signatures with available treatment options. Notable uses its analytical services to aggregate individual analyses to stratify patient subgroups who may respond to existing, approved therapies."

Planning Code Definitions

As noted in your letter, 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.

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).

Chloe Angelis
Reuben, Junius & Rose, LLP
1 Bush Street, Suite 600
San Francisco, CA 94104

April 21, 2017
Letter of Determination
Notable Labs

Determination

Based upon the information provided in your request letter, it is my determination that Notable Labs 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 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,



Corey A. Teague
Acting Zoning Administrator

cc: Citywide Mailing List

REUBEN, JUNIUS & ROSE, LLP

February 17, 2017

Via Hand Delivery

Mr. Scott Sanchez, Zoning Administrator
San Francisco Planning Department
1650 Mission Street, 4th Floor
San Francisco, CA 94103

R # 2017-002295 ZAV
CK # 28100 \$ 664. -
C. TEAGUE

Re: Request for Written Determination
Subject: Confirming Notable Labs as a Laboratory Use
Our File No.: 10393.01

Dear Mr. Sanchez:

This office represents Notable Labs, a medical testing company that uses an automated robotic laboratory and proprietary software to analyze how combinations of existing FDA approved drugs can be used by a physician to treat cancer.

Facing the end of its current lease, Notable Labs is looking to find a new laboratory space that will allow the company to keep its headquarters in San Francisco. To that end, and pursuant to San Francisco Planning Code Section 307(a), we respectfully request a written determination that Notable Labs is a Laboratory use pursuant to Planning Code Sections 890.52 and 102.

I. Background

Notable Labs is a medical testing company that provides medical professionals with analytic data demonstrating how existing drugs can be used in combination with one another to treat cancer. Bringing a new drug to market costs upwards of \$2.5 billion and can take at least 10 years.¹ Notable's mission is to provide personalized treatment options by analyzing how drugs that have already been approved and brought to market can be combined with one another to provide doctors with cancer treatment options that do not require any new regulatory approvals. The company is currently focused on identifying treatment options for patients with blood cancers.

¹ "Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B," *Scientific American*, Nov. 24, 2014 (available at: <http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/>) last accessed May 31, 2016.

James A. Reuben | Andrew J. Junius | Kevin H. Rose | Daniel A. Frattin | John Kevlin
Tuija I. Catalano | Jay F. Drake | Lindsay M. Petrone | Sheryl Reuben¹ | Thomas Tunny
David Silverman | Melinda A. Sarjapur | Mark H. Loper | Jody Knight | Chloe V. Angelis
Louis J. Sarmiento, Jr. | Corie A. Edwards | Jared Eigerman^{2,3} | John McInerney III²

1. Also admitted in New York 2. Of Counsel 3. Also admitted in Massachusetts

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The work begins with a blood draw or bone marrow aspiration performed off-site by a medical professional at a hospital. The patient sample is sent to Notable in a sealed tube via prepaid overnight shipping. Upon receipt, red blood cells are removed from the sample and the remaining components are analyzed using flow cytometry to assess the patient sample's physical and chemical characteristics. (See process chart attached as **Exhibit A.**) Similar flow cytometry techniques have been used routinely in clinical laboratory practice for over 60 years. Combinations of approved drugs are then applied to the patient sample in Notable's automated, robotic laboratory. The company operates under Biosafety Level 2 controls and the biological equipment and techniques that are used in Notable's testing process are basic and in-line with long accepted, traditional clinical lab industry standards.

Notable's core value lies in its ability to rapidly screen therapeutic candidates on patient samples and observe previously unseen effects using cutting edge analytics tools. The company uses the information obtained from the samples it processes to build a proprietary database of treatment responses and correlated patient metadata. The database is used to map patient-specific omics signatures with available treatment options. Notable uses its analytical services to aggregate individual analyses to stratify patient subgroups who may respond to existing, approved therapies.

II. Notable Labs is a Laboratory Use

A. Planning Code Definitions

Planning Code Sections 890 and 102 set forth nearly identical sets of definitions for "Laboratory" and "Life Science" uses. In Section 890.52, a Laboratory is defined 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;

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- (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.²

A subset of Laboratory use, Planning Code Section 890.53 defines a 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).³

According to these definitions, a Life Science Laboratory is a particular subset of Laboratory that includes certain biological laboratories and animal facilities or vivaria. More specifically, Life Science Laboratories are those that integrate “natural and engineering sciences and advanced biological techniques using organisms, cells, and parts thereof for products and services.” Notable does not fall within the Life Science category based on this definition.

B. Notable Labs is a Laboratory Use

Notable Labs is medical testing company. What makes the company innovative is its automated robotics and use of custom analytics software to test thousands of combinations of drugs in a short period of time. Notable Labs does not develop new drugs or study the causes of cancer. Instead, the company provides data to medical professionals who use it to determine whether there are combinations of existing drugs that could be used in concert to treat particular mutations of cancer.

² The only difference between the definition of laboratory in Section 890.52 and the definition in Section 102 is that in Section 102, a laboratory is specified as “[a] Non-Retail Sales and Services Use intended or primarily suitable for scientific research.” The definition of laboratory set forth in Section 890.52 lacks such a specification.

³ Again, the only substantive difference between the definition of life science in Section 890.53 and that in Section 102, is that the Section 102 definition states that a life science use is a “Non-Retail Sales and Service Use.”

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Mr. Scott Sanchez
Zoning Administrator
February 17, 2017
Page 4

The data sets that Notable Labs compiles and provides to medical professionals are comparable to the genetic data provided by another San Francisco medical testing company, Invitae. In a July 28, 2015 Letter of Determination, the Planning Department described Invitae as a company that extracts DNA from a blood sample and processes genetic information using genetic sequencing technology. “The information is shared with the medical professional or patient to identify a client’s predisposition to disorders” (See Invitae Letter of Determination (July 28, 2015); attached at **Exhibit B**.) Based on this description, the Planning Department concluded that “[w]hile Invitae performs genetic testing on blood samples, it does not use ‘. . . organisms, cells and parts thereof for products and services . . .’ which is a prerequisite for being a Life Science use.” (*Id.*)

Notable is also directly comparable to Driver, which the Planning Department determined was not a Life Science Laboratory use in a Letter of Determination dated October 26, 2016 (attached at **Exhibit B**). As described in that letter:

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.”
(Driver Letter of Determination (October 26, 2016).)

Based on that description, the Planning Department concluded that Driver is a laboratory use, “and, more specifically, an analytical/biochemistry/biological laboratory (with Biosafety level 2) . . . [t]his is due to the focus on analytical work and the means and methods of research described” (*Id.*)

Given the Laboratory designations of Invitae and Driver, Notable must also be categorized as a non-Life Science Laboratory. The company uses custom analytics algorithms and a mechanized testing system to analyze how thousands of combinations of drugs could combat particular cancer mutations when used in concert with one another—in other words, Notable tests the effects of mixing the chemical properties of different kinds of existing drugs. It then shares the data with a medical professional, who will study it to determine how the tested combinations of drugs could be used against a given patient’s particular kind of cancer. Like Invitae and Driver, Notable Labs performs testing on blood and tissue samples, but does not manufacture a product and does not use “advanced biological techniques” or “organisms, cells and parts thereof for products and services.” Furthermore, Notable does no testing on humans or animals, and its laboratory does not include animal facilities or vivaria. It therefore falls outside

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Mr. Scott Sanchez
Zoning Administrator
February 17, 2017
Page 5

the definition of a Life Science use, and instead is an analytical Laboratory use pursuant to Sections 102 and 890.52(a).

III. Conclusion

As explained herein, Notable is an analytical laboratory that employs its propriety software and a system of advanced robotics to test how the chemical properties of different existing drugs can be mixed to combat particular kinds of cancer. By applying its state-of-the-art technology to basic biological analytic techniques, the company is able to screen thousands of combinations of existing therapeutic compounds in a short period of time. Then, like Invitae and Driver, Notable provides its analysis to the medical professionals who use the data to make treatment recommendations to individual patients.

This process does not involve the “integration of natural and engineering sciences and advanced biological techniques using organisms, cells, and parts thereof for products and services.” Accordingly, we respectfully request a written determination that Notable Labs meets the Planning Code definition of a non-Life Science Laboratory use pursuant to Sections 102 and 890.52. Enclosed is a check in the amount of \$664 made payable to the San Francisco Planning Department. Please feel free to contact me should you have any questions.

Very truly yours,

REUBEN, JUNIUS & ROSE, LLP



Chloe Angelis

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REUBEN, JUNIUS & ROSE, LLP

EXHIBIT A

Process chart pulled from Notable Labs website homepage
February 15, 2017



[HOME](#)

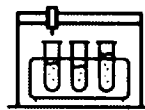
Our Process



Your doctor sends a sample of your tumor to Notable Labs.



Based on your tumor we choose a panel of FDA-approved drugs that have published anti-cancer effects.



We test thousands of combinations of these drugs against your tumor.



We provide a report of the results to your doctor within several days.



Your doctor uses our report to make treatment recommendations for you.

EXHIBIT B



SAN FRANCISCO PLANNING DEPARTMENT

Letter of Determination

July 28, 2015

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

1650 Mission St.
Suite 400
San Francisco,
CA 94103-2479

Reception:
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Fax:
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Planning
Information:
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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

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



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

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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.

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

October 26, 2016
Letter of Determination
Driver Group, LLC.

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:

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- (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

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October 26, 2016
Letter of Determination
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