

United States Environmental Protection Agency Region 2 Clean Water Division 290 Broadway New York, New York 10007

# FACT SHEET

# DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM Pfizer Pharmaceuticals, LLC PERMIT No. PR0023451

This Fact Sheet sets forth the principle facts and technical rationale that serve as the legal basis for the requirements of the accompanying draft permit. The draft permit has been prepared in accordance with Clean Water Act (CWA) section 402 and its implementing regulations at Title 40 of the *Code of Federal Regulations* (CFR), Parts 122 through 124, and the interim Water Quality Certificate (WQC) issued by the Puerto Rico Environmental Quality Board (EQB) pursuant to CWA section 401 requirements.

Pursuant to 40 CFR 124.53, the Commonwealth of Puerto Rico must either grant a certification pursuant to CWA section 401 or waive this certification before the U.S. Environmental Protection Agency (EPA) may issue a final permit. On March 17, 2017, EQB provided in the interim WQC that the allowed discharge will not cause violations to the applicable water quality standards at the receiving water body if the limitations and monitoring requirements in the WQC are met. EQB issued a final WQC *December 20, 2018* which following Comments submitted by Pfizer Pharmaceuticals, LLC on *December 5, 2018*. In accordance with CWA section 401, EPA has incorporated the conditions of the modified WQC into the draft permit. Any changes to the WQC will be incorporated into the final issuance of the permit. The WQC conditions are discussed in this Fact Sheet and are no less stringent than allowed by federal requirements. Additional requirements might apply to comply with other sections of the CWA. Review and appeals of limitations and conditions attributable to the WQC were made through the applicable procedures of the Commonwealth of Puerto Rico and not through EPA procedures.

#### Background

#### A. Permittee and Facility Description

The Pfizer Pharmaceuticals, LLC (referred to throughout as the Permittee) has applied for renewal of its National Pollutant Discharge Elimination System (NPDES) permit. The Permittee is discharging pursuant to NPDES Permit No. PR0023451. The Permittee submitted Application Form 1 dated May 13, 2013, Form 1 and 2C, and applied for an NPDES permit to discharge pharmaceutical and consumer products process; sanitary waste; boilers, and cooling tower blowdown; process area flood drains according to Best Management Practices Plan; water treatment systems; reverse osmosis brine, and storm water to outfall 001 from the Pfizer Pharmaceuticals, LLC, Vega Baja, called the facility. The facility has been classified as a major discharger by EPA in accordance with the EPA rating criteria.

The Permittee owns and operates a Pharmaceutical Company. Attachment A of this Fact Sheet provides a map of the area around the facility and a flow schematic of the facility.

The treatment system for outfall 001 consists of the following:

The Reverse Osmosis System.

The Permittee will discharge through Outfall 001 When Flow Occurs.

#### **Summary of Permittee and Facility Information**

Permittee	Pfizer Pharmaceuticals, LLC		
Facility contact, title, phone	Mr. Jose Aleman, EHS Manager 787-855-2323 ext. 2290		
Permittee (mailing) address	P.O. Box 4119, Vega Baja, PR 00694		
Facility (location) address	State Road No. 689 KM 1.9, Vega Baja, PR 00694		
Type of facility	Industrial with SIC code 2834		
Pretreatment program	N/A		
Facility monthly average flow	WFO		
Facility design flow	0.25		
Facility classification	Major		

#### B. Discharge Points and Receiving Water Information

Wastewater is discharged from Outfall 001 to the Rio Cibuco of the United States.

The draft permit authorizes the discharge from the following discharge point(s):

Outfall	Effluent description	Outfall latitude	Outfall longitude	Receiving water name and classification
001	Wastewater	18.00°, 25.00', 6.72" N	66.00°, 8.0', 10.73" W	Rio Cibuco, SD

As indicated in the Puerto Rico Water Quality Standards (PRWQS) Regulations, the designated use for Class SD receiving waters include:

Class SD – Use as raw water supply and propagation; and preservation of desirable species including threatened and endangered species.

CWA section 303(d) requires the Commonwealth of Puerto Rico to develop a list of impaired waters, establish priority rankings for waters on the list, and develop TMDLs for those waters. The receiving water has not been determined to have water quality impairments for one or more of the designated uses as determined by section 303(d) of the CWA.

# C. Mixing Zone/Dilution Allowance

The WQC has not authorized an interim mixing zone for this discharge in accordance with Rule 1305 of PRWQS.

#### D. Compliance Orders/Consent Decrees

The Permittee does not have any compliance orders or consent decrees.

#### E. Summary of Basis for Effluent Limitations and Permit Conditions - General

The effluent limitations and permit conditions in the permit have been developed to ensure compliance with the following, as applicable:

- 1. Clean Water Act section 401 Certification
- 2. NPDES Regulations (40 CFR Part 122)
- 3. PRWQS (March 2010), and
- 4. Secondary Treatment Requirements (40 CFR 133).

# PART I. RATIONALE FOR EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

CWA section 301(b) and 40 CFR 122.44(d) require that permits include limitations more stringent than applicable technology-based requirements where necessary to achieve applicable water quality standards. In addition, 40 CFR 122.44(d)(1)(i) requires that permits include effluent limitations for all pollutants that are or may be discharged at levels that cause, have the reasonable potential to cause, or contribute to an exceedance of a water quality criterion, including a narrative criterion. The process for determining reasonable potential and calculating water quality-based effluent limits (WQBELs) is intended to protect the designated uses of the receiving water, and achieve applicable water quality criteria. Where reasonable potential has been established for a pollutant, but there is no numeric criterion for the pollutant, WQBELs must be established using (1) EPA criteria guidance under CWA section 304(a), supplemented where necessary by other relevant information; (2) an indicator parameter for the pollutant of concern; or (3) a calculated numeric water quality criterion, such as a proposed state criterion or policy interpreting the state's narrative criterion, supplemented with other relevant information, as provided in 40 CFR 122.44(d)(1)(vi).

The effluent limitations and permit conditions in the permit have been developed to ensure compliance with all federal and state regulations, including PRWQS. The basis for each limitation or condition is discussed below.

#### A. Effluent Limitations

The permit establishes Technology-based Effluent Limitations (TBELs) and WQBELs for several pollutants and the basis for these limitations are discussed below.

- 1. **Flow:** Effluent limitations for flow has been established in the permit. Monitoring conditions are applied pursuant to 40 CFR 122.21(j)(4)(ii) and the WQC.
- 2. **5-Day Biochemical Oxygen Demand (BOD**<sub>5</sub>): The effluent concentrations are based on technologybased secondary treatment standards for biological treatment.
- 3. **pH:** The effluent limitation for pH is based on the water quality criterion for Class SD waters as specified in Rule 1303 and 1306 of PRWQS, and the WQC.
- 4. **Temperature:** The effluent limitation for temperature is based on the water quality criterion for Class SD waters as specified in Rule 1303 and 1306 of PRWQS, and the WQC.
- 5. Enterococci: The discharge consists pharmaceutical and consumer products process; sanitary waste; boilers, and cooling tower blowdown; process area flood drains according to Best Management Practices Plan; water treatment systems; reverse osmosis brine, and storm water to outfall 001 that is a source of pathogens. To ensure that the recreational use of the water body is met, effluent limitations for enterococci are established in the permit and are based on the water quality criterion for Class SD waters as specified in Rule 1301, 1303 and 1306 of PRWQS, and the WQC. Consistent with the expression of the water quality criteria for enterococci, the geometric mean shall not exceed 35 colonies/100mL in any 90 day interval; neither the 90<sup>th</sup> percentile of the samples taken shall exceed 130 colonies/100mL in the same 90 day interval.
- 6. **Dissolved Oxygen (DO):** The effluent limitation is based on the water quality criterion for Class SD waters as specified in Rule1301, 1303 and 1306 of PRWQS, and the WQC.
- 7. Whole Effluent Toxicity (WET): CWA section 101(a) establishes a national policy of restoring and maintaining the chemical, physical, and biological integrity of the nation's waters. Specifically, CWA section 101(a)(3) and PRWQS Rule 1303(I) prohibit the discharge of toxic pollutants in toxic amounts. Federal regulations at 40 CFR 122.44(d) also require that where the permitting authority determines, through the analysis of site-specific WET data, that a discharge causes, shows a reasonable potential to cause, or contributes to an excursion above a water quality standard, including a narrative water quality criterion, the permitting authority must establish effluent limits for WET. To satisfy the requirements of the CWA, its implementing regulations, and the PRWQS, a reasonable potential analysis for WET was conducted for this discharge.

PRWQS do not provide a numeric criterion for toxicity. Therefore, consistent with the recommendations of section 2.3.3 of EPA's *Technical Support Document* (TSD) *for Water Quality-Based Toxics Control* (EPA-505-2-90-001), values of 0.3 acute toxic unit (TUa) and 1.0 chronic toxic unit (TUc) were used to interpret the narrative water quality criteria for WET established in PRWQS Rule 1303(I). No limits have been established, however, the permit establishes monitoring requirements which will be evaluated by EQB to determine if effluent limitations are necessary.

In addition, the permit establishes a requirement for the Permittee to conduct accelerated testing and develop a Toxicity Reduction Evaluation (TRE) Workplan as Special Conditions. These requirements are necessary to ensure that the Permittee has a process for addressing effluent toxicity if toxicity is observed.

8. Toxic Metals, Organic Compounds, Sulfide and Cyanide: In accordance with 40 CFR 122.44(d), a WQBEL must be established if the discharge of a pollutant demonstrates that it is or might be discharged at a level that will cause, have the reasonable potential to cause, or contributes to an excursion above any state water quality standard. The need for WQBELs is based on the procedures specified in section 5 of EPA's TSD and by comparing effluent data and water quality criteria established in PRWQS Rule 1303 and the National Toxics Rule at 40 CFR 131.36(d)(4). On the basis of review of effluent and other data, EPA has determined the following:

Arsenic, Copper, Lead, Mercury, Selenium and Silver have been identified as contaminants of concern for the facility.

The Nitrate and Nitrite has not been included in the Draft WQC. Instead a limitation for Total Nitrogen has been set.

2.4,6-Trichlorophenol, 2,4-Dichlorophenol, 2,4-Dimethylphenol, 2,4-Dinitophenol, 2-Chlorophenol, 2-Methyl-4,6-Dinitrophenol, Bis 2-Ethylhexyphylate, Pentachlorophenol, Phenol, and Total Ammonia Nitrogen have been identified as potential contaminants of concern for the facility. A monitoring program has been established for these parameters.

Turbidity limitations remain in the permit.

# B. Effluent Limitations Summary Table

#### **Outfall Number 001**

	Units	Effluent limitations						
Parameter		Averaging period	Highest Reported Value (1)	Existing limits	Interim limits	Final limits	Basis	
Effluent Flow	mgd	Continuous recording		0.250		0.250	TBEL	
Effluent BOD, 5-day (20ºC)	mg/L	Average Monthly Daily Maximum		 20		 20	TBEL	
Color	Pt-C Units	Daily Maximum Average Monthly		15 		15	WQBEL	
Copper	μg/L	Daily Maximum		13		8.85	WQBEL	
Dissolved Oxygen	mg/L	Daily Minimum		5.0		5.0	WQBEL	
рН	standard units	Minimum Maximum		6.0 9.0		6.0 9.0	WQBEL	
Enterococci	(colonies/ 100 ml)					35/130	WQBEL	
Solids and other Matter	N/A	N/A		Narrative		Narrative	WQBEL	
Surfactants as MBAS	µg/L	Daily Maximum		251		100	WQBEL	
Suspended, Colloidal or Settleable Solids	(mL/L)	Daily		Narrative		Narrative	WQBEL	

NPDES Fact Sheet

	Units	Effluent limitations						
Parameter		Averaging period	Highest Reported Value (1)	Existing limits	Interim limits	Final limits	Basis	
Taste and Odor Producing Substances	N/A	N/A		Narrative		Narrative	WQBEL	
Temperature	°F (°C)	Daily Maximum		90º (32.2º) and Narrative		90° (32.2°) and Narrative	WQBEL	
Total Ammonia Nitrogen (TAN) (NH <sub>4</sub> <sup>+</sup> , NH <sub>3</sub> )	µg/L	Daily Maximum					WQBEL	
Total Dissolved Solids	mg/L			994		500	WQBEL	
Total Nitrogen (TKN, NO <sub>2</sub> , NO <sub>3</sub> )	µg/L	Daily Maximum				1,700	WQBEL	
Total Phosphorus (P)	µg/L	Monitor only		1.34		160	WQBEL	
Phenol	µg/L	Monitor only				Monitor only	N/A	
2,4-Dichlorophenol	µg/L	Monitor only				Monitor only	N/A	
2,4-Dimethylphenol	μg/L	Monitor only				Monitor only	N/A	
2,4-Dinitophenol	μg/L	Monitor only				Monitor only	N/A	
2-Chlorophenol	μg/L	Monitor only				Monitor only	N/A	
2-Methyl-4,6-Dinitrophenol	μg/L	Monitor only				Monitor only	N/A	
Bis 2-EthylhexyPhythalate	μg/L	Monitor only				Monitor only	N/A	
Residual Chlorine	µg/L	Daily Maximum		0.50		11	WQBEL	
Arsenic (As)	µg/L	Daily Maximum		.18		10	WQBEL	
Lead (Pb)	µg/L	Daily Maximum		10.6		5.76	WQBEL	
Mercury (Hg)	µg/L	Daily Maximum		0.012		0.050	WQBEL	
Silver (Ag)	µg/L	Daily Maximum		9.6		8.44	WQBEL	
Turbidity	NTU	Daily Maximum		50		50	WQBEL	

#### Notes, Footnotes and Abbreviations

Note: Dashes (--) indicate there are no effluent data, no limitations, or no monitoring requirements for this parameter. (1) There has been no discharge, therefore, no Wastewater data is available.

#### C. Monitoring Requirements

NPDES regulations at 40 CFR 122.48 require that all permits specify requirements for recording and reporting monitoring results. The Part III of the Permit establishes monitoring and reporting requirements to implement federal and state requirements. The following provides the rationale for the monitoring and reporting requirements for this facility.

#### 1. Effluent Monitoring Requirements

Effluent monitoring frequency and sample type have been established in accordance with the requirements of 40 CFR 122.44(i) and recommendations in EPA's TSD. Consistent with 40 CFR Part 136 monitoring data for toxic metals must be expressed as total recoverable metal.

#### D. Compliance with Federal Anti-Backsliding Requirements and Puerto Rico's Anti-Degradation Policy

Federal regulations at 40 CFR 131.12 require that state water quality standards include an anti-degradation policy consistent with the federal policy. The discharge is consistent with the anti-degradation provision of 40 CFR 131.12, 72 Federal Register 238 (December 12, 2007, pages 70517-70526) and EQB's *Anti-Degradation Policy Implementation Procedure* in Attachment A of PRWQS. In addition, CWA sections 402(o)(2) and 303(d)(4) and federal regulations at 40 CFR 122.44(I) prohibit backsliding in NPDES permits. Further, the Region 2 Anti-backsliding Policy provides guidance regarding relaxation of effluent limitations based on water quality for Puerto Rico NPDES permits. These anti-backsliding provisions require effluent limitations in a reissued permit to be as stringent as those in the previous permit with some exceptions where limitations may be relaxed. The effluent limitations in the permit are at least as stringent as the effluent limitations in the existing permit.

# PART II. RATIONALE FOR STANDARD AND SPECIAL CONDITIONS

# A. Standard Conditions

In accordance with 40 CFR 122.41, standard conditions that apply to all NPDES permits have been incorporated by reference in Part IV.A.1 of the permit and expressly in Attachment B of the permit. The Permittee must comply with all standard conditions and with those additional conditions that are applicable to specified categories of permits under 40 CFR 122.42 and specified in Part IV.A.2 of the Permit.

# **B.** Special Conditions

In accordance with 40 CFR 122.42 and other regulations cited below, special conditions have been incorporated into the permit. This section addresses the justification for special studies, additional monitoring requirements, Best Management Practices, Compliance Schedules, and/or special provisions for POTWs as needed. The special conditions for this facility are as follows:

# 1. Special Conditions from the Water Quality Certificate

In accordance with 40 CFR 124.55, EPA has established Special Conditions from the WQC in the permit that EQB determined were necessary to meet PRWQS. The Special Conditions established in this section are only those conditions from the WQC that have not been established in other parts of the permit.

# 2. Best Management Practices (BMP) Plan

The Permittee has developed a BMP in accordance with 40 CFR 122.2 and 122.44(k). The BMPs include schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution to waters of the United States.

# 3. Compliance Schedules

The schedule (activity/compliance deadline) of the Compliance Plan (CP) is the established in the Work Plan – Decommission and Demolition of Industrial Wastewater Treatment Plant, submitted by PECLLC to the Water Quality Area and approved on October 18, 2013. PECLLC must prepare and submit to EQB and EPA bimonthly Progress Reports of the compliance of the Schedule of Activities established in the approved CP. The first Progress Report shall be submitted in the EDP + 2 months, and thereafter until all work is completed. PECLLC must notify EQB and EPA in written when all the activities established in the approved CP have been completed.

# 4. Other Special Conditions - N/A

# PART III. COMPLIANCE WITH APPLICABLE PROVISIONS OF OTHER FEDERAL LAWS OR EXECUTIVE ORDERS

# A. Coastal Zone Management Act

Under 40 CFR 122.49(d), and in accordance with the Coastal Zone Management Act of 1972, as amended, 16 *United States Code* (U.S.C.) 1451 *et seq.* section 307(c) of the act and its implementing regulations (15 CFR Part 930), EPA may not issue an NPDES permit that affects land or water use in the coastal zone until the Permittee certifies that the proposed activity complies with the Coastal Zone Management Program in Puerto Rico, and that the discharge is certified by the Commonwealth of Puerto Rico to be consistent with the Commonwealth's Coastal Zone Management Program. The Permittee has indicated the outfall is not in a coastal area managed by the Commonwealth's Coastal Zone Management Program and, although nearby, EPA has determined it will not affect the coastal area. Therefore, the requirements of 40 CFR 122.49(d) do not apply to this discharge.

#### **B. Endangered Species Act**

Under 40 CFR 122.49(c), EPA is required pursuant to section 7 of the Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq.* and its implementing regulations (50 CFR Part 402) to ensure, in consultation with the National Marine Fisheries Service (NMFS) and U.S. Fish and Wildlife Service (USFWS) that the discharge authorized by the permit is not likely to jeopardize the continued existence of any endangered or threatened species or adversely affect its critical habitat.

In a May 2000 memo to the Regions, EPA Headquarters provided guidance to the Regions in making a determination as to whether a final permit may be issued while waiting for consultation to be concluded. As part of this permit action, if consultation has not been completed by final permit issuance and EPA has concluded that permit issuance is consistent with section 7 prior to the conclusion of consultation, EPA will re-issue the final permit before consultation is concluded and will document this decision in the Administrative Record. At the time consultation is completed, EPA may decide that changes to the permit are warranted after permit issuance based on the results of the consultation. Therefore, a reopener provision to this effect has been included in the Permit.

#### C. Environmental Justice

EPA has performed an Environmental Justice (EJ) Analysis for the discharge in accordance with Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Population and Low-Income Populations*, and EPA's Plan EJ 2014. EJ is the right to a safe, healthy, productive and sustainable environment for all, where "environment" is considered in its totality to include the ecological, physical, social, political, aesthetic and economic environments. In the NPDES permitting program, the public participation process provides opportunities to address EJ concerns by providing appropriate avenues for public participation, seeking out and facilitating involvement of those potentially affected, and including public notices in more than one language where appropriate. The facility is in an area characterized as a Community of Concern and therefore is subject to the EJ requirements. In the EJ Analysis, EPA determined that the area is low-income. As a result, EPA has established conditions in the permit to minimize the impact(s) on the Community of Concern affected by the discharge. These conditions include providing public notice of the availability of the draft permit for public comment. EPA is committed to taking all necessary actions to minimize potential adverse effects in the Vega Baja area from Pfizer Pharmaceuticals, LLC. A detailed discussion of the EJ Analysis is provided in the Administrative Record and is available for review upon request.

# **D. Coral Reef Protection**

Under Executive Order 13089, *Coral Reef Protection*, EPA is required to ensure that discharge authorized under the permit will not degrade any coral reef ecosystem. No corals or coral ecosystems are in the vicinity of the discharge.

# E. Climate Change

EPA has considered climate change when developing the conditions of the permit. This is in accordance with the draft *National Water Program 2012 Strategy: Response to Climate Change* that identifies ways to address climate change impacts by NPDES permitting authorities (77 Federal Register 63, April 2, 2012, 19661-19662). Climate change is expected to affect surface waters in several ways, affecting both human health and ecological endpoints. As outlined in the draft National Water Program 2012 Strategy, EPA is committed to protecting surface water, drinking water, and ground water quality, and diminishing the risks of climate change to human health and the environment, through a variety of adaptation and mitigation strategies. These strategies include encouraging communities and NPDES permitting authorities to incorporate climate change strategies into their water quality

planning, encouraging green infrastructure and recommending that water quality authorities consider climate change impacts when developing water load and load allocations for new TMDLs, identifying and protecting designated uses at risk from climate change impacts. The 2010 *NPDES Permit Writers' Manual* also identifies climate change considerations for establishing low-flow conditions that account for possible climatic changes to stream flow. The conditions established in the permit are consistent with the draft National Water Program 2012 Strategy.

# F. National Historic Preservation Act

Under 40 CFR 122.49(b), EPA is required to assess the impact of the discharge authorized by the permit on any properties listed or eligible for listing in the National Register of Historic Places (NRHP) and mitigate any adverse effects when necessary in accordance with the National Historic Preservation Act, 16 U.S.C. 470 et seq. EPA's analysis indicates that no soil disturbing or construction-related activities are being authorized by approval of this permit; accordingly, adverse effects to resources on or eligible for inclusion in the NHRP are not anticipated as part of this permitted action.

#### G. Magnuson-Stevens Fishery Conservation and Management Act

Under 40 CFR 122.49, EPA is required to ensure that the discharge authorized by the permit will not adversely affect Essential Fish Habitat (EFH) as specified in section 305(b)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA), 16 U.S.C. 1801 *et seq*. The permit may be modified or revoked and reissued based on the results of coordination with National Marine Fisheries Service regarding essential fish habitats (EFH) pursuant to Section 305(b)(2) of the Magnuson-Stevens Fishery Conservation and Management Act.

# PART IV. PUBLIC PARTICIPATION

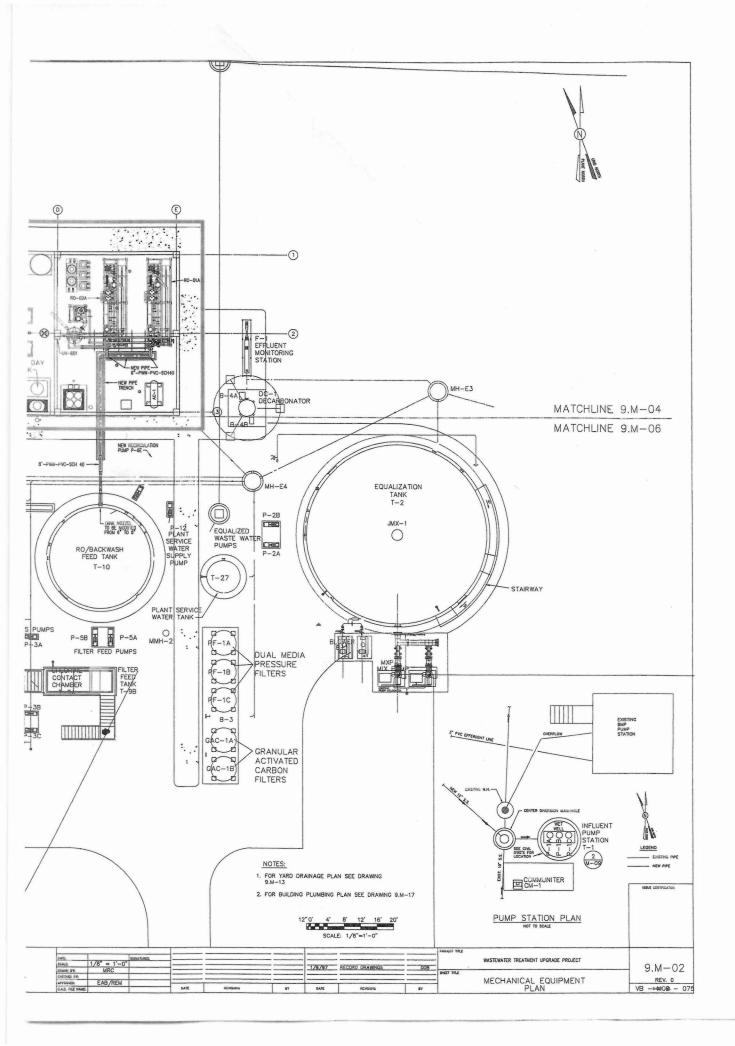
The procedures for reaching a final decision on the draft permit are set forth in 40 CFR Part 124 and are described in the public notice for the draft permit, which is published in *newspaper name>*. Included in the public notice are requirements for the submission of comments by a specified date, procedures for requesting a hearing and the nature of the hearing, and other procedures for participation in the final agency decision. EPA will consider and respond in writing to all significant comments received during the public comment period in reaching a final decision on the draft permit. Requests for information or questions regarding the draft permit should be directed to

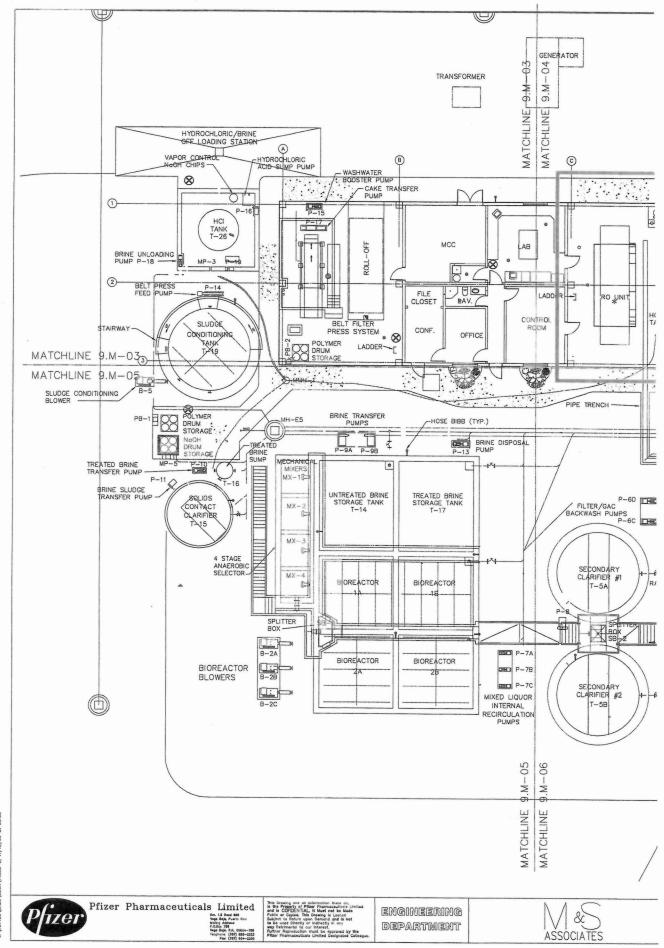
Andrea Coats EPA Region 2, Clean Water Division Permit Writer Phone: 212-637-3850 Permit Writer Email: <u>coats.andrea@epa.gov</u>

A copy of the draft permit is also available on EPA's website at www.epa.gov/region02/water/permits.html.

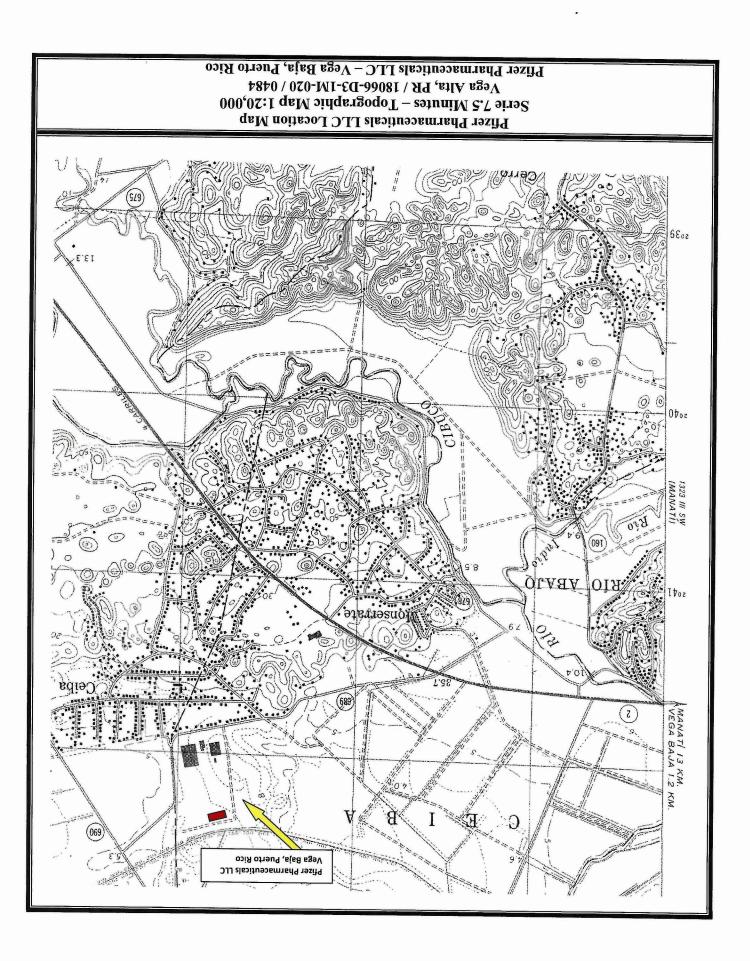
# ATTACHMENT A — FACILITY MAP AND FLOW SCHEMATIC

The facility map and flow schematic are attached as provided by the discharger in the application.





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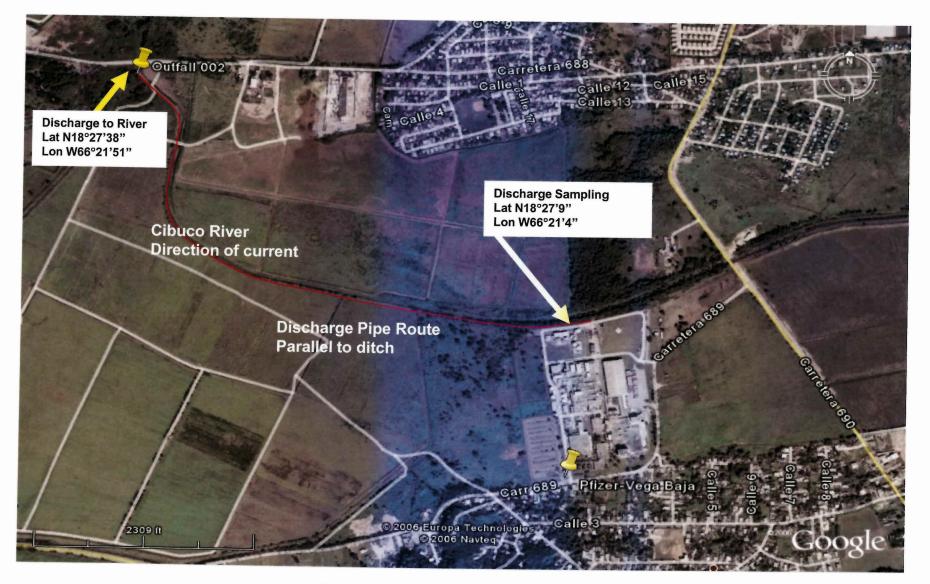


Figure 1: Topographic Map Site Location Pfizer Pharmaceuticals LLC, Vega Baja, Puerto Rico