HALEY WARD
ENGINEERING | ENVIRONMENTAL | SURVEYING
FORMERLY: CES INC

April 1, 2021

Town of Boxborough Planning Board
Mr. Simon Corson, Town Planner
29 Middle Road
Boxborough, MA 01719

Re: Peer Review Services | 1414 Massachusetts Avenue

Dear Simon,

Haley Ward, Inc. (Haley Ward) has reviewed submitted documents with respect to the request for site plan approval for the resumption of discontinued use and/or expansion of existing use of a facility located at 1414 Massachusetts Avenue, Boxborough, MA (Site). The applicant, Vibalogics, intends on using an existing building for the purposes of office space, research and development activities, and light manufacturing associated with the development, manufacture, and analysis of pharmaceutical products. The existing building is supported by an on-site wastewater treatment facility (WWTF) operated by the property owner to serve the Site.

The following comments, questions and/or requests for additional information are based on our review of 032221 Planning Board Agenda Packet Revised- Opt, the public hearing conducted on March 22, 2021, and written questions and comments provided to us following the public hearing. We have consolidated similar questions/comments as they pertain to safety and environmental management to assist the Planning Board in generating a comprehensive response from the Applicant.

Existing On-Site Wastewater Treatment Facility (WWTF)
Inconsistencies were noted in the projected generation of wastewater at the Site which will be directed to an existing on-site WWTF operated by the landlord/property owner (LPCH Boxborough, LP).

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The upper most figure in the submittal anticipates 10,500 gallons of wastewater per day discharged to a 23,000-gallon septic tank connected to the WWTF for treatment/processing prior to discharge to the soil/leach field which appears to be in a recharge area adjacent to a defined Aquifer Protection Zone.

- Confirm expected wastewater discharge rate to WWTF based on planned activities and operations for the Site.
- Identify remaining WWTF capacity available to Site for additional tenants or expansion of operations at the Site.
- Provide detail on how wastewater discharge will meet the definition of sanitary wastes under current by-laws.
- Confirm that industrial waste treatment is permitted under the current groundwater discharge permit.
- Confirm locations, condition and most recent sampling dates and results for onsite monitoring wells.
- Provide existing or draft lease agreements demonstrating the landlord's acceptance of the industrial waste flow and pass through of site plan or special permit conditions applied to Vibalogics by the Planning Board.

The following questions or comments are based on the Pare Memorandum dated February 8, 2021 included with the applicant's submission:

- A single equalization tank was reported in use at the WWTF. Two equalization tanks were expected. Is the stated capacity of the WWTF accurate with a single equalization tank?
- Provide details of current system design and function (e.g., process flow diagrams, total capacity, limitations) and whether the WWTF can provide service to the currently proposed and projected use of the Site.
- An aeration tank, to replenish oxygen in wastewater effluent after treatment, was identified in the WWTF and the operator was unsure if it was being used for treatment. Will WWTF resume aeration in the treatment process for the planned wastewater generation at the Site?
- A sodium bicarbonate system, for pH control, without any chemical injection pumps and disconnected feed lines was reported at the WWTF. Has or will this presumed treatment system be connected and reactivated as part of the proposed activities at the Site?
- Provide wastewater characterization profiles to ensure wastewater discharge from Site to WWTF will meet capacity of WWTF.
- What types of salts and quantities are expected to be distributed in wastewater received by WWTF?
- Provide information as to how wastewater constituents are evaluated/identified

before discharge to WWTF and leaching system (e.g., sampling, continuous measurement, automated controls).

Research/Production Wastewater Treatments Prior to Release to WWTF

The submittal documents provided information regarding pretreatment of wastewater before release to WWTF. Our understanding is that there is a "Kill Tank" or "Bio Kill" system proposed for the operation, and a pH neutralization tank to ensure production and/or laboratory wastewater is release at a pH of 7. The following additional information is requested:

General

- Will all drains (e.g., production processes, laboratory sinks, floor drains, internal perimeter drains) lead to pH neutralization tank and/or "Kill Tank"/"Bio Kill" system as necessary to manage production and laboratory wastes which go to sanitary system drain (i.e., septic tank, WWTF)?

- Provide detail on specific wastewater flows to internal treatment systems and specific wastewater flows that lead directly to septic tank and WWTF.

"Kill Tank"/"Bio Kill" System

- What is the volume capacity of the "Kill Tank"/"Bio Kill" system?

- Provide detail on how from the "Kill Tank"/"Bio Kill" system(s) work(s) and mechanisms of operation (e.g., principles of operation, flow diagrams, control mechanisms, fail safes, backup power sources, secondary containment, etc.). Please include information on expected state of effluent from the system.

- What is the expected temperature of the outflow of liquid waste from the "Kill Tank"/"Bio Kill" system?" (Application mentions a cool down prior to discharge to wastewater system.)

- Will the steam blow downs associated with the "Kill Tank"/"Bio Kill" or other steam operations be discharged to the wastewater system?

- Does the heat sterilization of the "Kill Tank" deactivate any viral vectors used in research and/or production? Is there a planned method of confirmation?

- Does the "Kill Tank"/"Bio Kill" system act as an industrial scale autoclave?

pH Neutralization

- Will all wastewater flowing out of building to the septic tank run through the pH treatment systems?

- Describe operation of pH neutralization system, expected capacity, and mechanism of operation or treatment (e.g., principles of operation, flow diagrams, control mechanisms, fail safes, backup power sources, etc.).

Production/Laboratory/Site Wastewater

In addition to real time monitoring of pH and temperature of wastewater prior to release to septic tank and WWTF, application mentions periodic sampling of the waste stream (Page 3, 2/9/2021 Level Design letter).

- What specific parameters or substances would this periodic wastewater sampling identify? List expected parameters and/or substances of interest.

- How many autoclaves are expected within the Site?

- How will any liquid drained, or steam blow down from any autoclaves be tempered prior to release to sanitary sewer (noted 140°F comment in DPS project note)?

- Salts were mentioned as a feature of production wastewater. What types of salts and quantities/concentrations are expected to be in wastewater from production, laboratory, or other activities?

- Will there be any treatment or evaluation of salt content of production wastewater prior to discharge to the sanitary sewer?

- Will production areas/clean rooms be equipped with sprinkler systems for fire extinguishing? If so and in the event of a sprinkler discharge, will water in laboratory or production areas be contained and treated within the production/laboratory treatment systems prior to discharge to septic tank and WWTF?

Hazardous Materials/Wastes Used or Generated on Site

- Describe facilities for storage, containment and safety precautions for the hazardous materials used.

- Are there plans for pre-treatment of domestic water for use in production and research processes? If so, what hazardous materials will be used or generated

as part of water treatment?

- What are the "Spor Klenz-like" solutions? Provide expected bulk quantities, safety procedures, storage, and disposal methods.
  Note: Undiluted Spor Klenz Ready to Use reportedly has a pH of 1.8 and is an EPA registered pesticide. This requires specific handling and control of product and containers. The proposed use of the product is sterilization of equipment and surfaces. Generally, the use of the product requires spraying on surfaces and allowing sufficient contact time to achieve sterilization of the surface. Proper use is not expected to generate waste outside of containers and wipes. Disposal of unused/remaining undiluted Spor Klenz would be considered a hazardous waste due to its reported corrosivity requiring either permitted on-site treatment or disposal as hazardous waste.

- Describe the "bleach like" solutions used to treat biowaste prior to discharge to wastewater system? Provide expected bulk quantities, safety procedures, storage, and disposal methods.

- Describe provisions for secondary containment of all bulk hazardous materials (e.g., bulk ethanol)?

- Describe method of hazardous waste determination specific to laboratory research work and production activities. Estimate volumes generated and/or category of Hazardous Waste Generator (e.g., Very Small Quantity Generator, Small Quantity Generator, Large Quantity Generator). Will waste storage be provided within the building or outside until shipped off site by Triumvirate or other hazardous waste vendor?

- Describe method of biohazardous waste/regulated medical waste determination specific to laboratory research and production activities. Estimate volumes generated. Will waste storage be provided within the building or outside until shipped off site?

- Are there plans to be working with Select Agents or toxins currently regulated by State or Federal authorities?

- Describe means to minimize the amount of solid and hazardous waste generated at the Site.

- Are there any generators associated with the Site (one generator was noted associated with the WWTF)? If so and they are fueled by petroleum products,

are the generators housed or are associated tanks provided with secondary containment?

- Are there any other sources of petroleum products or oils either on site or being introduced on site requiring spill containment and control?

Biological Safety

- Will there be recombinant DNA research conducted within this Site?

- Will the Site follow *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines)?

- Describe plans to establish or currently established institutional biosafety committee (IBC) for the facility, including any strategy to include at least two members that shall not be affiliated with the facility/company who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).

Haley Ward appreciates the opportunity to review the submittals and provide these questions and comments for the Planning Board's use in evaluating the request for site plan approval for the Site. Please reach out to either of the undersigned if you have any questions or require further information.

Sincerely,
Haley Ward, Inc.

Michael D. Sauda, MPH, CSP
Senior Project Scientist

Bethany Ordung, PE
Project Manager/Vice President

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FORMERLY: CES INC

April 6, 2021

Town of Boxborough Planning Board
Mr. Simon Corson, Town Planner
29 Middle Road
Boxborough, MA 01719

Re: Peer Review Services | 1414 Massachusetts Avenue

Dear Simon,

Haley Ward, Inc. (Haley Ward) has reviewed the recently submitted written responses and information presented by Vibalogics at the April 5, 2021 Planning Board meeting with respect to the request for site plan approval for the resumption of discontinued use and/or expansion of existing use of a facility located at 1414 Massachusetts Avenue, Boxborough, MA (Site).

Based on recent submissions (e.g., April 2, 2021 letter from Alphen & Santos, P.C., supplemental site plan, calculations, and presentation slides distributed April 5, 2021), Vibalogics intends to collect all process wastes associated with production and laboratory activities and ship the waste off-site. This modified approach limits the waste discharged to the on-site wastewater treatment facility (WWTF) to only sanitary waste to meet the same conditions as when the Site was previously operational. Hazardous wastes and medical wastes associated with Vibalogics activities are proposed to be collected separately from the process waste and sanitary waste and will also be shipped off site for proper treatment and/or disposal.

The Applicant addressed most of the questions associated with process and laboratory wastes raised in our April 1, 2021 letter. The specific layout and plumbing of the modified collection and holding systems will be designed following the Site Plan approval process. As a result, the process and laboratory wastewater flows to be constructed within the facility could not be reviewed.

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Haley Ward recommends, using normal review and permitting processes, that the installation and operation of the process and laboratory waste plumbing and associated holding tank(s) be evaluated once designed to confirm that the management of these wastes will be achieved.

Vibalogics' strategy also addressed questions and requests for additional information outlined in our letter of April 1, 2021 related to industrial or process waste discharge to the on-site WWTF and the associated leach field system. The following questions or requests for information related to the WWTF did not appear to be specifically addressed in the reviewed submissions:

1. Confirm locations, condition, and recent sampling dates and results for on-site monitoring wells (associated with the WWTF).
2. Will the WWTF resume aeration for the treatment of sanitary waste as originally designed?
3. Will the WWTF sodium bicarbonate system for pH control be connected and reactivated as originally designed?

Vibalogics has indicated that the WWTF will become operational prior to construction of interior space and the start of operations. The WWTF is operated by the property owner, Lincoln Property Company.

Recommended Conditions

Haley Ward recommends the Planning Board consider the following conditions to Site Plan approval to facilitate "*determination that adequate facilities are provided for handling and disposal of waste and other production by-products,*" and "*to prevent pollution of surface and groundwater.*"

Prior to the issuance of an occupancy permit by the Town of Boxborough:

1. Provide documentation demonstrating the WWTF is fully operational and meets all permitting requirements of the Massachusetts Department of Environmental Protection and/or the Board of Health, as applicable and including follow-up on compliance items from the October 2020 MA DEP compliance inspection.
2. Provide existing or draft lease agreement documenting pass through of site plan or special permit conditions applied to Vibalogics by the Planning Board and documenting the property owner's restriction on industrial and hazardous wastewater effluent from the onsite sanitary wastewater treatment and disposal system.

3. Provide permitted and/or approved design plans delineating separation and control of process and laboratory wastewater systems to demonstrate management of process waste, industrial waste, biomedical waste, hazardous waste, and/or water reclamation systems. This would include associated process and/or laboratory waste plumbing, pretreatment systems, holding tanks, and/or secured waste containers, as appropriate,

We are satisfied the remainder of our requests for information and questions have been answered or are no longer applicable. Haley Ward appreciates the opportunity to support the Town of Boxborough and Planning Board in the evaluation of the Site Plan Approval Application. If you have any questions or require further information, please contact either of the undersigned.

Sincerely,
Haley Ward, Inc.

Michael D. Sauda, MPH, CSP
Senior Project Scientist

Bethany Ordung, PE
Project Manager/Vice President