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Mayor

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James Freas
Acting Director

PUBLIC HEARING MEMORANDUM

Public Hearing Date:	November 6, 2014
Land Use Action Date:	November 18, 2014
Board of Aldermen Action Date:	December 1, 2014
Action Expiration Date:	January 19, 2015

DATE: October 31, 2014

TO: Board of Aldermen

FROM: James Freas, Acting Director of Planning and Development
Alexandra Ananth, Chief Planner for Current Planning
Stephen Pantalone, Senior Planner

SUBJECT: **Petition #365-14,** KARYOPHARM THERAPUETICS/NS WELLS ACQUISITION LLC, for a SPECIAL PERMIT/SITE PLAN APPROVAL to allow for recombinant DNA research and technology at 75-95 WELLS AVENUE, Ward 8, on land known as SBL 84, 34, 2C, containing approximately 557,570 sf of land in a district zoned LIMITED MANUFACTURING. Ref: Sec 30-24, 30-23, 30-12(e)(9) of the City of Newton Rev Zoning Ord., 2012.

The purpose of this memorandum is to provide the Board of Aldermen and the public with technical information and planning analysis which may be useful in the special permit decision making process of the Board of Aldermen. The Planning Department's intention is to provide a balanced view of the issues with the information it has at the time of the public hearing. There may be other information presented at or after the public hearing that the Land Use Committee of the Board of Aldermen will want to consider in its discussion at a subsequent Working Session.

75-95 Wells Avenue

EXECUTIVE SUMMARY

The subject property is located at 75-95 Wells Avenue in the Wells Avenue Office Park ("Office Park") and consists of a 557,570 square foot lot improved with a three-story, approximately 263,260 square foot commercial building. The petitioner is Karyopharm Therapeutics, which is a clinical-stage pharmaceutical company focused on discovery and development of drugs for the treatment of cancer and other major diseases. The petitioner is already operating at the site, and is seeking a special permit to allow recombinant DNA research and technology (rDNA) as part of their laboratory operations.

rDNA research and technology is regulated under Chapter 12 (Health and Human Services) (**ATTACHMENT A**) and Chapter 30 (Zoning) of the City's Ordinances. Under Chapter 12, Article III, companies seeking to utilize rDNA research and technology in their laboratories must submit a permit application to the Commissioner of Health and Human Services (the "Commissioner"). The application is reviewed by the Commissioner in concert with the Newton Biosafety Committee, which is established under Chapter 12 and is comprised of the Commissioner and eight other members with expertise in applicable areas. Chapter 12 and Chapter 30 also require that applicants obtain a special permit from the Board of Alderman, as rDNA is only allowed by special permit, and only in Limited Manufacturing, Manufacturing and Mixed Use 1 & 2 zoning districts. Section 30-24 requires that the Board of Alderman consult the Biosafety Committee for their recommendation during the special permit process.

The petitioner has followed these steps, and received approval from the Biosafety Committee at their meeting held on September 3, 2014. As noted in the attached letter from the Interim Commissioner (**ATTACHMENT B**), the petitioner has met all applicable guidelines. If the special permit is granted, the petitioner will undergo annual inspections by the City as required under Chapter 12. Based on the recommendation of the Interim Commissioner and the nature of the research, the Planning Department does not have any concerns with the proposed rDNA use at this site.

I. SIGNIFICANT ISSUES FOR CONSIDERATION:

When reviewing this request, the Board should consider whether:

- The specific site is an appropriate location for the proposed rDNA use, as the petitioner has received approval from the Newton Biosafety Committee. (§30-24(d)(1))
- The proposed rDNA use will not adversely affect the neighborhood, as the Newton Biosafety Committee has reviewed the petitioner's application to the Commissioner of Health and Human Services to ensure that its laboratory design and operations meet applicable guidelines. (§30-24(d)(2))

II. CHARACTERISTICS OF THE SITE AND NEIGHBORHOOD

A. Neighborhood and Zoning

The subject property is located in the Office Park, which includes office uses, day-care uses, education uses, and a sports club (**ATTACHMENT C**). The Office Park is zoned for Limited Manufacturing (**ATTACHMENT D**), and is subject to a Deed Restriction, which limits the types of land uses and provides stricter dimensional requirements for structures. The proposed rDNA laboratory use is allowed under the Deed Restriction.

B. Site

The subject property consists of 557,570 square feet of land, and is improved with a three-story, approximately 263,260 square foot commercial building and parking lot.

III. PROJECT DESCRIPTION AND ANALYSIS

A. Land Use

The petitioner is a clinical-stage pharmaceutical company focused on discovery and development of drugs directed against nuclear transport targets for the treatment of cancer and other major diseases. The petitioner is currently utilizing approximately 21,300 square feet of the building for office space, and approximately 2,300 square feet for laboratory space. The petitioner is proposing to incorporate rDNA materials into its laboratory operations, which requires a permit from the Commissioner of Health and Human Resources and a special permit from the Board of Alderman. The integration of rDNA will not require any modifications to the exterior or interior of the building. The Biosafety Committee has reviewed the petitioner's application under Chapter 12 and recommended approval to the Interim Commissioner. The Interim Commissioner has provided a letter to the Board of Alderman expressing her support and requesting approval of the special permit.

In the most basic terms, rDNA is a form of artificial DNA that is created by combining two or more sequences that would not normally occur together. rDNA research and technology was introduced in the 1970's and is commonly used in many types of life science research today. Guidelines for rDNA research are issued by the National Institute of Health (NIH) and the CDC, which require certain safety measures depending on the type of materials used in the research. The materials are classified on a Biosafety Level of one to four. The type of material used at the petitioner's laboratory is considered Biosafety Level 2 ("BSL-2"). For BSL-2 laboratories, the NIH and CDC guidelines require the petitioner to control the laboratory environment, properly dispose of waste, and provide specific training for employees. The materials that the petitioner is proposing to use at the subject property are not hazardous and do not pose a threat to the general public.

The Planning Department relies on the Biosafety Committee's review of the proposed rDNA activities for compliance with applicable guidelines and safety measures. Based on their approval, the Planning Department does not have any concerns with the proposed use. The Planning Department notes that Chapter 12 requires the petitioner to undergo annual inspections, and therefore does not believe any additional conditions are necessary.

B. Building and Site Design

There will be no changes to the site plan or building.

C. Parking and Circulation

There will be no change to the parking or circulation of the site due to the proposed development.

D. Landscape Screening

No landscape plan is required for this petition.

IV. TECHNICAL REVIEW

A. Technical Considerations (Chapter 30, Newton Zoning Ordinance)

The Zoning Review Memorandum **(ATTACHMENT E)** provides an analysis of the proposal with regard to zoning. Based on this review, the petitioner is seeking a Special Permit/Site Plan Approval for the following reliefs:

- §30-12(e)(9), to allow an rDNA use.

B. Engineering Review

This project does not require review by the Engineering Division of Public Works.

V. PETITIONERS' RESPONSIBILITIES

The petition is considered complete at this time.

ATTACHMENTS:

Attachment A: Chapter 12 of the Newton Ordinance
Attachment B: Letter from the Interim Commissioner of Health and Human Services
Attachment C: Land Use Map
Attachment D: Zoning Map
Attachment E: Zoning Review Memorandum
Attachment F: Letter from the Economic Development Commission

Cross references—Regulations governing appointment and service on commissions, boards, committees and councils, § 2-8; council on aging, Ch. 14, Art. II.

ARTICLE III.
RECOMBINANT DNA RESEARCH

Sec. 12-21. Regulation of recombinant DNA technology.

(a) All recombinant deoxyriboneucleic acid (DNA) research or technology in the City of Newton shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institutes of Health (NIH), by other Federal Agencies, or by Act of Congress, and in conformity also with such other health regulations as the commissioner of health and human services may from time to time promulgate or as the Newton biosafety committee (NBC) may adopt.

(b) In the context of this article the following definitions are adopted:

(1) *Recombinant DNA molecules (rDNA)*, and organisms and viruses containing rDNA, are those defined in the NIH Guidelines promulgated in the Federal Register on July 1, 1981.

(2) An *institution* is any person, group of persons, business entity, association or any other organization, whether public or private, for profit or non-profit.

(3) *Guidelines* are defined as:

a) National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules, published in the Federal Register on August 27, 1982, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and approved by the NBC.

b) National Institutes of Health Physical Containment Recommendations for Large Scale Use of Organisms Containing Recombinant DNA Molecules, as published in the Federal Register of April 11, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and adopted by the NBC.

c) Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules, as issued by the Office of Recombinant DNA Activities, November, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and adopted by the NBC.

(4) *Large-scale* means the use, for the purpose of containing recombinant DNA culture media, of any stainless steel vessel which has a volume greater than sixteen liters, or such use of any non-stainless steel vessel which has a volume greater than ten liters. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 5-26-2005)

Sec. 12-22. Newton biosafety committee.

(a) There shall be a Newton biosafety committee (NBC) which shall be comprised of nine (9) members which include the following:

The commissioner of health and human services;

Two (2) members of the Newton health advisory council, appointed by the commissioner of health;

Three (3) members appointed by the mayor, at least one of whom is a scientist knowledgeable in the field of rDNA research and technology. The other two shall represent the fields of public health, occupational health, infectious disease or environmental health.

Three (3) members appointed by the board of aldermen, at least one of whom represents the fields of public health, occupational health, infectious disease or environmental health.

Members appointed by the mayor and the board of aldermen shall serve three (3) year terms; provided however, that of the first three members appointed to the committee by the mayor and the board of aldermen one shall serve for a term of one (1) year, one shall serve for a term of two (2) years, and one shall serve for a term of three (3) years. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Sec. 12-23. Institutional biotechnology committee.

(a) An institutional biotechnology committee (IBC) must be established for each institution conducting rDNA research or technology. The IBC shall include the commissioner of health and human services and two community representatives with expertise in rDNA research and technology and/or safety issues. One of these representatives shall be appointed by the mayor and one shall be appointed by the board of aldermen for a term of three years. The IBC shall meet at least once a year. Each institution shall name at least three (3) members of its staff to the IBC, including the safety officer.

(b) The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once annually to enforce these regulations. Each institution shall name a safety officer who shall be responsible for enforcing the policies of the IBC. In addition, the IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of non-compliance by the institution with any section of this ordinance or the NIH guidelines. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

Sec. 12-24. Permit requirement.

(a) All institutions planning to conduct rDNA research or to use rDNA technology must obtain a permit from the commissioner of health and human services with the prior approval of the NBC, before commencing said research or technology. Institutions receiving such permits shall conduct research or technology only as specifically set out in its permit application and supporting documents filed with such application.

(b) All institutions requesting a permit from the commissioner of health and human services to commence rDNA research or technology in the Limited Manufacturing Zoning District (Sec. 30-12), the Manufacturing Zoning District (Sec. 30-12), and the Mixed Use 1 and 2 Zoning Districts (Sec. 30-13), must also receive a special permit from the board of aldermen pursuant to section 30-24 prior to the original issuance, but not the renewal, of said permit. Institutions seeking such permit from the commissioner of health and human services must first submit the following to the NBC:

(1) A completed application form obtained from the Newton health and human services department.

(2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.

(3) A listing of all organisms, including containment levels, to be employed in rDNA research or technology, and including the screening process to be performed by institutions conducting rDNA research or technology in order to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.

Host organisms obtained from independent laboratories shall undergo the same screening process.

(4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.

(5) Establish a training program of safeguards and procedures for personnel using rDNA;

(6) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC for all persons engaged in the use of rDNA. Such programs shall include, but shall not necessarily be limited to:

a) A pre-employment medical examination for employees. Facilities using rDNA research or technology requiring BL2 or BL3 as defined in the National Institutes of Health (NIH) guidelines published in the Federal Register, as amended, physical containment, or large scale use, shall take employee serum samples at the time of employment and maintain said samples to permit future testing for at least ten years.

b) Prompt reporting of significant or potentially related employee illnesses to the IBC.

c) Retention of medical and health records for at least ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.

d). Effective rodent and insect control programs must be in place.

(7) The name of the safety officer who shall be responsible for enforcing the policies of the IBC.

(8) A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.

(c) The NDC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the commissioner of health and human services.

(d) Not later than sixty (60) days after an institution has commenced rDNA research or technology as determined by the commissioner of health and human services, the institution shall file with the commissioner:

(1) The names and qualifications of members of IBC.

(2) Copies of Newton building department and Newton fire department certification.

(3) Evidence of certification, as necessary, from the Massachusetts Department of Environmental Quality Engineering and the Massachusetts Department of Public Health.

(e) Permits granted by the commissioner of health and human services shall be renewed annually.

(f) The fee for a permit granted by the commissioner of health and human services, or annual renewal thereof, shall be $250. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No.X-175, 05-26-05)

Sec. 12-25. Inspection and review.

(a) The institution shall allow inspections and review of the procedures and practices of rDNA use for compliance with this ordinance.

(b) The Newton health and human services department shall retain a competent professional person, agency or institution to perform inspections and review. The results shall be reported to the commissioner of health and human services, the NBC and the institution involved.

(c) Inspections will be conducted at least annually.

(d) The institution shall reimburse the city for the direct expense of inspections and review. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05

Sec. 12-26. Procedure for requesting and holding a hearing.

Institutions denied a permit, or the renewal thereof, or any person aggrieved by the granting of a permit, may request a hearing by filing a written petition with the commissioner of health and human services within ten (10) days from the denial or grant of a permit. Upon receipt of such petition the commissioner of health and human services shall set a time and place for such hearing and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing the petitioner shall be given an opportunity to be heard and to show why the permit should be granted or denied. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

Sec. 12-27. Appeal.

Any institution or person aggrieved by the final decision of the commissioner of health and human services with respect to the denial or grant of a permit may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of this commonwealth. (Ord. No. R-237, 3-15-82)

Sec. 12-28. Restrictions.

Recombinant DNA use requiring physical containment greater than the BL3 level shall not be permitted in the City of Newton. (Ord. No. R-237, 3-15-82)

Sec. 12-29. Violations.

An institution which violates any provision of this article shall be subject to a fine of three hundred dollars ($300.00) per offense, each day of violation constituting a separate and distinct offense. The commissioner of health and human services shall be empowered to enforce this ordinance in any court of competent jurisdiction. In addition to a fine, an institution which violates any provision of this ordinance or whose continued conduct of recombinant DNA technology poses an immediate threat to the public health or environment may be closed by the commissioner of health and human services. Any institution aggrieved by such action of the commissioner of health and human services shall appeal the same under the provisions of Sections 12-25 and 12-26. (Ord. No. R-237, 3-15-82; Ord. no. X-175, 05-26-05)

Sec. 12-30. Severability.

If any provision(s) or portion(s) of this article or the application of any provision(s) or portion(s) thereof to any person or circumstance is/are held to be invalid, such invalidity shall not affect the validity of the remainder of said provision or other provisions of this article. (Ord. No. R-237, 3-15-82; Ord.
No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Secs. 12-31—12-39. Reserved.

ARTICLE IV.

ATTACHMENT B

City of Newton

HEALTH AND HUMAN SERVICES DEPARTMENT
1000 Commonwealth Avenue
Newton, MA 02459

Telephone 617.796.1420 Fax 617.552.7063
TDD/TTY 617.796.1089

Public Health
Prevent. Promote. Protect.

October 30, 2014

Subject: Karyopharm Therapeutics Special Permit

Dear Aldermen,

It is my pleasure to write to the Board of Aldermen regarding the special permit application from Karyopharm Therapeutics for its laboratory facility located at 85 Wells Avenue. Karyopharm recently moved to Newton from its prior location in Natick.

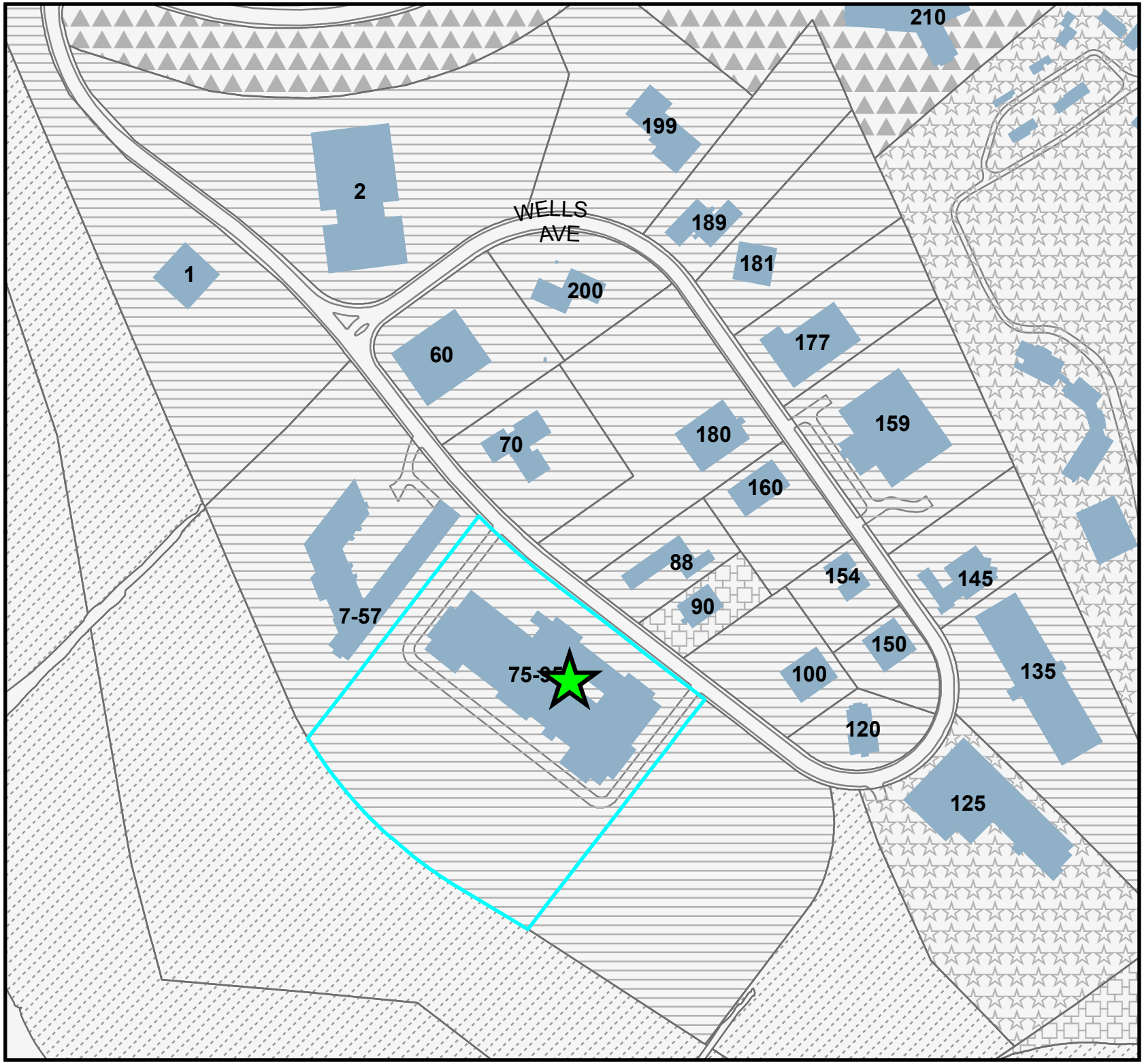
The newly reconstituted Bio Safety Committee met with representatives from Karyopharm at its meeting on September 3, 2014 to review the permit application. Karyopharm presented the committee with all the required documents and protocols. They will be operating in compliance with the National Institutes of Health (NIH) guidelines. The committee requested some clarification and the additional documentation has been received.

The Bio Safety Committee members were unanimous in their recommendation to the Interim Commissioner of Health and Human Services for approval of the rDNA permit. As such we respectfully recommend the approval of the special permit for Karyopharm Therapeutics.

Sincerely,

Linda M. Walsh
Interim Commissioner Health and Human Services

Land Use Map
75-95
Wells Avenue



Legend

Land Use

- Multi-Family Residential
- Commercial
- Open Space
- Private Educational
- Nonprofit Organizations

ATTACHMENT C

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NEWTON GIS

The information on this map is from the Newton Geographic Information System (GIS). The City of Newton cannot guarantee the accuracy of this information. Each user of this map is responsible for determining its suitability for his or her intended purpose. City departments will not necessarily approve applications based solely on GIS data.

CITY OF NEWTON, MASSACHUSETTS
Mayor - Setti D. Warren
GIS Administrator - Douglas Greenfield

0 25 50 75 100 0 25 50 75 200 0 25 50 75 300 0 25 50 75 400 0 25 50 Feet

Map Date: October 29, 2014

Zoning Map
75-95
Wells Avenue

City of Newton, Massachusetts

Legend

Zoning

- Single Residence 1
- Limited Manufacturing
- Public Use

ATTACHMENT D

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NEWTON GIS

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CITY OF NEWTON, MASSACHUSETTS
Mayor - Setti D. Warren
GIS Administrator - Douglas Greenfield

0 25 50 75 100 0 25 50 75 200 0 25 50 75 300 0 25 50 75 400 0 25 50
Feet

Map Date: October 29, 2014

ATTACHMENT E

Setti D. Warren
Mayor

City of Newton, Massachusetts
Department of Planning and Development
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James Freas
Acting Director

ZONING REVIEW MEMORANDUM

Date: September 23, 2014

To: John Lojek, Commissioner of Inspectional Services

From: Jane Santosuosso, Chief Zoning Code Official
Alexandra Ananth, Chief Planner for Current Planning

Cc: Ronit Milstein, Karyopharm Therapeutics
James Freas, Acting Director of Planning and Development
Ouida Young, Associate City Solicitor

RE: Request to allow a recombinant DNA lab facility

Applicant: Karyopharm Therapeutics, Inc	
Site: 75/85 Wells Ave	**SBL:** 84034 0002C
Zoning: Limited Manufacturing	**Lot Area:** 557,570 square feet
Current use: Office	**Proposed use:** Office with rDNA lab

BACKGROUND:

The property at 75-95 Wells Ave consists of a 557,570 square foot lot improved with a multi-tenanted 260,000+ square foot office building. Karyopharm Therapeutics Inc, a pharmaceutical company, recently relocated its offices to the site, and proposes to expand its operations on site to include their labs, which utilize recombinant DNA research and technologies. Karyopharm's mission is to discover and develop drugs directed against nuclear transport targets for the treatment of cancer and other major diseases.

Karyopharm's offices occupy 21,300 square feet, and they propose to add an additional 2,300 square feet of laboratory space. There are currently 45 employees for the company, with anticipated growth up to 60, as well as five additional employees in their labs, for a total of 50-65 employees.

The following review is based on plans and materials submitted to date as noted below.

- Zoning Review Application, prepared by Ronit Milstein, Senior Director of Operations, dated 9/18/2014

ADMINISTRATIVE DETERMINATIONS:

1. The applicant proposes to use 2,300 square feet of space for labs utilizing recombinant DNA research and technology. Per Section 30-12(e)(9), a special permit is required for a facility engaged in recombinant DNA research and technology

2. The applicant must seek approval from the Newton Biosafety Committee for siting of the proposed facility.

3. Karyopharm is housed in a total of 23,600 square feet, of which 21,300 is used for office space and 2,300 is used as lab space. The entirety of the space was previously used as office, which required one parking stall per every 250 square feet; or 95 parking stalls. Karyopharm's use of the property requires one stall per every 250 square feet for the 21,300 square feet of office space, and one stall for every four employees in the lab, as well as one stall for every 1,000 square feet of floor space in the 2,300 square foot lab. Karyopharm's parking requirement is 90 parking stalls. No relief is required for the parking.

4. See "Zoning Relief Summary" below:

Zoning Relief Required		
Ordinance		Action Required
§30-12(e)(9)	Special permit to allow a for recombinant DNA research and technology	S.P. per §30-24

ATTACHMENT F

CITY OF NEWTON, MASSACHUSETTS

Economic Development Commission

October 31, 2014

City of Newton
1000 Commonwealth Avenue
Newton, MA 02459

Dear Aldermen,

On behalf of the Newton Economic Development Commission, I wish to express strong support for the special permit application from Karyopharm Therapeutics for its laboratory facility located at 85 Wells Avenue.

We understand that Newton's Bio Safety Committee met with company representatives from Karyopharm on September 3, 2014 to review required documents and protocols. The Bio Safety Committee has subsequently signaled its unanimous support their recommendation to the Interim Commissioner of Health and Human Services for approval of the rDNA permit.

As you already know, Karyopharm recently moved to Newton from its prior location in Natick, and is representative of the innovation, science, and technology companies we wish to attract to Newton as part of the N^2 initiative. As a result of this, the Economic Development Commission voted on September 9 to support the special permit for rDNA activities.

In closing, we strongly support Kayopharm's application, and urge that you award the special permit.

Sincerely,

Christopher Steele, Chairman, Newton Economic Development Commission

1000 Commonwealth Ave.
Newton, MA 02459
T 617/796-1120
F 617/796-1142

http://www.newtonma.gov/gov/planning/lrplan/econdev/