

City of Newton, Massachusetts

Department of Planning and Development 1000 Commonwealth Avenue Newton, Massachusetts 02459 Telephone (617) 796-1120 Telefax (617) 796-1142 TDD/TTY (617) 796-1089 www.newtonma.gov

James Freas Acting Director

PUBLIC HEARING/WORKING SESSION MEMORANDUM

DATE: March 27, 2015

MEETING DATE: March 31, 2015

TO: Land Use Committee of the Board of Aldermen

FROM: James Freas, Acting Director of Planning and Development

Alexandra Ananth, Chief Planner for Current Planning

Daniel Sexton, Senior Planner

CC: Petitioner

In response to questions raised at the Land Use Committee public hearings, and/or staff technical reviews, the Planning Department is providing the following information for the upcoming public hearing/working session. This information is supplemental to staff analysis previously provided at the public hearing.

PETITION #2-15 300 Boylston Street

Request for Special Permit/Site Plan Approval to repurpose a vacant mixed-use building to include medical office, laboratory, general office, retail, and restaurant uses.

The Land Use Committee (Committee) held a public hearing on February 3, 2015, which was held open so that the petitioner could respond to concerns/questions that were raised in the Planning Department's memorandum and at the public hearing by the Committee and public. The petitioner submitted information on March 5, 2015, in response to the questions/concerns that were raised. Overall, the Planning Department finds that the petitioner's responses are complete, and provides the following comments.

Supplemental Information. The petitioner's supplemental information clarifies a number of questions raised by the Committee and public during the public hearing. The Planning Department believes the petitioner has thoroughly responded to the concerns raised. To better understand the approvals for the Matritech, Inc. (BO #247-95) (**ATTACHMENT A**) and Karyopharm Therapeutics, Inc. (BO #365-14) (**ATTACHMENT B**) facilities, the Planning Department is including copies of the board orders for these projects.

Newton Biosafety Committee Responses. The Committee asked the Planning Department to forward a series of questions to the Newton Biosafety Committee (NBC) regarding recombinant DNA (rDNA) laboratories. The NBC responded to these questions in a letter, dated March 24, 2015



(ATTACHMENT C). According to the letter, the NBC believe that the site would be an appropriate location for a qualified facility, assuming any potential tenant passes the vetting process established in §12-24 Permit Requirements and §12-25 Inspections and Review of the Newton Health and Human Services ordinances.

Conditions. The Planning Department recommends that conditions from prior special permit approvals be consolidated into the board order for this petition. The Planning Department is also proposing a number of additional safeguards that should address many of the concerns raised during the public hearing process (**ATTACHMENT D**).

Recommendation.

Based on the supplemental information submitted, the Planning Department finds the petition to be complete. The Planning Department is supportive of the project and recommends approval with conditions.

ATTACHMENTS:

ATTACHMENT A: Board Order #247-95 for Matritech, Inc.

ATTACHMENT B: Board Order #365-14, for Karyopharm Therapeutics, Inc.

ATTACHMENT C: Letter for Newton Biosafety Committee, dated March 24, 2015

ATTACHMENT D: Draft Board Order

CITY OF NEWTON

IN BOARD OF ALDERMEN

August 14, 1995

ORDERED:

That the Board, finding that the public convenience and welfare will be substantially served by its action and that said action will be without substantial detriment to the public good, and without substantially derogating from the intent or purpose of the Zoning Ordinance, the following SPECIAL PERMIT/SITE PLAN APPROVAL is hereby granted, in accordance with the recommendation of the Land Use Committee and the reasons given by the Committee therefor, through its Chairman, Alderman Susan M. Basham:

- 1. The Board finds that research and manufacturing uses are allowed as of right in a Manufacturing District.
- 2. The Board finds that the petitioner uses Recombinant DNA only in the development of products, not in the products (cancer testing kits) themselves, and that the only very small amounts of recombinant DNA are used.
- 3. The Board finds that the petitioner has represented that the product manufactured on the site is non-invasive, accurate and inexpensive and will further efforts for early detection of cancer.
- 4. The Board finds that the procedures for the operation of the facility and research of all aspects of the petitioner's company have been reviewed and accepted by the Newton Biosafety Committee in accordance with FDA, NIH, NRC, OSHA and State and local health standards.
- 5. The Board finds that the petitioner will establish an Institutional Biosafety Committee which will have two community representatives on it. The Committee will review the report of an outside biosafety consultant who will conduct and inspection at least once a year under the direction of the Health Department.
- 6. The Board finds that the Newton Fire Department has reviewed the plans for the facility and will instruct fire fighter about the location of potentially hazardous materials in order to insure that emergency procedures can be handled safely.

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A True Copy
Attent:

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- 7. The Board finds that the site has been vacant for several years and that the petitioner's use of the site will enhance the diversity of businesses and the economic base for the City.
- 8. The Board finds that the proposed research use is a low intensity use in a building which could have by-right uses with more intense levels of activity.
- 9. The Board finds that while the site is located next to residential uses, the type of vectors used in the research and the quantities kept on site are appropriate for this site.
- 10. The Board finds that by designating the Chief Executive Office of the company as a liaison to the community, the Petitioner is relieving the anxiety of the community about biotechnology and the use of Recombinant DNA.
- 11. The Board finds that the Petitioner has voluntarily agreed to conduct only BL 1 research.

PETITION NUMBER:

247-95

PETITIONER:

Matritech, Inc.

LOCATION:

330 Nevada Street, Ward 1, on land known as Section 14, Block 8, Lot 9, containing approximately 94,509 sf. of

land

OWNER:

One Nevada Realty Trust, Joseph Biotti, Jr., Trustee

ADDRESS OF OWNER:

97 Adams Street Newton, MA 02158

TO BE USED FOR:

A Biotechnology laboratory which uses Recombinant DNA

in its research

CONSTRUCTION:

Interior only

EXPLANATORY NOTE:

Section 30-12(c)(15) allows the Board of Aldermen to grant

a Special Permit for Recombinant DNA research as defined

in Section 12-20 et. seq.

Land referred to is in a Manufacturing District.

Approved, subject to the following conditions:

A True Copy
Attest:

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Chy Cherk of Newton, Names.

- That all buildings, parking areas, driveways, walkways, landscaping and other site 1. features shall be located and constructed consistent with plans entitled "Site Plan -Parking Layout" dated June 1, 1993, by Albert Costa and "Matritech Lab - Second Floor Plan", dated May 24, 1995, submitted by the petitioner and filed herewith.
- 2. That only Biotechnology Level 1 recombinant DNA research can be used in the facility; no other level of recombinant DNA research can to conducted without an amendment to this special permit.
- That no building permit shall be issued in pursuance of the SPECIAL PERMIT/SITE 3. PLAN APPROVAL until:
 - The petitioner shall have recorded with the Registry of Deeds for the Southern a. District of Middlesex County a Certified copy of this Board Order granting this SPECIAL PERMIT/SITE PLAN APPROVAL with appropriate reference to the book and page of the recording of the Petitioner's title deed or notice of lease endorsed thereon.¥ as shown on Certificate of Title No. 171784, Book 989, Page 34
 - A certified copy of such recorded notice shall have been filed with the City đ. Clerk, the Inspectional Services Department and the Department of Planning an Lots 142 Bt. 989 P. 34 Lot CI Bt. 420 P. 265 Development.

Under Suspension of Rules Readings Waived and Approved 18 yeas 5 nays (Ald. Bryson, Bullwinkle, Ciccone, Lupo, O'Halloran) 1 absent (Ald. MacLeish)

The undersigned hereby certifies that the foregoing copy of the decision of the Board of Aldermen granting a SPECIAL PERMIT and SITE PLAN APPROVAL and is a true accurate copy of said decision, the original of which having been filed with the CITY CLERK'on August 14, 1995. The undersigned further certifies that all statutory requirements for the issuance of such SPECIAL PERMIT/SITE PLAN APPROVAL have been complied with and that all plans referred to in the decision have been filed with the Planning and Development Board and the City Clerk.

ATTEST

Clerk of the Board of Aldermen

A True Copy Attest:

I, Edward G. English, as the <u>Clerk of the Board of Aldermen</u> and keeper of its records and as the <u>City Clerk</u> and official keeper of the records of the <u>CITY OF NEWTON</u>, hereby certify that Twenty days have elapsed since the filing of the foregoing decision of the Board of Aldermen in the <u>Office of the City Clerk</u> on <u>August 14, 1995</u> and that <u>NO APPEAL</u> to said decision pursuant to M.G.Laws Chapter 40, Section 17 has been filed thereto.

ATTEST May May Laughish EDWARD G. ENGLISH, City Clerk

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A True Copy
Attest:

Literal J. Bughik
City Chark of Newton, Massa.

3. Karyopharm Therapeutics Inc

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ATTACHMENT B

#365-14

CITY OF NEWTON

IN BOARD OF ALDERMEN

November 17, 2014

ORDERED:

That the Board, finding that the public convenience and welfare will be substantially served by its action, that the use of the site will be in harmony with the conditions, safeguards and limitations set forth in the Zoning Ordinance, and that said action will be without substantial detriment to the public good, and without substantially derogating from the intent or purpose of the Zoning Ordinance, grants approval of the following SPECIAL PERMIT/SITE PLAN APPROVAL to allow an Recombinant DNA use, as recommended by the Land Use Committee for the reasons given by the Committee through its Chairman, Alderman Marc Laredo:

- 1. The site is an appropriate location for the proposed Recombinant DNA use, as it is located within a limited manufacturing zoning district, and the petitioner has received approval from the Newton Biosafety Committee. (§30-24(d)(1))
- 2. The proposed Recombinant DNA use as developed and operated will not adversely affect the neighborhood, as the laboratory facility and operations meet all required health and safety guidelines. (§30-24(d)(2))

PETITION NUMBER:

#365-14

PETITIONER:

Karyopharm Therapuetics

LOCATION:

75-95 Wells Avenue, on land known as SBL 84, 34, 2C,

containing approximately 557,570 square feet of land.

OWNER:

NS Wells Acquisition LLC

47864-441

ADDRESS OF OWNER:

7/57 Wells Avenue

Newton, MA 02459

TO BE USED FOR:

Laboratory with Recombinant DNA materials

EXPLANATORY NOTES:

§30-12(c)(9); to allow an rDNA use

ZONING:

Limited Manufacturing District

Approved subject to the following conditions:

1. All Floor Plans associated with this Special Permit/Site Plan approval shall be located and constructed consistent with:

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#365-14 Page 2 of 3

- a. Floor Plan for Karyopharm Therapeutics, prepared by Safety Partners Inc.
- 2. The petitioner shall record a certified copy of this Board Order for the approved Special Permit/Site Plan with the Registry of Deeds for the Southern District of Middlesex County, and shall file a copy of such recorded Board Order with the City Clerk, the Department of Inspectional Services, and the Department of Planning and Development.
- 3. The petitioner shall file a copy of the permit approved by the Health and Human Services Department with the Department of Inspectional Services, and the Department of Planning and Development.
- 4. This special pennit is granted to the petitioner hereunder and does not permit any future occupant of the site to conduct a Recombinant DNA use.
- 5. In the event that the petitioner fails to comply with the provisions of Chapter 12, Article III of the Revised Ordinances of the City of Newton, as may be amended from time to time, or any successor regulations, or the petitioner's continued conduct of Recombinant DNA technology poses an immediate threat to the public health or environment, as determined by the Commissioner of Health and Human Services, then this special permit shall terminate

Under Suspension of Rules Readings Waived and Approved 24 yeas 0 nays

The undersigned hereby certifies that the foregoing copy of the decision of the Board of Aldermen granting a SPECIAL PERMIT/SITE PLAN APPROVAL is a true accurate copy of said decision, the original of which having been filed with the CITY CLERK on November 20, 2014. The undersigned further certifies that all statutory requirements for the issuance of such SPECIAL PERMIT/SITE PLAN APPROVAL have been complied with and that all plans referred to in the decision have been filed with the City Clerk.

attest:

(SGD) DAVID A. OLSON, City Clerk

Clerk of the Board of Aldermen

I, David A. Olson, as the <u>Clerk of the Board of Aldermen</u> and keeper of its records and as the <u>City Clerk</u> and official keeper of the records of the <u>CITY OF NEWTON</u>, hereby certify that Twenty days have elapsed since the filing of the foregoing decision of the Board of Aldermen in the <u>Office of the City Clerk</u> on <u>N/20</u> and that <u>NO APPEAL</u> to said decision pursuant to G.L. c. 40A, §17 has been filed thereto.

ADDIEST.

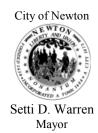
(SGD) DAVID A. OLSON, City Clerk

Clerk of the Board of Aldermen

A True Copy

COLUMN AS NUMBER DESIGN

ATTACHMENT C



HEALTH AND HUMAN SERVICES DEPARTMENT Linda Walsh, Interim Commissioner 1000 Commonwealth Avenue

Public Health

Telephone 617.796.1420 Fax 617.552.7063 TDD/TTY 617.796.1089

Newton, MA 02459

TO: Marc Laredo, Board of Alderman Land Use Committee, Chair

FROM: Linda Walsh, Newton Biosafety Committee, Chair

RE: Biosafety Committee Response to Questions from Land Use Committee regarding

special permit application for Atrium Center

DATE: March 24, 2015

Ouestion 1

In general, what are Level I and Level II laboratory uses? What is rDNA research or technology and how does it fit in with Level I and Level II laboratory uses? Please provide examples of such uses, explain where such uses are conducted, and whether such uses are considered safe.

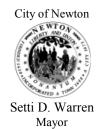
BSL (Biosafety Level)-1 and BSL (Biosafety Level)-2 laboratories are facilities that are used to safely conduct life science research under strict federal, state and local guidelines and oversight.

BSL-1: BSL-1 activities pose no or low individual and community risk. BSL-1 Labs are typically not separated from the general traffic patterns of others, work is performed on open bench tops and special containment equipment and devices are not needed. BSL-1 laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by personnel with general training in microbiology or related field. This is the type of laboratory found in municipal water-testing laboratories, in high schools, and in some community colleges

BSL-2: BSL-2 activities involve agents of moderate potential risk to personnel and the environment. These agents can cause disease in healthy individuals and pose a moderate risk to the environment. Precautions for use of these agents include BSL-1 practices plus limited laboratory access when work with these organisms is being performed and the recommended use of "biological safety cabinets" and/or protective equipment when performing work which may generate aerosols (transferring liquids, rapid mixing, etc.). In BSL-2 labs, personnel have training in the handling pathogenic materials, are familiar with the hazards associated with the specific agents they are using, and are directed by scientists who are competent and familiar with good microbiological laboratory technique. BSL-2 labs may handle clinical materials (biopsies, etc.) diagnostic quantities of infectious cultures and human blood.

rDNA: The term recombinant DNA (rDNA) refers to the result of modifying genetic material (DNA), typically in a laboratory setting, to change it in some way. A simple example would be the ability to insert a small piece of new or foreign DNA into the existing DNA of a cell or organism (for example a bacterium) as illustrated in the figure below.

Email: lwalsh@newtonma.gov



HEALTH AND HUMAN SERVICES DEPARTMENT

Linda Walsh, Interim Commissioner 1000 Commonwealth Avenue Newton, MA 02459



Telephone 617.796.1420 Fax 617.552.7063 TDD/TTY 617.796.1089

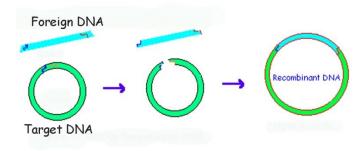


Figure: Cartoon illustration of the construction of recombinant DNA (rDNA).

One example of rDNA technology is the insertion of a new or foreign piece of DNA into the DNA of human or bacterial cells being grown in a laboratory. The result is that the modified cells produce medically useful (sometimes lifesaving) materials that they would otherwise not produce. Insulin, for example, can be produced in this way. Recombinant DNA techniques such as that illustrated above are now universally used in life science research and in the manufacture of drugs by the biotechnology and pharmaceutical industries. Other applications of rDNA include but are not limited to basic research into gene structure-function and applied microbiology applications like FROSTBAN which was tested but never marketed (*P. syringae* "ice-minus" genetically altered strain) or for foods based on microbial fermentation.

Safety: Decades of experience has shown that when performed under the appropriate conditions (ie BSL 1, BSL-2, etc) and oversight (see below) the process of modifying the genetic material of cells or organisms in this way is safe and poses little or no risk to workers or to the community in which the work is done.

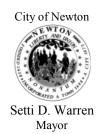
The potential risks of creating or using rDNA are based on the risks associated with the source of the DNA and its function and are determined according to NIH risk guidelines. People may perform rDNA research in BSL-1 and BSL-2 facilities when they are properly trained and equipped and the facilities have been properly constructed, maintained and all activities are in adherence to official safety guidelines

In the Boston area, there are literally hundreds of BSL-1 and BSL-2 laboratories. Such facilities are found in colleges, universities, medical laboratories, hospitals, and in biotech and pharmaceutical companies.

The safety of such laboratories is such that they are typically found in buildings also containing dining and patient treatment areas, and are in close proximity to schools, daycare centers, and homes.

**Please see appendices for more detailed information and sources about Risk Group definitions, and the practices required of BSL-1 and -2 work.

Email: lwalsh@newtonma.gov



HEALTH AND HUMAN SERVICES DEPARTMENT

Linda Walsh, Interim Commissioner 1000 Commonwealth Avenue Newton, MA 02459



Telephone 617.796.1420 Fax 617.552.7063 TDD/TTY 617.796.1089

Question 2

What are the processes for vetting a laboratory utilizing rDNA technology under federal and/or state regulations as well as under Newton ordinances? Once established, is there any continuing oversight?

The Newton City Ordinance regulating rDNA research requires that laboratories must first obtain a permit from the HHS Commissioner.

The role of the Newton Biosafety Committee (NBC) is to review laboratory applications, ensuring that the applicants plan to adhere the regulations and practices for Biosafety and rDNA research that have been established by the NIH and CDC. If the application is found to be acceptable, a recommendation is given by the NBC to the HHS Commissioner to issue the requested permit.

Criteria for the NBC review include ensuring that the planned research can be safely conducted at the proposed biosafety level, according to established CDC and NIH guidelines. The NBC then determines if the facilities, waste disposal plans, employee expertise, etc. are adequate for the proposed biosafety level, and that the training and ongoing oversight of the program meets the requirements of the proposed biosafety level.

Ongoing oversight includes the establishment of an Institutional Biosafety Committee (IBC), which includes representatives from the Health and Human Services Department and community members appointed by the Mayor and Board of Aldermen. The IBC inspects the facility and program annually, and reviews and approves all proposed work requiring biosafety regulation

Ouestion 3

Hypothetically speaking, would the Atrium Wellness Center be an appropriate site for a qualified Level I or Level II laboratory use, including the use of rDNA technology, assuming that such laboratory successfully passed all vetting processes and received a Health Department permit to conduct rDNA technology?

Yes, assuming the tenant successfully passed all the above vetting processes.

Specific applications by potential laboratory tenants will need to be carefully reviewed on a case-by-case basis, and the proposal to perform rDNA work must adhere to established safety guidelines in order for it to be approved by the NBC, as described in the answer to Question 2. Our positive answer to this question does not positively or negatively dispose the NBC to grant approval to conduct work under the rDNA ordinance to any specific applicant.

Email: lwalsh@newtonma.gov

Appendix 1, 2 and 3

Biosafety Committee Response to Questions from Land Use Committee regarding special permit application for Atrium Center March 24, 2015

Appendix 1: NIH/CDC Risk Group Classifications

IN GENERAL, Level I and Level II (or Biosafety Level 1: BSL-1 and Biosafety Level 2: BSL-2) are designations for sets of biology research practices mandated by the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) that aim to manage the risk of working with biological hazards from the RG-1 and RG-2 risk groups.

Table 1: Classification of Infectious Microorganisms by Risk Group

| Risk Group Classification | NIH Guidelines for Research involving Recombinant DNA Molecules 2002 ² | World Health Organization Laboratory Biosafety Manual 3 rd Edition 2004 ¹ | |
|------------------------------|--|---|--|
| Risk Group 1 | Agents not associated with disease in healthy adult humans. | (No or low individual and community risk) A microorganism unlikely to cause human or animal disease. | |
| Risk Group 2 | Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available. | (Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited. | |
| Risk Group 3 | Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). | (High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available. | |
| Risk Group 4 | Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). | (High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. ³ | |

Source of Table: Biosafety in Microbiological and Biomedical Laboratories, 5th edition.

HHS Publication No. (CDC) 21-1112, Revised December 2009.

Please also see: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid

Molecules, November 2013. For lists of micro-organisms and their designated

Risk Group.

Appendix 2: NIH/CDC Biosafety Level 1 and 2 Practices.

Table 2. Summary of Recommended Biosafety Levels for Infectious Agents

| BSL | Agents | Practices | Primary Barriers and Safety Equipment | Facilities (Secondary Barriers) |
|-----|---|--|---|------------------------------------|
| 1 | Not known to consistently cause diseases in healthy adults | Standard microbiological practices | No primary barriers required. PPE: laboratory coats and gloves; eye, face protection, as needed | Laboratory bench and sink required |
| 2 | Agents associated with human disease Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure | BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies | Primary barriers: BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPE: Laboratory coats, gloves, face and eye protection, as needed | BSL-1 plus: Autoclave available |

"Standard Microbiological Practices" include:

- Wash hands after completion of work and before leaving laboratory.
- No eating, smoking, drinking, handling contact lenses, applying cosmetics, or food storage.
- No mouth pipetting.
- Careful handling and disposal of sharps.
- Minimize aerosols and splashes.
- Decontaminate surfaces, cultures, and equipment after work is complete.
- Laboratory biohazard signage.
- Ensure appropriate training and supervision of personnel.

Source: Biosafety in Microbiological and Biomedical Laboratories, 5th edition. HHS Publication No. (CDC) 21-1112, Revised December 2009

Appendix 3: More detailed information regarding definitions of biosafety and rDNA work

- A general definition of "biosafety" encompasses the practices, procedures, and use of equipment needed to ensure adequate safety conditions in all facilities that work with potentially infectious microorganisms and other biological hazards. These include health care settings, clinical and diagnostic laboratories that handle human clinical samples, veterinary facilities that work with animal tissue samples, biological research laboratories, and teaching laboratories. All of these facilities must seek to reduce the risks associated with handling potential biological hazards by employing a continuous process of hazard recognition, risk assessment, and hazard mitigation.
- "Biosafety levels" (BSLs) are designations of laboratories in ascending order based on the degree of risk associated with the work being conducted. A biosafety level is a level of the biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4). In the United States, the Centers for Disease Control and Prevention (CDC) have specified these levels. In the European Union, the same biosafety levels are defined in a directive.
- BSL1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. (no or low individual and community risk). A microorganism that is unlikely to cause human disease or animal disease This is the type of laboratory found in municipal water-testing laboratories, in high schools, and in some community colleges teaching introductory microbiology classes, where the agents are not considered hazardous. At BSL-1 there is no specific recommendation that the laboratory be isolated from other parts of the building. The use of gloves and hand washing is one of the most important procedures that can be used by laboratory workers to prevent removal of unwanted microbiological agents, radioactive materials, or chemicals from the laboratory environment.
- BSL2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited. It includes various bacteria and viruses that cause only mild disease to humans, or are difficult to contract via aerosol in a lab setting. BSL-2 differs from BSL-1 in that:
 - laboratory personnel have specific training in handling pathogenic agents and are directed by scientists with advanced training;
 - access to the laboratory is limited when work is being conducted;
 - extreme precautions are taken with contaminated sharp items; and
 - certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

In general, Level I and Level II (BSL-1 and BSL-2) laboratory uses comprise the overwhelming majority of academic, biotech, and pharmaceutical research activities in biology.

In life science research, Recombinant DNA is the general name for taking a piece of one DNA, combining it with another strand of DNA. Recombinant DNA (rDNA) molecules are DNA molecules formed by laboratory methods of genetic recombination (such as molecular cloning) to bring together genetic material from multiple sources, creating sequences that would not otherwise be found in biological organisms. Recombinant DNA is possible because DNA molecules from all organisms share the same chemical structure. They differ only in the nucleotide sequence within that identical overall structure. Using recombinant DNA technology and synthetic DNA, any DNA sequence may be created and introduced into any of a very wide range of living organisms. Following transplantation into the host organism, the foreign DNA contained within the recombinant DNA construct may or may not be designed to make a protein, or other biochemical product. Recombinant DNA is widely used in biotechnology, medicine and research. The most common application of recombinant DNA is in basic research, in which the technology is important to most current work in the biological and biomedical sciences. However, recombinant proteins and other products that result from the use of rDNA technology are found in essentially every western pharmacy, doctor's or veterinarian's office (e.g. recombinant insulin, growth hormone, blood clotting factors, etc.), medical testing laboratory (e.g. diagnostic probes and primers to detect HIV, etc.), and in biological research laboratory searching for new cures to disease. In addition, organisms that have been manipulated using recombinant DNA technology, as well as products derived from those organisms, have found their way into many farms, supermarkets, home medicine cabinets, and even pet shops, such as those that sell GloFish and other genetically modified animals.

- Scientists and regulatory bodies such as the CDC and NIH have recognized that the potential existed for organisms containing recombinant DNA to have undesirable or dangerous properties. In the US, agencies like the CDC and NIH have developed rigorous guidelines which mitigate or eliminate risks posed by rDNA research. Research involving rDNA must now comply with the National Institute of Health's "Guidelines for Research Involving Recombinant DNA Molecules" as published in the Federal Register. The recombinant DNA guidelines are applicable to all recombinant DNA research within the United States or its territories, which is conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH but serve as the basis for all regulations.
- Recombinant DNA (rDNA) research is an example of a situation where the appropriate biosafety level for the work must be considered.
 - Usually, the biosafety level of an rDNA research project is at the same level as the host organism, but this is determined after careful scientific review.

Attachment D

DRAFT #2-15

CITY OF NEWTON

IN BOARD OF ALDERMEN

April 6, 2015

ORDFRFD:

That the Board, finding that the public convenience and welfare will be substantially served by its action, that the use of the site will be in harmony with the conditions, safeguards and limitations set forth in the Zoning Ordinance, and that said action will be without substantial detriment to the public good, and without substantially derogating from the intent or purpose of the Zoning Ordinance, grants approval of the following SPECIAL PERMIT/SITE PLAN APPROVAL and EXTENSION of a NONCONFORMING STRUCTURE to repurpose an existing vacant building into a mixed-use commercial facility including general office, medical office, laboratory, retail, and restaurant (with more than 50 seats) uses, as recommended by the Land Use Committee for the reasons given by the Committee through its Chairman, Alderman Marc Laredo:

- 1. The proposed change of use in a nonconforming structure will not be substantially more detrimental than the existing structure to the neighborhood. (§30-21(b))
- 2. The site, which is in a Business 1 district, is an appropriate location for the development of a mixed-use facility with laboratory and restaurant (with more than 50 seats) uses, as it is located in an area with a mix of uses and along a major transportation corridor. (§30-24(d)(1))
- 3. The proposed uses as develop and operated will not adversely affect the surrounding area and neighborhood, as they will complement other uses in the immediate vicinity. Any future laboratory tenant planning to conduct recombinant DNA (rDNA) research or use rDNA technology will be limited to Biosafety Levels 1 and 2, and need to obtain a permit from the Commissioner of Health and Human Services and approval by the Newton Biosafety Committee. (§30-24(d)(2)
- 4. The access to the site over Boylston Street and Florence Street is appropriate for the types and numbers of vehicles that will be accessing the site. (§30-24(d)(4))

PETITION NUMBER: #2-15

PETITIONER: Atrium Wellness Center, LLC.

LOCATION: 300 Boylston Street, Ward 7, on land known as Section 82, Block

2, Lot 1, containing approximately 125,771 square feet of land

OWNER: Atrium Wellness Center, LLC.

ADDRESS OF OWNER: 250 First Avenue, Suite 200

Needham, MA 02494

TO BE USED FOR: Mixed-Use commercial facility consisting of general office,

medical office, retail, laboratory, and restaurant (with greater

than 50 seats) uses

EXPLANATORY NOTES: §30-11(b)(3), to allow a laboratory use; and §30-11(d)(9), to allow

restaurants with greater than 50 seats.

ZONING: Business 1 district

This special permit supersedes, consolidates, and incorporates prior special permits #303-90(3), #466-94, and #176-98. Herein, those conditions and provisions from such prior special permits that remain applicable, are still in full force and effect, and are set forth in this special permit. Any conditions in such prior special permits not set forth in this special permit are null and void.

Approved subject to the following conditions:

Conditions associated with this Special Permit/Site Plan Approval, Board Order #2-15:

- 1. All buildings, parking areas, driveways, walkways, landscaping and other site features associated with this Special Permit/Site Plan Approval shall be located and constructed consistent with:
 - a. "Site Plan Atrium Mall, 300 Boylston Street, Newton MA", prepared by R.E. Cameron & Associates, Inc. and stamped and signed by Larry Grossman, Registered Architect, of Add, Inc., dated December 3, 2014.
 - b. Atrium Center plan set, prepared, stamped, and signed by Larry Grossman, Registered Architect, of Add Inc., dated November 25, 2014, and consisting of the following ten (10) sheets:
 - i. Parcel Map;
 - ii. Exhibit 20141124 Level 1, dated November 25, 2014;
 - iii. Exhibit 20141124 Level 2, dated November 25, 2014;
 - iv. Exhibit 20141124 Level 3, dated November 25, 2014;
 - v. Exhibit 20141124 Level 4, dated November 25, 2014;
 - vi. New Floor Plan Parking Level E, dated February 18, 2014 and revised on November 21, 2014;
 - vii. New Floor Plan Parking Level D, dated February 18, 2014 and revised on November 21, 2014;
 - viii. New Floor Plan Parking Level C, dated February 18, 2014 and revised on November 21, 2014;
 - ix. New Floor Plan Parking Level B, dated February 18, 2014 and revised on November 21, 2014; and

- x. Building Elevations, dated December 17, 2012 and revised on November 26, 2014.
- 2. All laboratory tenants planning to conduct rDNA research or use rDNA technology shall be limited to Biosafety Levels 1 and 2, and the development of a laboratory conducting rDNA research or using rDNA technology at a Biosafety Level 3 or above shall be prohibited.
- 3. Prior to the issuance of any building permit for a laboratory tenant planning to conduct recombinant DNA (rDNA) research or use rDNA technology, the tenant shall obtain a permit from the Commissioner of Health and Human Services with prior approval of the Newton Biosafety Committee.
- 4. Signage shall conform to City standards. The Urban Design Commission and the Director of Planning and Development will review and approve all by-right signs.
- 5. The petitioner shall maintain all trash and recycling receptacles or areas in a sanitary condition at all times. The collection/emptying of such receptacles shall only occur on weekdays between 8:00 a.m. and 5:00 p.m.
- 6. Any additional air conditioning or other mechanical or ventilation systems related to the laboratory or restaurant uses shall be acoustically and visually screened, and shall be reviewed and approved by the Director of Planning and Development prior to installation.
- 7. Prior to the issuance of any building permit, the petitioner shall submit a Construction Management Plan for review and approval by the Director of Planning and Development and the Commissioner of Inspectional Services. The Construction Management Plan shall discourages construction workers from parking on Florence Street and construction materials being delivered on Florence Street, and shall be consistent and not in conflict with relevant conditions of the Board Order and shall include, but not limited to, the following provisions:
 - a. 24-hour contact information for the general contractor of the project.
 - b. Hours of construction: construction shall be limited to between the hours of 7:00 a.m. and 7:00 p.m. on weekdays, and between the hours of 8:00 a.m. and 5:00 p.m. on Saturdays. No construction is permitted on Sundays or holidays except in emergencies, and only with prior approval from the Commissioner of Inspectional Services.
 - c. The proposed schedule of the project, including the general phasing of the construction activities.
 - d. Site plan(s) showing the proposed location of contractor and subcontractor parking, on-site material storage area(s), on-site staging areas(s) for delivery vehicles, and location of any security fencing.
 - e. Proposed truck route(s) that minimize travel on local streets.
 - f. Proposed methods for dust control including, but not limited to: covering trucks for transportation of excavated material; minimizing storage of debris on-site by using dumpsters and regularly emptying them; using tarps to cover piles of bulk building materials and soil; locating a truck washing station to clean muddy wheels on all truck and construction vehicles before exiting the site.
 - g. Proposed methods of noise control, in accordance with the City of Newton's Ordinances. Staging activities should be conducted in a manner that will minimize off-

- site impacts of noise. Noise producing staging activities should be located as far as practical from noise sensitive locations.
- h. Tree preservation plan to define the proposed method for protection of any existing trees to remain on the site.
- i. A plan for rodent control during construction.
- 8. The storage of snow on the site shall not be allowed, and it is the responsibility of the property owner to remove snow from the site.
- 9. If in the future the existing building is demolished and the site is redeveloped, all the relief granted by this or previous special permits shall be null and void, and the site shall comply with all current and applicable requirements of the Newton Zoning Ordinance.
- 10. No Building Permit shall be issued pursuant to this Special Permit/Site Plan Approval until the petitioner has:
 - a. Recorded a certified copy of this Board Order for the approved Special Permit/Site Plan Approval with the Registry of Deeds for the Southern District of Middlesex County.
 - b. Filed a copy of such recorded Board Order with the City Clerk, the Department of Inspectional Services, and the Department of Planning and Development.
 - c. Obtained a written statement from the Planning Department that confirms plans submitted with any Building Permit are consistent with plans approved in Condition #1.
 - d. Obtained the necessary permit from the Commissioner of Health and Human Services with the approval of the Newton Biosafety Committee for a laboratory tenant planning to conduct rDNA research or use rDNA technology in accordance with Condition #3.
- 11. No Final Inspection/Occupancy Permit for the uses covered by this Special Permit/Site Plan Approval shall be issued until the petitioner has:
 - a. Filed with the City Clerk, the Department of Inspectional Services, and the Department of Planning and Development a statement by a registered architect or surveyor certifying compliance with Condition #1.
 - b. Submitted to the Department of Inspectional Services, and the Department of Planning and Development a final as-built survey plan in digital format by a licensed surveyor.
 - c. Obtained a written statement from the Planning Department that confirms the project has been constructed consistent with the plans approved in Condition #1.

No conditions were incorporated from Board Order #176-98.

Conditions incorporated from Board Order #466-94:

12. That the final design, color, and illumination of the proposed signs shall be reviewed and approved by the Director of Planning and Development for consistency with the submitted sign package.

- 13. That any changes to the existing landscaping be reviewed by the Director of Planning and Development.
- 14. The petitioner shall use best efforts to recycle materials used in the operation of all the businesses on the site.

No conditions were incorporated from Board Order #303-90(3).