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August 3, 2021

Planning Board
Town of Boxborough
29 Middle Road
Boxborough, MA 01719
Via email

Re: Site Plan Review/Arranta Bio MA2, LLC (“Arranta Bio”)/ Proposed Facility/
1414 & 1320 Massachusetts Avenue; 244A & 244B Adams Place; 984, 984A, 984B, 984C,
1451, 1497 & 1634 Hazard Lane; 328 & 1451 Rear Hazard Lane, Boxborough, MA 01719
Assessor Parcel Numbers: 12-027, 12-028, 12-030, 13-004, 13-002, 17-005, 17-009, 17-
010, 17-022, 17-023, 17-024, 17-025, 18-001

Dear Members of the Board,

This office represents Arranta Bio regarding its Site Plan review application applicable to its intent to occupy portions of the of the existing two-story facility at 1414 Massachusetts Avenue. At the July 19, 2019 Planning Board hearing, the applicant was asked if the proposed uses were in compliance with the most recent requirements contained in the Zoning Bylaw (as amended at the June Town Meeting), the most recent Board of Health Ground Water Protection Regulations and the most recent Board of Health Biological Safety Regulations. Please accept this correspondence in response to said inquiry, a copy of which is being provided to the Board of Health (whereas the Board of Health has jurisdiction over the interpretation and enforcement of its regulations). We also sought and received confirmation from the agent for the Board of Health that we were reviewing the most recent sets of regulations.

1. Zoning Bylaw.

Employing past practice, we submitted a “Form of Intent” with back up materials requesting a Zoning Determination to the Building Commissioner on June 4, 2021. The request was substantially similar to the submission made on behalf of Vibalogics, to which the Building Commissioner responded with a positive zoning determination letter. On July 6, 2021 we were informed that Mr. Herget was not reappointed by the Select Board and he did not respond to our request before departing the position. Meanwhile, Town Meeting had adopted some changes to the applicable provisions of the Zoning Bylaw. We updated the request for a zoning

determination and resubmitted same on July 12, 2021 to the Building Commissioner (with a simultaneous copy to your office). The July 12th request specifically addressed the amendments to the Zoning Bylaw adopted at the June 12, 2021 Town Meeting. We were advised on July 21, 2021 by Mr. Ramsbottom that he does not issue zoning determinations for anything other than a complete application, and he recommended that we proceed before the Planning Board and discuss the matter with the Board. To that end, please refer to the package we submitted on July 21, 2021 describing Arranta Bio's proposed uses of the facility and describing how such uses are in compliance with the applicable provisions of the Zoning Bylaw.

2. Proposed Groundwater Protection Regulation, Town of Boxborough Board of Health 3/31/21

The subject premises are located within the Groundwater Protection Area as defined in the regulations, and, therefore are subject to the regulations. As you can see from the Site Plan application materials, the applicant is not proposing to perform any of the activities prohibited in the Groundwater Protection Area, but to anticipate some of your more precise questions, we have identified some of the prohibited activities that you may question, and are able to provide the following clarifications:

A. Section V.A. 6 prohibits “[T]reatment or disposal works, subject to 314 CMR 5.00, for non-sanitary wastewater, including those activities listed under 310 CMR 15.004(6), except for a. replacement or repair of an existing treatment works that will not result in a design capacity greater than the design capacity of the existing treatment works; [and other exceptions]”. As reported in the materials submitted, Arranta Bio will separate non-sanitary wastewater from sanitary wastewater, and will use the existing treatment plant and leaching field for only sanitary waste. Non-sanitary waste will be placed in holding vessels and trucked off site for proper disposal.

B. Section V.A.7 prohibits “Facilities that generate, treat, store, or dispose of hazardous waste subject to MGL. c. 21C and 310 CMR 30.000, except for:
a. very small quantity generators (VSQGs);
b. household hazardous waste collection centers or collection events;
c. waste oil retention facilities; and
d. treatment works for the restoration of contaminated ground or surface waters in compliance with MGL. c.21E and 310 CMR 40.000.”

A Very Small Quantity Generator (VSQG) is defined in the Regulations as “Any public or private entity, other than residential, which produces less than 27 gallons (100 kilograms) a month of hazardous waste or waste oil, but not including any acutely hazardous waste as defined in 310 CMR 30.136.”

Beyond VSQG status are Small Quantity Generator (SQG) and Large Quantity Generator (LQG) statuses, which define expanded waste quantities but impose additional limitations around waste accumulation quantities and timeframes and employee training requirements, not seen in VSQG requirements. Arranta Bio currently holds VSQG status for their Watertown, MA facility and is anticipating the same in Boxborough. Arranta Bio contracts Triumvirate Environmental for

professional hazardous management and emergency response services, to ensure compliance with EPA and MADEP requirements and safe handling and disposal of waste materials.

C. Section V.B.1. prohibits the following activities, unless designed in accordance with the specified performance standards: “Storage of liquid hazardous materials and/or liquid petroleum products, unless such materials are stored above ground and on an impervious surface, and in containers (or above ground tanks) within a building, or outdoors in covered containers (or above ground tanks) designed and operated to hold either 10% of the total possible storage capacity of all containers, or 110% of the largest container’s storage capacity, whichever is greater. However these storage requirements shall not apply to the replacement of existing tanks or systems for the keeping, dispensing or storing of gasoline provided the replacement is performed in a manner consistent with state and local requirements.”

There have been above ground storage containers for the fuel for the emergency generators, for the Waste Water Treatment Plant, and for the diesel fire pump. A list of the equipment and the dates they were originally installed is provided below. Each of the tanks has the benefit of a Permit from the Fire Department . Each of them pre-date the regulations and, as provided by the last sentence, their continued use and/or replacement are exempt from the new requirements.

1. 1500 KW Caterpillar Generator (Outside of loading dock) 5/15/2000
2500 gallons #2 Diesel Fuel. Belly tank on bottom of Generator.
2. 1500 KW Caterpillar Generator (Outside of loading dock) 5/15/2000
2500 gallons #2 Diesel Fuel. Belly tank on bottom of Generator.
3. 250 KW Caterpillar Generator (Left side of driveway to loading dock – building life safety)
11/1/2013 400 gallons #2 Diesel Fuel. Belly tank on bottom of generator.
4. 225 KW Koehler Generator (Waste Water Treatment Plant) 7/5/2007
275 gallons #2 Diesel Fuel. Belly Tank on bottom of generator.
5. Two Propane Tanks (Outside Waste Water Treatment Plant – WWTP HVAC)
6. 275-gallon #2 Diesel Fuel Tank (Fire Pump House) 3/10/2006
Feeds diesel fire pump.

The incidental hazardous process/lab waste shall be captured and contained in above-ground containers and will be trucked off site. As mentioned above, Arranta Bio contracts Triumvirate Environmental for professional hazardous management and emergency response services, to ensure compliance with EPA and MADEP requirements and safe handling and disposal of waste materials.

For purposes of clarification, the non-hazardous process/lab waste and the non-hazardous pure water reject do not meet the definitions in the regulations for “Hazardous Materials” or “Hazardous Waste”. The definitions are:

Hazardous Material: Any substance in any form which because of its quantity, concentration, or its chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with one or more

substances, constitutes a present or potential threat to human health, safety, welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. Hazardous materials include, without limitation, synthetic organic chemicals, petroleum products, heavy metals, radioactive or infectious materials, and all substances defined as toxic or hazardous under MGL c. 21E. This term shall not include hazardous waste or oil.

Hazardous Waste: A substance or combination of substances, which because of quantity, concentration, or physical, chemical or infectious characteristics may cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness or pose a substantial present or potential hazard to human health, safety, or welfare or to the environment when improperly treated, stored, transported, used or disposed of, or otherwise managed. This term shall include all substances identified as hazardous pursuant to the Hazardous Waste Regulations, 310 CMR 30.000.

3. Biological Safety Regulations- Boxborough Board of Health

The Regulations apply to the following “Regulated Biological Agents”: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that:

1. Is identified as a "Recombinant or Synthetic Nucleic Acid Molecules " in Section I-B (Definition of Recombinant or Synthetic Nucleic Acid Molecules) of the most recent revision of the NIH Guidelines, or
2. Is classified as a Risk Group 3 or 4 agent in the NIH Guidelines or the BMBL, or
3. Is identified as a "select agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 CFR 73.3, 73.4, 73.5, 73.6, 7 CFR 331.3 and 9 CFR 121.4, and the rulings made by the CDC and the USDA relative thereto, as such regulations and rulings may be amended from time to time. “Select agent" as used herein shall not include *de minimis* amounts of agents or toxins which are excluded from 42 CFR 73.00 et seq.

Arranta Bio has a Biological Safety Program which governs how we assess the risk of incoming biological material, including determining the controls needed to safely handle, store, and contain biological agents. At the center of the biosafety program is the implementation of an Institutional Biosafety Committee (IBC) which formally reviews risk assessments of potential biological agents and considers each project for approval for use on site. It should be noted that a member of the Boxborough Board of Health will be included on our Institutional Biosafety Committee and we will have full transparency with the town as required by the regulations (see below for excerpts:

From Section 7:

D. Excerpt: "All minutes of the IBC meetings must be forwarded to the Board of Health... [and will] include sufficient detail to allow the Board of Health and its staff or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined biosafety level and corresponding safety practices."

E. "The IBC, acting on behalf of an institution, shall review and approve all work involving regulated biological agents, assessing risk and biosafety policy in compliance with NIH Guidelines and BMBL, in an ongoing manner. The IBC is responsible for assuring all work in the facility is in compliance with the standards set forth in these regulations at all times. The IBC will provide the Board of Health description of each project or protocol as approved by the IBC, indicating the assigned biosafety containment level, in a format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project."

Arranta Bio has gone on record that it will not be handling biological agents classified as a Risk Group 3 or 4 agent in the NIH Guidelines or the BMBL, or such select agents. Should Arranta Bio propose to use Regulated Biological Agents in the future, unless specifically exempt from the Regulations, Arranta Bio, must obtain a permit from the Board of Health before commencing or continuing research, manufacturing, or other use of regulated biological agents.

Additionally, be advised that in April 2021, Arranta Bio attained a Biologic Agents Permit for their manufacturing facility located in Watertown, MA, which recently adopted Biological Safety Regulations similar to Boxborough.

We hope the above information is responsive to your inquiry. Thank you for your attention to this matter.

Very truly yours,
Alphen & Santos, P.C.



Paul F. Alphen, Esq.

copy to: Boxborough Board of Health