

**RE: Application for Special Use Permit to Town of Harwich Planning Department/Planning Board
Submitted March 8, 2022 for placement on April 12, 2022 hearing agenda.**

NARRATIVE FOR PROPOSED SCOPE OF USE

For 35 years, Charles River Microbial Solutions, a division of Charles River Laboratories (global headquarters located in Wilmington, Mass.) has been ensuring the safety of the global biopharmaceutical supply chain. Over 55% of all injectable pharmaceuticals, including approved COVID-19 vaccines, and implantable medical devices are tested with Charles River’s endotoxin tests to ensure the absence of deadly contaminants and verify product safety. These critical endotoxin tests are developed using *limulus ameobocyte lysate* (LAL) that is only found in the blood obtained from horseshoe crabs.

Since 1995, Charles River has successfully operated as the only U.S.A.- based company to be issued and maintain its FDA Biological Products license for the extraction and processing of blood drawn from horseshoe crabs. Charles River has a proven 27-year track record of operating its existing horseshoe crab processing facility in Charleston and has developed Standard Operating Procedures based on established best practices the company has pioneered.

With the ever-increasing demand for critical endotoxin testing products, especially within the global Covid 19 pandemic, the company is seeking to extend its supply base for processing horseshoe crabs. As such, Charles River would like to open a local LAL processing operations facility at the newly constructed commercial property located within the Town of Harwich in designated industrial zone (I-L) at 195 Queen Anne Road. We plan to lease three contiguous units at this facility.

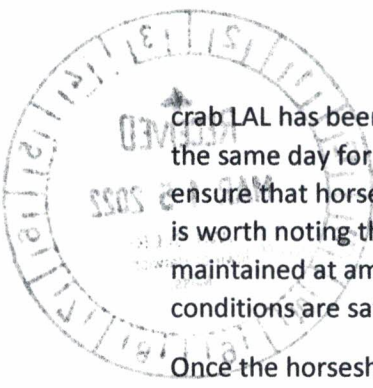
OPERATIONS

Akin to the local commercial fishing industry, Charles River anticipates operating year-round with the ability to scale up and/or down based on the seasonality of horseshoe crab harvesting and the current and potential future need for LAL. At the outset, it is anticipated that normal business operations would occur between 6 am - 7pm Monday through Saturday, but we would request permission from The Harwich Planning Board to expand daily hours of operation should the need arise. Hours of operation could also expand, when necessary, when volume of crabs could increase with seasonal availability.

For staffing purposes, Charles River anticipates hiring 20-25 employees who would be organized into shifts with staggered arrival and departure times. As such, there is sufficient parking availability onsite to accommodate employees. Additionally, employees would be encouraged to carpool where applicable and when possible. A supervisor(s) would be present at all times during operating hours and would also be reachable after-hours.

WORKFLOW

Horseshoe crabs received at the facility would be sourced from locally licensed harvesters holding current permits issued by the Massachusetts Division of Marine Fisheries. Once received, the horseshoe crabs would then be cleaned with water (to remove any barnacles and seaweed), then staged in the processing area where a portion of their blood is drawn in a highly controlled and monitored environment in accordance with our existing and standard operating procedures. Once the horseshoe



crab LAL has been collected, the horseshoe crabs would then be organized for collection and transport the same day for their return to the area where they originally collected. We will make every effort to ensure that horse crabs are returned to their natural habitat within 24 hours of delivery to our facility. It is worth noting that adverse weather could impose delays, in which case the horseshoe crabs would be maintained at ambient temperatures, at the proposed facility until retrieval and broadcast weather conditions are safe for the fisherman to return the crabs.

Once the horseshoe crab blood is collected, it is then transferred to the processing rooms where the LAL is made ready for transport back to the Charles River facility located in Charleston, South Carolina. Additional processing occurs in Charleston in order to prepare for the manufacture of endotoxin detection tests.

NO ADVERSE IMPACT ON NEIGHBORHOOD

We believe that Charles River's proposed operations at 195 Queen Anne Road would not adversely impact abutters and the existing operations of surrounding businesses. Except for the loading and unloading of horseshoe crabs, all operations would be conducted inside the facility. Horseshoe crabs would be stored and processed inside where environmental temperature controls can be properly maintained. It is anticipated that 6 to 8 deliveries/ pickups would occur during the proposed hours of operation. Other than the use of a small forklift (5,000 lbs.) there would be no need for similar heavy equipment that currently operates in this industrial zone and noise pollution would be minimal. Vehicles delivering/picking up horseshoe crabs would typically consist of pick-up trucks with a contractor sized trailer, as well as trailered small boats typically used by local and licensed fisherman. As such, we anticipate the traffic will be equal to or less than the traffic for the existing business at this location, as compared to the surrounding businesses engaged in landscaping, construction, automotive sales, and the transport of solid waste from the Harwich Transfer Facility.

ENVIRONMENTAL IMPACT CONSIDERATIONS

The proposed operations would not create any hazardous solid waste or hazardous wastewater, nor would there be any materials used or stored at the facility that would be classified as hazardous. The processing of horseshoe crabs would not create any airborne particulate matter or noticeable odor. Akin to a seafood wholesaler operation, Charles River's use of water during its operations is primarily for cleaning and sanitation purposes. A bleach solution is primarily used for disinfection. A Material Safety Data Sheets folder would be onsite and available for review.

Rubbish and recycling would be placed in designated receptacles and removed by a contracted trash removal company.

Additionally, a small (200 gal- 300 gal) industrial above ground water holding tank would be placed inside the facility to collect any non-hazardous horseshoe crab byproduct produced during the processing in order to prevent its introduction into the septic system. The tank would be pumped out as needed by a locally contracted pump-out provider.

CLOSING

Charles River has researched several different locations on Cape Cod and we believe that Harwich, given its proximity to Nantucket Sound and important horseshoe crab harvesting areas, is ideal. We are hopeful that our proposal will not only provide important local employment but also act as an economic

multiplier to the surrounding local businesses. Ultimately, Charles River's continued goal is to be able to provide critical support to the bio-pharmaceutical supply chain whilst continuing critical patient safety in the US and throughout the globe. We are hopeful that The Town of Harwich would become a partner in this important endeavor. We thank you for your consideration.

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