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Complete the following application and return it to:

ONTARIO MUNICIPAL UTILITIES COMPANY
ENVIRONMENTAL PROGRAMS DIVISION
1425 SOUTH BON VIEW AVE
Ontario, CA 91861
Phone: (909) 395-2678/Fax (909) 395-2608

SUPPLEMENTAL APPLICATION FOR PHARMACEUTICAL RESEARCH, DEVELOPMENT, AND MANUFACTURING FACILITIES

1) COMPANY NAME: _____

2) FACILITY ADDRESS: _____

3) MAILING ADDRESS: _____

4) DATE CONSTRUCTION OF MANUFACTURING FACILITY COMMENCED: _____

5) DATE FACILITY BEGAN MANUFACTURING PRODUCTS FOR SALE: _____

6) DATE FACILITY INITIATED DISCHARGE TO SEWER FROM COMMERCIAL MANUFACTURING OPERATIONS: _____

7) OWNER OF COMPANY: _____

8) STANDARD INDUSTRIAL CLASSIFICATION (SIC) CODE: _____

9) NAME OF CONTACT PERSON: _____

TITLE: _____ PHONE/FAX: _____

10) BRIEF DESCRIPTION OF RESEARCH/DEVELOPMENT AND MANUFACTURING OPERATIONS PERFORMED AT THIS FACILITY: _____

_____

_____

Entities subject to the Federal Categorical Pretreatment Standards for Pharmaceutical Manufacturers set forth in 40 CFR Part 439 include, but are not limited to, those facilities that manufacture pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating. Facilities performing federally regulated processes are required to notify the Publicly Owned Treatment Works (POTW) that such processes are being performed. This Supplemental Application will serve as the required notification. To determine whether your facility is regulated or exempt from this regulation, you should carefully examine the applicability criteria in Sections 439.0, 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of the final rule. Then, utilizing the checklists contained in Sections A and B below, please indicate if your company is subject to or exempt from these regulations.

A. REGULATED FACILITIES

☐ This facility is subject to the regulations established for the Pharmaceutical Manufacturing Point Source Category set forth in 40 CFR Part 439 because one or more of the operations shown below are currently performed at this facility:

☐ The facility will be subject to the regulations established for the Pharmaceutical Manufacturing Point Source Category set forth in 40 CFR Part 439 because one or more of the operations shown below will be performed at this facility in the future:

Estimated start date:_____

☐ Research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

☐ Manufacture of products not covered under SIC 2833, SIC 2834 and SIC 2836, but discharges from the manufacture of other products by one or more of the following processes; fermentation, extraction, chemical synthesis, mixing/compounding and formulation, and considered by the Food and Drug Administration to be pharmaceutical active ingredients.

☐ Manufacture of multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) not reported under SIC 2833, SIC 2834 and SIC 2836 but derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications.

☐ Manufacture of pharmaceutical products and intermediates that are not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid).

☐ Manufacture of cosmetic preparations that are reported under SIC 2844 and contain pharmaceutically active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.

☐ Other:_____

_____

_____

_____

_____

_____

☐ Check here if production operations are currently performed on a “Bench” or “Pilot Plant” scale.

B. EXEMPT FACILITIES

☐ Operations/Processes conducted in this facility are limited to one or more of the activities described below, therefore, the facility is not subject to regulation under 40 CFR Part 439:

☐ Manufacture of surgical and medical instruments and apparatus reported under SIC 3841 or orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842.

☐ Manufacture of dental equipment and supplies reported under SIC 3843.

☐ Provider of medical laboratory services reported under SIC 8071.

☐ Provider of dental laboratory services reported under SIC 8072.

☐ Provider of outpatient care facility services reported under SIC 8081.

☐ Provider of health and allied services reported under SIC 8091, and not classified elsewhere.

☐ Diagnostic devices other than those reported under SIC 3841

☐ Manufacture of animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.

☐ Manufacture of food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.

☐ Manufacture of pharmaceutical products and intermediates subject to the provisions of the Organic Chemicals, Plastics, and Synthetic Fibers Point Source Category set forth in 40 CFR Part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR Part 414 at the facility.

☐ Other:_____

_____

_____

Facilities that are subject to Federal Categorical Pretreatment Standards are required to submit a Baseline Monitoring Report under 40 CFR Part 403.12. In addition, facilities discharging both federally and locally regulated wastewaterter to the sewer must apply for an Industrial Wastewater Discharge Permit. If, based upon the information contained within this application, it is determined that one or both of these forms is required and has not yet been submitted, blank forms will be mailed to the contact person that is listed on this application.

Should your facility begin discharging a federally regulated process at some point in the future, you are required to notify either the Ontario Municipal Utilities Company at the contact information listed above or the Inland Empire Utilities Agency at (909) 993-1600, submit the Baseline Monitoring Report, and submit an Industrial User Discharge Permit Application at least 90 days prior to commencing discharge from these processes.

Questions related to this form may be directed to the Ontario Municipal Utilities Company, Environmental Programs Manager at (909) 395-2661.

CERTIFICATION STATEMENT

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Signature: _____ Date: _____

Printed Name: _____ Title: _____