Resolution 19-078

RESOLUTION AUTHORIZING THE ISSUANCE OF A PUBLIC NOTICE
PRIOR TO RENEWAL OF AN INDUSTRIAL SEWER CONNECTION PERMIT FOR

ENTERIS BIOPHARMA
83 FULTON STREET
TOWN OF BOONTON, NEW JERSEY

BE IT RESOLVED BY THE ROCKAWAY VALLEY REGIONAL SEWERAGE AUTHORITY (RVRSA) AS FOLLOWS:

The Executive Director, JoAnn Mondsini, is hereby authorized to issue a public notice of the commencement of the 30-day public comment period, in accordance with N.J.A.C. 7:14A-15.10 and N.J.A.C. 7:14A-15.11, prior to consideration of an Industrial Sewer Connection Permit Renewal for Enteris Biopharma, 83 Fulton Street, Town of Boonton, NJ.

The proposed form of Industrial Sewer Connection Permit is marked Schedule "A," attached hereto and made a part hereof, a copy of which is also on file at the offices of RVRSA. The terms and conditions proposed include renewal of existing terms and conditions and updating of effluent limitations consistent with local limits study dated November 2014, last revised December 2016, including April 14, 2017 Addendum, approved by NJDEP on April 24, 2017.

I hereby certify that this Resolution was adopted at a meeting of the Rockaway Valley Regional Authority held on September 12, 2019.

On motion of Glenn Corbett

Second by Michael Guadagno

And a Roll Call Vote as Follows:

Yeas: (10) Andes, Cegelka, Corbett, Guadagno, Isselin, Lowell, Recchia, Rossi, Schorno, Zuppa)

Nays: (0) None

Abstain: (0) None

Absent: (0) None

Michael Guadagno
Board Secretary

Schedule A

FACT SHEET
Enteris Biopharma

This fact sheet sets forth the principal facts and the significant factual, legal, and policy considerations examined during preparation of the draft permit.

PERMIT ACTION: Renewal of the Industrial Sewer Connection Permit
Effective Date: 12/01/2019 Expiration Date: 11/30/2022

PERMITEE NAME AND ADDRESS:
Enteris Biopharma
83 Fulton Street
Boonton, NJ 07005
Phone No.: (973) 453-3530

FACILITY NAME AND ADDRESS:
Enteris Biopharma
83 Fulton Street
Boonton, NJ 07005

FACILITY CONTACT INFORMATION:
Mr. Andrejs (Andy) Rasums
Director, Quality Assurance
Phone No.: (973) 453-3517
Fax No.: (973) 588-5966
Email: arasums@enterisbiopharma.com

RECEIVING LOCAL AGENCY: Rockaway Valley Regional Sewerage Authority

RECEIVING COLLECTION SYSTEM: Local collection system owned and operated by the Town of Boonton

DESCRIPTION OF FACILITY OPERATIONS:

Enteris Biopharma develops, tests, and manufactures pharmaceutical products and finished pharmaceutical dosage forms. This facility's SIC code is 2834. This facility is subjected to 40 CFR § 439 – Pharmaceutical Manufacturing Point Source Category, Subpart E – Research. Enteris Biopharma is discharging approximately **11,000 GPD** (monthly average) of combined waste stream generated from its research facility, laboratory and offices. The process wastewater is pretreated prior to discharge. The pretreatment consists of neutralization tanks for pH correction.

DESCRIPTION OF DISCHARGE LOCATION (see attached Figure 1):

Name: 001
Latitude: 40° 54' 51.43" N
Longitude: 74° 23' 37.98" W
Description: Manhole located in the parking lot of the facility.

SUMMARY OF PERMIT CONDITIONS (see attached Table 1):

The following pollutants are regulated: 5-day Biochemical Oxygen Demand (BOD_5), 5-day Carbonaceous Biochemical Oxygen Demand ($CBOD_5$), Total Suspended Solids (TSS), Total Dissolved Solids (TDS), pH, Oil & Grease (HEM), Total Petroleum Hydrocarbon (TPHC), Total phosphorus, Ammonia-Nitrogen (NH_3-N), Copper, Lead, Molybdenum, Selenium, Zinc, and flow.

The basis for the limitations established is summarized in the local limits evaluation report titled RVRSA Local Limit Study, dated November 2014, last revised December 2016, including the April 14, 2017 Addendum; approved by the NJDEP on April 24, 2017, and approved by the RVRSA board on August 10, 2017 and on December 14, 2017.

Below is a summary of key aspects of this permit renewal:

1. *Flow:* Flow limitation is carried over from the previous permit.

2. *Parameters of Concern:* None

3. *Other parameters:* The following parameters limitations have been removed from the permit: Arsenic, Cadmium, Chromium, Mercury, Nickel, Cyanide, Phenols, Acetonitrile and Ethanol. RVRSA reviewed both Enteris Biopharma and RVRSA sampling data from the previous permit cycle (2016 – 2019) and found that all of these parameters have been Non-Detect.

4. As per the Enteris Biopharma renewal permit application cover letter received by RVRSA on February 27, 2019, Enteris Biopharma reminded RVRSA that their production has changed and they have permanently discontinued all fermentation operations and they are now engaged only in pharmaceutical research and development. Therefore, the CFR subcategory has changed from Subpart A (Fermentation Product) to Subpart E (Research) and they are no longer subject to regulations under Subpart CFR 439.16. RVRSA reviewed both Enteris Biopharma and RVRSA sampling data and safety data sheets of the chemicals used, and concluded that the organic parameters Acetone, 4-methyl-2-penatanone (MIBK), Isobutyraldehyde, n-Amyl acetate, n-Butyl acetate, Ethyl acetate, Isopropyl acetate, Methyl formate, Isopropyl Ether, Tetrahydrofuran, Benzene, Toluene, Xylenes, n-Hexane, n-Heptane, Methylene chloride, Chloroform, 1,2-Dichloroethane, Chlorobenzene, o-Dichlorobenzene, Diethyl amine, Triethyl amine will no longer need to be analyzed during this permit cycle.

VARIANCES OR ALTERNATIVES TO PERMIT CONDITIONS:

None

REGULATIONS APPLICABLE TO THIS PERMIT ACTION:

This permit is issued in accordance with N.J.S.A 58:10A-6f, N.J.A.C. 7:14A-19.8, and 40CFR Part 403.8. Requirements for the contents of this Fact Sheet are in accordance with N.J.A.C. 7:14A-15.8.

This facility is subjected to 40 CFR § 439: Pharmaceutical Manufacturing Point Source Category; Subpart E: Research

INDUSTRIAL PRETREATMENT PROGRAM CONTACT PERSON:

Additional information concerning this permit may be obtained from Natalie Pisarcik, RVRSA IPP Coordinator, at 973-263-1555, ext. 213.

TABLE – 1 : DISCHARGE LIMITATIONS

ENTERIS BIOPHARMA

Sample Location: Sampling Manhole (Combined)

Parameter	Daily Max. Limit	Mo. Avg. Limit	Sample Frequency	Sample-Type
Flow	Report	11,000 GPD (3)	Continuous	Metered
$CBOD_5$	500 mg/L (1) (2)		Monthly	Composite
BOD_5	Report		Monthly	Composite
TSS	500 mg/L (1) (2)		Monthly	Composite
TDS	Report		Monthly	Composite
pH	5.5 - 9.5 S.U. (1) (4)		Monthly	Grab
NH_3-N	80 mg/L (1) (2)		Quarterly	Composite
O & G (HEM)	350 mg/L (1)		Quarterly	Grab
TPHC	150 mg/l (1)	100 mg/L (1)	Quarterly	Grab
Phosphorus (T)	Report		Quarterly	Composite
Copper	1.7 mg/L (1)		Annually	Composite
Lead	1.0 mg/L (1)		Annually	Composite
Molybdenum	0.3 mg/L (1)		Annually	Composite
Selenium	0.2 mg/L (1)		Annually	Composite
Zinc	2.1 mg/L (1)		Annually	Composite

Notes:

(1) Discharge limits are based upon the RVRSA local limits.

(2) $CBOD_5$ and/or TSS concentration exceeding 250 mg/l and NH_3-N concentration exceeding 40 mg/L are subject to the Surcharge for Wastewaters of Excessive Strength as per Section 8B of this ISCP. Permittee may not discharge over the $CBOD_5$ limit of 500 mg/L, the TSS limit of 500 mg/L, or the NH_3-N limit of 80 mg/L unless a variance has been issued by the RVRSA providing therefore. Discharge above the above stated limitations will be considered a permit violation and subject to applicable enforcement actions.

(3) Flow limitation is a total of combined process and sanitary flows. Monthly average flow of not more than 11,000 gallons per day (GPD).

(4) The pH sample shall be analyzed by a NJDEP certified lab, within 15 minutes of collection of the sample.

Additional Notes:

The Self-Monitoring Report (SMR) is due and shall be received by the RVRSA office on or before the 21st day of the month following the sampling month, or next business day (if date shall fall on a weekend and/or holiday). If no pollutant sample is collected or analyzed during a month, then the monthly report shall include at least flow data.

Parameters shall be tested according to the monitoring frequency and submitted in a monthly SMR along with copies of analytical results and chain of custody. All SMR's submitted must comply with and contain the signatory requirement as required under 40 CFR § 403.6 (a)(2)(ii) and must be signed by a responsible corporate officer as required under 40 CFR § 430.12(l).

Composite samples shall be collected over a twenty-four (24) hour period (programmed to sample every 15 minutes, unless otherwise stated). Each composite sample shall be a representative composite of the regulated discharge (e.g. 24-hour composite sample for 24-hour operation/discharge).

This facility is subject to 40 CFR § 439 "Pharmaceutical Manufacturing Point Source Category, Subpart E: Research"

"Quarterly" sampling shall occur during the following months:

- 2019: February, May, August, November
- 2020: March, June, September, December
- 2021: January, April, July, October
- 2022: February, May, August, November

The "Annually" sample period shall correspond to the January – December calendar year.

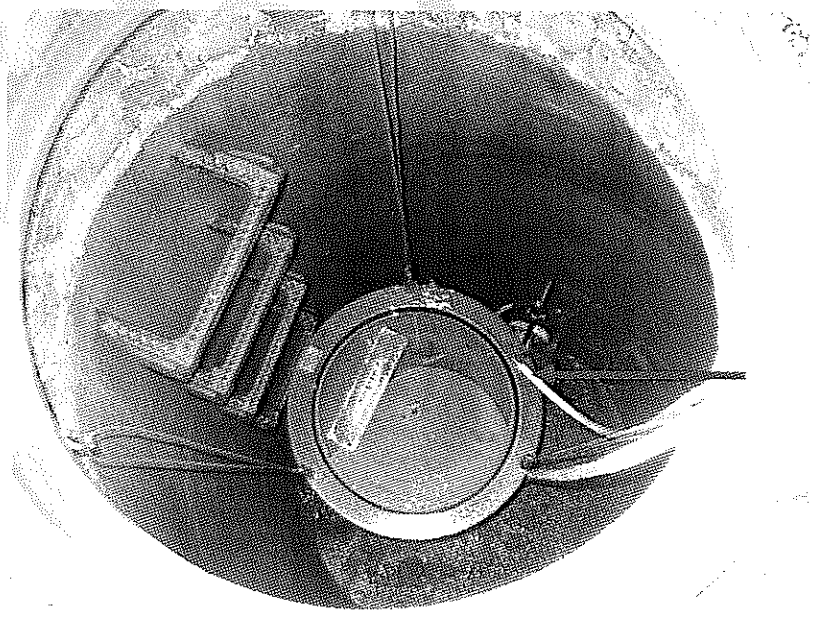
Copies of manifests for process wastewater trucked offsite for disposal shall be made available for review by our offices.

FIGURE 1: Photos of Sampling Location

ENTERIS BIOPHARAMA

SAMPLE MANHOLE (**Discharge location: 001**)
Manhole located in the parking lot of the facility.

Sampling Manhole Picture (Sampling Event)



Arrow is indicating where to place sampling probe during sampling events.