UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
Region 1
5 Post Office Square, Suite 100
BOSTON, MA 02109-3912

May 10, 2018

Herve Berdou
Site Head, Portsmouth
Lonza Biologics INC
101 International Drive
Portsmouth, NH 03801

RE: Categorical Determination Request

Dear Mr. Berdou:

This letter is written in response to your request of August 25, 2017 for a categorical determination for the Lonza Biologics manufacturing facility located in Portsmouth, NH. EPA apologizes for the delay in responding to your original request.

In your letter, you described a process that uses mammalian cell culture techniques that are used for cell therapy treatment. You also indicated that cell therapy is a bioengineered process that did not exist when the Development Document was published in 1998. You have concluded that the fermentation subcategory does not apply to manufacture of bioengineered products.

Based upon our review, EPA has determined that processes you described would not be covered under the Pharmaceutical Manufacturing Point Source Category, 40 CFR 439.

Please keep in mind that although certain Lonza wastestreams may be exempt from federal categorical limitations, process wastewater discharge from any of Lonza's facilities is subject to the conditions set forth in the Portsmouth Sewer Use Ordinance (SUO). The SUO establishes conditions, i.e. local discharge limits that must be complied with prior to discharging to the sewer system.

If you have any questions regarding the contents of this letter, please contact me at (617) 918-1531.

Sincerely,

Justin Pimpare
Regional Pretreatment Coordinator

Cc: Alexis Rastorguyeff, NH DES