ATTACHMENT I

RESPONSE TO COMMENTS ON
DRAFT NPDES PERMIT FOR
Pfizer Pharmaceuticals LLC – Vega Baja – PR0023451

On April 5, 2019, the United States Environmental Protection Agency (EPA) issued a draft National Pollutant Discharge Elimination System (NPDES) permit PR0023451 to Pfizer Pharmaceuticals LLC for its Wasterwater Treatment Plant (WWTP) facility. The public comment period for the draft NPDES permit expired on May 6, 2019.

According to 40 Code of Federal Regulations (CFR) §124.17, at the time that any final permit decision is issued under §124.15, EPA shall issue a response to comments. This response shall (1) specify which provisions, if any, of the draft permit have been changed in the final permit decision, and the reasons for the change; and (2) briefly describe and respond to all significant comments on the draft permit raised during the public comment period, or during any hearing.

Comments on behalf of Pfizer Pharmaceuticals LLC, from Jose Aleman-Figueroa, PE EHS Manager were received in a letter dated May 6, 2019 from the following address:

Pfizer Pharmaceuticals LLC
State Road No. 689, KM 1.9
Vega Baja, PR 00694

All comments received have been reviewed and considered in this final permit decision. A discussion and response to the comments received is as follows:

Comment 1: Background: Fact Sheet and Permit

The draft permit refers to the permitee as Pfizer Pharmaceuticals. However, the correct reference is Pfizer Pharmaceuticals LLC as mentioned at the Fact Sheet to the draft permit.

Response 1:

EPA agrees with the comment and LLC has been added accordingly to the permit.

Comment 2: Background: Fact Sheet and Permit

The draft permit and the fact sheet provide incorrect location coordinates. The coordinates refer to the Gulf Refinery facility in Cataño Puerto Rico (Caribbean Petroleum Corporation oil refinery). The correct coordinates are 18° 27' 8.7'' N and 66° 21' 3.8'' W.

Response 2:

EPA agrees and has corrected this typographical error.

Comments 3 through 5

3. At Part I.C the draft permit indicates the facility discharges to an impaired water. Currently the permitee has implemented a water reuse process enabling a zero-discharge status for several years. The permittee desires to clarify that it is capable of discharging but currently does not.
4. At Part II.A – Effluent Limitation Table, a composite sampling is required for BOD5. Definitions indicate that for a continuous discharge, a minimum of 24 individual grab samples (at hourly intervals) must be collected and combined to constitute a 24-hour composite sample. For intermittent discharges of more than 4 hours duration, grab samples must be taken at a minimum of 30-minute intervals.

   Please clarify at what intervals are grab samples required to be taken for intermittent discharge of less than 4 hours duration.
5. As is of knowledge to EPA, the permitee has been a Zero discharge facility for many years through its implementation of its treated water reuse system. Although Part II Section A clearly indicates the facility must maintain compliance when in effect flow occurs, the permit proposes monitoring requirements at the point of discharge where flow will be measured (Outfall 001). Sampling with no discharge would mean sampling in an alternate location which could trigger violations that did not impact the receiving water. These requirements in the draft permit are:
   a. Part II.A – Effluent Limitation Table Footnote (1) establishes that enterococci density geometric mean and the 90th Percentile shall be calculated on a monthly basis beginning on EDP + 90 days, using the 6 point data set obtained during the previous 90 day interval. A monthly report with the calculations and the data set shall be submitted to EQB's Water Quality Area and to the EPA's Region 2 Clean Water Division, beginning on EDP + 105 days and during the effectiveness of the permit.
   b. Part II.A – Effluent Limitation Table Footnote (3) establishes the requirement for the implementation of a monthly monitoring plan for 1 year then annually. The program must be conducted no later than 30 days after the approval of a Quality Assurance Project Plan which must be submitted within 30 days of the effective date of permit (EDP).
   c. Part IV.B.m. requires that no later than 180 days after the effective date of permit the permittee shall conduct semi-annually acute toxicity tests for a period of (1) year, after which the tests shall be performed annually.

Pfizer requests the following be considered while the facility maintains its zero-discharge operation:

a. Need clarification of Part II.A – Effluent Limitation Table Footnote (1) for applicability, calculation and reporting when no discharge occurs or is intermittent not having 90-day data collection.
b. Part II.A – Effluent Limitation Table Footnote (3); Quality Assurance Project Plan to be submitted to the Environmental Quality Board (EQB) within 30 days of the effective date of permit (EDP). However, the monitoring plan and required reporting will not occur while the zero-discharge status is maintained during a monitoring period. If discharge occurs, sampling will be conducted at least for 1 sampling event within the month of discharge.

c. Part IV.B.m requires that the permitee conducts acute toxicity tests semi-annually after the effective date of permit then annually. Due to the permitee zero discharge status, no flow will occur through Outfall 001. Pfizer requests that sampling requirement be considered a representative sampling and limited to once per year, becoming in effect annually if a discharge event occurs. Based on the review of the test results, the Regional Administrator of EPA or the EQB can require additional toxicity tests, including chronic tests and toxicity/treatability studies, and may impose toxicity limitations.

d. Pfizer requests clarification of sampling expectations under intermittent discharge scenarios. Discharge could occur in an event or period of incapability to continue reusing treated water but not expected to reoccur. Sampling will be conducted for the specific event but is not clear how to comply with continuous monthly and annual sampling requirements.

Response:

EPA acknowledges that the facility has had zero discharge for many years. The limitations table and other references/requirements for Outfall 001 specify "When Flow Occurs" to clarify that these conditions only apply when there is a flow. The permittee is only required to sample "When Flow Occurs" and is not expected to sample in an alternate location. In the case of the 24-hour composite sample when flow occurs, and the flow is expected to be less than 4 hours, time composite or flow-proportional composite samples can be taken.

Comment 6: Background: Fact Sheet

The Fact Sheet to the Draft NPDES Permit under Part II Section B.3 Compliance Schedule is referencing another industry with initials PECLLC. Pfizer Pharmaceuticals LLC in not under a Compliance Plan and has not submitted any work plan for decommission or demolition of a wastewater treatment plant. Pfizer Pharmaceuticals LLC understand this is not applicable to the Vega Baja facility.

Response:

EPA notes this typographical error which was included in the fact sheet. There is no compliance schedule for Pfizer Pharmaceuticals LLC.

ATTACHMENT II

Description of Changes to the Final Permit for Pfizer Pharmaceuticals LLC (PR0023451)

General

→ All references to EDP have been revised in the final permit to indicate the actual effective date, September 1, 2019.

→ All references to EDP + a specified time period have been revised to indicate the appropriate date.

Background: Fact Sheet and Permit

→ The draft permit refers to the permitee as Pfizer Pharmaceuticals. However, the correct reference is Pfizer Pharmaceuticals LLC. All references to the permittee have been corrected to add LLC.

→ The draft permit and the fact sheet provide incorrect location coordinates. The correct coordinates are 18° 27' 8.7'' N and 66° 21' 3.8'' W. The coordinates have been corrected.