



CITY COUNCIL AGENDA REPORT

Meeting Date: May 19, 2022

From: John Swiecki, Community Development Director

Subject: Use Permit Application 2022-UP-2, 1000 Sierra Point Parkway, within the SP-CRO Sierra Point Commercial District, to allow the use of minipigs in medical research and development (R&D) by Bristol-Myers Squibb.

Community Goal/Result

Safe Community - Residents and visitors will experience a sense of safety.

Purpose

To consider the proposed use permit application for Bristol-Myers Squibb (BMS) to conduct research on minipigs for cardiovascular research.

Recommendation

That the City Council approve the requested use permit application 2022-UP-2, via adoption of the draft Resolution, containing the findings and conditions of approval (Attachment 1).

Background

On June 16, 2008, City Council adopted Ordinance 528 which allowed for research and development (R&D) uses at Sierra Point. That ordinance, codified as BMC Section 17.18.035.B allows for R&D using certain live animals (live insects, rodents, rabbits, fish, and amphibians) as permitted by-right while certain others (live dogs, cats, or nonhuman primates) are prohibited. Those that are not identified as either permitted or prohibited are subject to a use permit, pursuant to Section 17.18.020.K. The findings required for Use Permit approval are contained in BMC Sections 17.40.060.A & B and are listed below in this report.

Notably, per Brisbane Municipal Code Section 17.18.035, R&D use permits in this district are subject **to the City Council's review and approval authority rather than the Planning Commission**, which typically has approval authority over use permits. The provision establishing City Council authority over R&D use permits in this zoning district was added by the City Council itself during deliberations on the draft ordinance in 2008. Until now no R&D use permit applications have been filed pursuant to the provisions of this ordinance.

The subject application was initially noticed in error for Planning Commission review; however it was removed from the Planning Commission agenda without being heard. All correspondence provided to the Planning Commission has been attached to this Council report for reference.

Discussion

As indicated above, the applicant proposes to utilize the existing vivarium to conduct R&D using minipigs. This is for cardiovascular medical research. The location of the use would be within BMS's existing, 9,000 square foot vivarium on the first floor of this 4-story, approximately 125K square foot R&D building, within The Shore biotechnology campus.

The applicant has indicated that the cardiovascular makeup of minipigs is similar to that of humans and so they serve an important function in this type of research. The BMS project description states that, "While smaller animals (rats and mice for instance) are valuable contributors at the beginning stages of disease research, many question about how a drug acts in the body need to be studied in an animal that more closely recapitulates the human physiology, metabolism, and disease process." The applicant has estimated that approximately 5 to 15 minipigs would be at the facility at any given time. Further details on the use are provided in the applicant's project description (Attachment 3)

The use permit provisions provide two findings for approval, per BMC Section 17.40.060. They are:

- i. In considering an application, the City Council shall consider and give due regard to the nature and condition of all adjacent uses and structures, and to general and specific plans for the area in question.
- ii. The City Council shall determine whether or not the establishment, maintenance or operation of the use applied for will, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, or whether it will be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city.

Adjacent Uses and General Plan Consistency— In regards to the first finding, the property is within The Shore biotechnology campus, adjacent to other R&D uses. The other nearest use is the City's Marina to the west. The use would be conducted indoors within a controlled vivarium environment in an existing R&D building.

The property is designated for a broad range of commercial land uses in the General Plan, including research and development, which is implemented through the SP-SCRO Sierra Point Commercial District zoning (BMC Chapter 17.18). This allows for the use via conditional use permit, as noted above.

Not Detrimental or Injurious to the Property, Neighborhood or City— On the second finding, the proposal would not be detrimental or injurious to the property, neighborhood or City. As noted above, the use would be conducted indoors within a controlled vivarium environment of an existing R&D building. As such, there would be no detrimental effects on any persons working in the neighborhood and there are no residences in the neighborhood, nor would there be injurious

or detrimental effects to property or improvements in the neighborhood or the general welfare of the City.

As such staff believes this use permit application meets the findings required for approval.

It should be noted that various correspondence has been received expressing opposition to the use of minipigs for research (Attachment 4). The opposition has been based on ethical questions that arise from R&D uses on minipigs, or animals in general. Conversely, the argument in favor of such research might be summarized in that it provides opportunities to advance research and knowledge into treatment of human heart disease and associated conditions, potentially providing broad health benefits. While staff recognizes and respects the differing perspectives surrounding this issue, the findings in the city's ordinance focus on whether there are impacts of a given use that would impact the health and safety of neighbors and potential impacts on property.

Despite that, note that the use is under the regulatory authority of the U.S. Department of Agriculture (USDA). Staff contacted the Veterinary Medical Officer with the USDA who has oversight responsibility for this facility. He indicated that the use will be subject to unannounced inspections by the USDA to ensure the welfare of the animals and indicated that there were no concerns with the proposed use at this facility. Zoning district requirements further require that R&D uses involving live animals comply with the latest version of *The Institute of Laboratory Animals Resources Guide for the Care and Use of Laboratory Animals*.

This application has also been reviewed by the Public Works Department, Police Department and North County Fire Authority and Building Department. None of the departments had objections to the proposed application.

Fiscal Impact

None.

Measure of Success

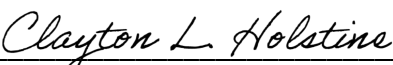
Processing of this application for an R&D use permit consistent with Brisbane's Municipal Code.

Attachments

1. Draft Resolution 2022-XX with Findings and Conditions of Approval
2. Aerial photo of site location & vicinity
3. Applicant's Project Description
4. Correspondence from the Public



John Swiecki, Community Development Director



Clay Holstine, City Manager

ATTACHMENT 1

**Draft - RESOLUTION 2022-XX
A RESOLUTION OF THE CITY COUNCIL OF BRISBANE
CONDITIONALLY APPROVING USE PERMIT 2022-UP-2
TO ALLOW FOR USE OF MINIPIGS FOR
RESEARCH AND DEVELOPMENT (R&D)
AT 1000 SIERRA POINT PARKWAY**

WHEREAS, Ricardo Garcia, the applicant, on behalf of the tenant Bristol-Myers Squibb (BMS), applied to the City of Brisbane for a Use Permit to allow for R&D use of minipigs within the existing BMS vivarium at 1000 Sierra Point Parkway, such application being identified as Use Permit 2022-UP-2; and

WHEREAS, the use of existing facilities are categorically exempt from the provisions of the California Environmental Quality Act (CEQA) per Section 15301 of the State CEQA Guidelines and the exceptions to the categorical exemptions referenced in Section 15300.2 do not apply; and

WHEREAS, notice of the City Council public hearing was posted and mailed to property owners within 300 feet of the boundaries of the subject property and all interested parties requesting notice, per BMC Section 17.54.020 prior to the City Council hearing; and

WHEREAS, on May 19, 2022, City Council conducted a hearing of the application, at which time any person interested in the matter was given an opportunity to be heard; and

WHEREAS, the City Council of the City of Brisbane hereby makes the findings attached herein as Exhibit A in connection with the Use Permit.

NOW THEREFORE, BE IT RESOLVED by the City Council that:

Section 1.

- A. The above recitals are true and correct and incorporated herein by reference as if set forth in full.
- B. The City Council approves Use Permit 2022-UP-2 based on the findings and with the conditions of approval attached herein as Exhibit A.

Section 2.

This Resolution shall take effect immediately upon its adoption.

COLEEN MACKIN, Mayor

I hereby certify that the foregoing Resolution No. 2022-XX was duly and regularly adopted at the regular meeting of the Brisbane City Council on May 19th, 2022 by the following vote:

AYES:

NOES:

ABSENT:

INGRID PADILLA, City Clerk

EXHIBIT A

Action Taken: Conditionally approve Use Permit 2022-UP-2 per the staff memorandum with attachments, via adoption of Resolution 2022-XX.

Findings:

1. The City Council has considered and given due regard to the nature and condition of adjacent uses and structures and the use permit is consistent with the general plan and there is no specific plan adopted by the city council for the area in question.
2. The establishment, maintenance and operation of the use applied for will not, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, nor will it be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city.

Conditions of Approval:

- A. The operator shall maintain its Business License with the City of Brisbane.
- B. The operator shall comply with the performance standards provided in BMC Section 17.18.045 regarding R&D uses.
- C. Operator shall comply with the requirements of the USDA, to ensure the welfare of the animals complies with USDA standards.
- D. Minor modifications to the use permit may be approved by the Community Development Director in conformance will all applicable requirements of the Municipal Code.

1000 Sierra Point Parkway Site Vicinity Map



Introduction

This application describes a request for a use permit for the use of minipigs (*Sus scrofa*) in research in the existing Bristol-Myers Squibb (BMS) vivarium at 1000 Sierra Point Parkway, per Sections 17.18.020(K), 17.18.035(B) of the City of Brisbane Municipal Code. The BMS vivarium at Sierra Point is already constructed and staffed with suitability for indoor pig housing. The permit for the existing structure was granted by the City in 2008 as Building D of the Shore at Sierra Point project, an approximately 23-acre research and development campus in the current SP-CRO Sierra Point Commercial District. Occupancy began in 2020; the site is currently fully operational with approximately 150 full-time employees.

No modifications to the building are proposed in this application or associated with this proposed use. No changes in hazardous chemical storage or noise/odor generation are associated with this proposed use. The facility itself will be used to house swine that will be the subject of ongoing scientific investigation to advance scientific knowledge and treatment of human heart disease and associated conditions. Typical laboratory equipment, office space and other furnishings typical of a science lab are housed within the building on the property in question.

Background and Objective

While smaller animals (mice and rats, for instance) are valuable contributors at the beginning stages of disease research, many questions about how a drug acts in the body need to be studied in an animal that more closely recapitulates the human physiology, metabolism, and disease process. Pigs are a particularly valuable species and are especially notable for their similarities to the human cardiovascular system. BMS employs sound, scientifically advanced methods to develop swine populations that mirror heart disease found in humans.

Project Conduct

BMS has substantial experience and expertise in conducting a wide range of scientific research which often necessarily involves the use of animals. It is for this reason that BMS has established strict internal policies and practices that are designed to meet our own standards and those of all applicable governmental agencies. BMS proudly promotes a culture of excellence in animal welfare, with an active oversight committee, 24/7 availability of laboratory animal veterinarians and veterinary staff, regular internal welfare assessments, and third-party accreditation in AAALAC International, the leading, internationally-recognized organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. All animal activities will comply with federal and local regulations, and the site has obtained and maintains a research registration with the United States Department of Agriculture. Additionally, the animal program will adhere to or exceed the standards described in the Guide for the Care and Use of Laboratory Animals (Institute for Laboratory Animal Research, National Research Council).

BMS is committed to the humane and scientifically appropriate use of animals in research, in unison with our dedication to innovative clinical advancements. Through sophisticated study methods and rigorous scientific principles, our investigators drive the development of high-quality medicines that address the unmet medical needs of patients with serious diseases. Establishing this research at the Sierra Point site will connect our existing cardiovascular team with the resources needed to rapidly develop and progress novel therapies to waiting patients. Beyond satisfying the City's permit requirements, BMS views its commitment to its planned operation at this location as vital to the continued scientific advances critical to our public health mission.

With approval, we look forward to initiating this much-needed work. We have carefully reviewed the permit submission requirements and guidance and believe we have furnished all information necessary to support issuance of the requested use permit. We appreciate the City Council's thoughtful review of this permit application for the use of minipigs in research at the BMS Sierra Point site. We are available for any questions, clarifications, or additional information the Council would find helpful during the review process.

Selected Scientific Publications:

Olivotto, I., Oreziak, A., Barriales-Villa, R., Abraham, T. P., Masri, A., Garcia-Pavia, P., Saberi, S., Lakdawala, N. K., Wheeler, M. T., Owens, A., Kubanek, M., Wojakowski, W., Jensen, M. K., Gimeno-Blanes, J., Afshar, K., Myers, J., Hegde, S. M., Solomon, S. D., Sehnert, A. J., ... Yamani, M. (2020). Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet*, 396(10253), 759-769. [https://doi.org/10.1016/s0140-6736\(20\)31792-x](https://doi.org/10.1016/s0140-6736(20)31792-x)

Ho, C. Y., Mealiffe, M. E., Bach, R. G., Bhattacharya, M., Choudhury, L., Edelberg, J. M., Hegde, S. M., Jacoby, D., Lakdawala, N. K., Lester, S. J., Ma, Y., Marian, A. J., Nagueh, S. F., Owens, A., Rader, F., Saberi, S., Sehnert, A. J., Sherrid, M. V., Solomon, S. D., Wang, A., ... Heitner, S. B. (2020). Evaluation of Mavacamten in Symptomatic Patients With Nonobstructive Hypertrophic Cardiomyopathy. *Journal of the American College of Cardiology*, 75(21), 2649-2660. <https://doi.org/10.1016/j.jacc.2020.03.064>

Silva, K., & Emter, C. A. (2020). Large Animal Models of Heart Failure: A Translational Bridge to Clinical Success. *JACC. Basic to translational science*, 5(8), 840-856. <https://doi.org/10.1016/j.jacbts.2020.04.011>

Stricker-Krongrad, A., Shoemake, C., Brocksmith, D., Liu, J., Hamlin, R., & Bouchard, G.. (2017). Comparative cardiovascular physiology and pathology in selected lineages of minipigs. *Toxicology Research and Application*, 1, 239784731769636. <https://doi.org/10.1177/2397847317696367>

Gutierrez, K., Dicks, N., Glanzner, W. G., Agellon, L. B., & Bordignon, V. (2015). Efficacy of the porcine species in biomedical research. *Frontiers in genetics*, 6, 293. <https://doi.org/10.3389/fgene.2015.00293>

Animal Welfare Resources:

Animal Welfare Act and Regulations (USDA): <https://www.nal.usda.gov/legacy/awic/animal-welfare-act>

Guide for the Care and Use of Laboratory Animals, 8th Ed. ("The Guide"):
<https://www.ncbi.nlm.nih.gov/books/NBK54050/>

AAALAC International: <https://www.aaalac.org/>

The "3Rs": <https://nc3rs.org.uk/the-3rs>

Attachment A

How has the project been designed and operated in order to be compatible with the nature and condition of all adjacent uses and structures, and with general and specific plans for the area in question?

This proposal incorporates no alterations to the existing area at or around 1000 Sierra Point Parkway. All work will be conducted entirely inside the facility.

How will the proposed use be designed and operated in order to not be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood?

The proposed use would have no detrimental effect on the safety, comfort, or general welfare of the persons residing in the Brisbane community. All elements of this work will be contained within the facility. All scientific work within BMS is designed and conducted in compliance with local, federal, and company safety requirements under the direction of the BMS biosafety officer.

How will the proposed use be designed and operated in order to not be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city?

The proposed use will be conducted entirely within the BMS facility, therefore, there is no risk of detrimental impact on the property or improvements in the neighborhood. The objective of all scientific work at BMS is for the ultimate improvement of human health, and seeks to improve the welfare of patients at a city level and global scale.

From: Chris Brinkman <chris@tnl-global.com>
Date: April 12, 2022 at 5:38:39 PM PDT
To: "Holstine, Clay" <clayholstine@ci.brisbane.ca.us>
Subject: Important - re: pig testing

Dear Clay,

I would like to register my very strong opposition to the permit application by Bristol-Myers Squibb to add baby pig testing in there vivarium. This type of testing is cruel and unusual to sentient beings particularly those as intelligent as pigs. These animals will suffer needlessly unless we deny this inappropriate testing scheme. As a society we can do better than taking shortcuts like this, we can improve and develop pharmaceuticals in more humane ways. If humans are the Apex creature, we need to use our brains in our compassion to care for other animals that don't have a voice in this matter. I hope you will use your best judgment in considering my request.

If you would, please forward my email to the planning commission and add this to the public document records for this permit application.

In mutual compassion,

Chris Brinkman
Santa Rosa, CA

From: Jennifer Kalk <jenkalk100@gmail.com>
Date: April 12, 2022 at 11:28:33 PM PDT
To: "Holstine, Clay" <clayholstine@ci.brisbane.ca.us>
Subject: Use of piglet's for testing

Dear Sir

I am very much against, in fact horrified that Bristol Myers Squibb is applying for a permit to use baby pigs for testing heart medications. This cannot be allowed!!

Please forward my email to the entire Planning Commission and make my request and comment public by making it part of the "Public Documents" for this permit application.

Thank you

Jennifer Kalk

Sent from my iPhone

From: Laura Watson <lauraxwatson@gmail.com>
Date: April 12, 2022 at 7:05:00 PM PDT
To: "Holstine, Clay" <clayholstine@ci.brisbane.ca.us>
Subject: Bristol Myers Squibb -- Pig Testing

Dear Clay Holstine,

As an advocate for animals and a volunteer at [Goatlandia](#), farm animal sanctuary, I am writing to you in regards to the application from Bristol Myers Squibb to put before the Brisbane Planning Commission to add baby pig testing in their Vivarium. This is an expansion of the testing that they do on Rats and Mice. In my experience, I have seen first-hand how so many animals are in desperate need to to have a safe and loving environment because they have been mistreated. Please do not allow the mistreatment and testing to go this far and expand to baby pigs.

I am asking for a **denial of the permit and for Bristol Myers Squibb to find appropriate and alternate ways to test their new heart medications.**

Please forward this email to the entire Planning Commission and please make this request public by making it part of the "Public Documents" for this permit application.

Thank you,
Laura Watson

From: Jane McLaughlin <askjane@mac.com>
Sent: Tuesday, April 12, 2022 4:44 PM
To: Holstine, Clay <clayholstine@ci.brisbane.ca.us>
Subject: NO pig testing

Dear Mr. Holstine,

I understand that Bristol Myers Squibb will be applying to the city of Brisbane for a permit that will allow them to test their product Vivarium on baby pigs. It's already bad enough that they test on rats and mice, but testing on baby pigs is especially disgusting.

As an advocate for all animals (yes, even rats and mice), I request that you deny Bristol Myers Squibb their permit application.

Please forward this email to the entire Planning Committee. At the same time, I ask that you make my opposition public by including this request as part of the "Public Documents" for the permit application.

Sincerely,
Jane McLaughlin
301 Orchards St
Healdsburg CA
650-533-5866

From: Michele Buchanan <mdb2218@gmail.com>
Sent: Wednesday, April 13, 2022 8:48 AM
To: Holstine, Clay <clayholstine@ci.brisbane.ca.us>
Subject: STOP Bristol Myers Squibb from testing on baby pigs

Mr. Holstine,

I am VERY opposed to the permit application to test on baby pigs by Bristol Myers Squibb for their Vivarium.

I am asking denial of the permit and for Bristol Myers Squibb to find appropriate and alternate ways to test their new heart medications.

Please forward my email to the entire Planning Commission and PLEASE make my request and comment public by making it part of the “Public Documents” for this permit application.

Thank you for considering the welfare of animals and humans.

Michele Derum

From: Jean Sieper <siepers@comcast.net>

Sent: Wednesday, April 13, 2022 12:56 PM

To: Planning Commissioners <PlanningCommissioners@ci.brisbane.ca.us>; cholsteine@ci.brisbane.ca.us

Subject: Urgent: Please Reject Use Permit 2022-UP-2

Dear Members of the Planning Commission,

As a physician and scientist, we urge you to reject Use Permit 2022-UP-2 for Bristol-Myers Squibb (BMS), which is requesting to expand its animal experimentation facility to include minipigs. Approval of this permit would be a detriment to our community and an endorsement of the inhumane and flawed use of animals in the testing of pharmaceuticals.

While the Food & Drug Administration (FDA) requires that companies test pharmaceuticals in nonhuman animals, 95 percent of drugs that prove safe in animals fail in human clinical trials. To address this problem, Sen. Cory Booker, who represents a state heavy with pharmaceutical and biotech companies, and Sen. Rand Paul co-sponsored the FDA Modernization Act. The bill, which is gaining steam in Congress, would help remove FDA's antiquated requirement for animal tests—a prerequisite that many pharmaceutical companies would like to see abolished.

One drug company, Vanda Pharmaceuticals, sued FDA in an effort to avoid unnecessarily testing its drug on beagles, pointing out that the test would not provide human-relevant data. While Vanda and others recognize the lack of scientific necessity when it comes to the use of animals, Bristol-Meyers Squibb is investing even more in the antiquated approach. FDA has even identified "Advancing Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing" as a priority area.

Brisbane should invest in organizations that are employing 21st century research methods. Further, high-paying jobs in science and research need not involve the use of animals. Many major pharmaceutical companies and private research labs have, in recent years, invested heavily in non-animal methods:

In 2013, Harvard University announced that it would close its New England Primate Research Center, choosing to instead focus on other areas of research.

In 2012, contract research company Covance announced that it was closing its animal testing facility in Chandler, Ariz., just 3 years after the local government had heavily aided its creation.

In comparison, labs entirely focused on non-animal methods or replacing animals in testing and research are more plentiful now than ever before. In Maryland, there is the Institute for In Vitro Sciences. Harvard now has the internationally recognized Wyss Institute, which is a leader in developing organs-on-a-chip, which allow for the testing of drugs and chemicals using human cells rather than

nonhuman animals.

One of the “Conditions of Approval” for the requested permit states that Bristol-Myers Squibb “shall comply with the requirements of the USDA, to ensure the welfare of the animals comply with USDA standards.” However, this requirement is toothless.

Compassionate people would like the laws governing the use of animals in laboratories to forbid cruelty, but that is simply not the case. Research facilities like Bristol-Myers Squibb are subject to incredibly weak federal laws and rules. Under the Animal Welfare Act, no experiments are prohibited—including those that inflict pain. The law is primarily a husbandry statute that regulates the size of cages, cleanliness, and food and water. In addition, the USDA, which is supposed to enforce the Animal Welfare Act, was cited by its own inspector general for closing investigations involving grave violations, including animal deaths and serious repeat violations; failing to properly apply financial penalties, reducing fines by an average of 86 percent; and wasting resources by conducting inspections at facilities that did not house animals covered by the Animal Welfare Act. In February 2019, *The Washington Post* reported: “USDA inspectors documented 60 percent fewer violations at animal facilities in 2018 from the previous year. ...The drop in citations is one illustration of a shift—or what critics call a gutting—in USDA’s oversight of animal industries.” In May 2021, *Science* reported that “USDA now only partially inspects some lab animal facilities, internal documents reveal,” further revealing the agency’s low standards.

We urge you to reject Use Permit 2022-UP-2 and stand up for modern science and the welfare of animals. If you have further questions about this issue, we urge you to contact the Physicians Committee for Responsible Medicine, a global nonprofit that is one of the world’s preeminent sources of education on modern research and testing methods.

Thank you for your time and attention to this issue.

Very truly,
William J. Sieper, D.O. and Jean M. Sieper, Ph.D.
475 Crestmont Dr.
San Francisco, CA 94131-1018