

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

In the Matter of:

**WYETH PHARMACEUTICALS  
COMPANY, INC.**

State Road 3, Km. 142.1  
Guayama, Puerto Rico 00784

**RESPONDENT**

PROCEEDING TO ASSESS A CLASS II  
CIVIL PENALTY

DOCKET NUMBER CWA-02-2009-3460

U.S. ENVIRONMENTAL  
PROTECTION AGENCY  
2009 OCT 25 PM 2:32  
REGIONAL HEARING  
OFFICE

**MOTION TO DISMISS**

TO THE HONORABLE ADMINISTRATIVE LAW JUDGE:

COMES NOW Respondent, Wyeth Pharmaceuticals Company, Inc. – Guayama Operations (“Wyeth-Guayama”)<sup>1</sup>, through its undersigned attorneys, and, for the reasons set forth below, respectfully moves for dismissal of the present action for failure by Complainant to establish a prima facie case, pursuant to 40 CFR § 22.20.

**Background**

Respondent is a pharmaceutical manufacturing facility located in the Municipality of Guayama, Puerto Rico. There are two distinct manufacturing operations located thereat: a prescription drug manufacturing operation, whose storm water runoff discharges are permitted under the individual NPDES permit number PR0024724<sup>2</sup> (hereinafter referred to as “Wyeth-Pharma”). The other manufacturing operation is dedicated to the production of over-the-counter (“OTC”) products, and its storm water runoff discharges are

<sup>1</sup> As of October 15, 2009, Wyeth, Wyeth-Guayama’s parent corporation, is a subsidiary of Pfizer, Inc.

discharged through a separate and distinct outfall pursuant to a Multi Sector General Permit (“MSGP”) for storm water discharges associated with industrial activity, under permit number PRR05A799/PRR05BN36 (hereinafter referred to as “Wyeth-OTC”).

**Wyeth-Pharma, and not Wyeth-OTC, is the object of the Complainant’s May 6, 2009 Notice of Assessment of a Class II Administrative Penalty.**

The Wyeth-Pharma facility has been designed to retain rather than discharge storm water runoff during storm events. It has two (2) detention ponds with a combined holding capacity of almost 4,000,000 gallons (3,000,000 in the south drainage pond and 930,000 gallons in the east drainage pond). Respondent’s Exhibit 4, at page 15. The east drainage pond drains into the south drainage pond. See, Respondent’s Exhibit 16. In turn, and only during significant storm water events, the south drainage pond will eventually drop discharge into a sump denominated Outfall 002. Respondent’s Exhibit 16. From Outfall 002, the storm water runoff is discharged to an underground discharge pipeline which runs outside of the Wyeth-Pharma property line, and eventually reaches an open channel discharging into Las Mareas Bay.

As a result of the design of the storm water management system, Wyeth-Pharma’s storm water discharges do not occur upon each and every rain event, but rather occur only when the storm water accumulation in the aforementioned detention ponds exceeds their holding capacity. In fact, in almost four (4) years since the current NPDES Permit

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<sup>2</sup> Hereinafter referred to as the “NPDES Permit”. The document was included as Complainant’s Exhibit 8 and Respondent’s Exhibit 3.

became effective (i.e., December 1, 2005), Wyeth-Pharma has only discharged through Outfall 002 in October 2007 and in September 2008. See, Respondent's Exhibit 6.

During the week of September 21 through 27, 2008, the Municipality of Guayama experienced a major precipitation event. Indeed, the National Oceanic and Atmospheric Administration ("NOAA"), at its Guayama 2E station, recorded twenty inches (20") of precipitation on September 22, 2008 alone; this constitutes a 97-year record for the area. See, Respondent's Exhibit 11.

On September 27, 2008, Wyeth-Pharma personnel discovered the discharge of water accumulated in an inactive wastewater treatment lagoon (the "South Lagoon") to an earthen area next to the active wastewater treatment lagoon (the "North Lagoon"). As a protective measure, even though the company did not believe there was any noncompliance with the NPDES Permit discharge limitations, Wyeth-Pharma made an oral report to the National Response Center, which was assigned event report notification number 885-549. This oral report was followed with a written report dated October 3, 2008 (Complainant's Exhibit 4g/Respondent's Exhibit 9<sup>3</sup>). In its pertinent part, the written report reads as follows:

... While we feel that the filing of an oral report in the first instance might not have been required (as we do not believe there was any noncompliance with the Permit discharge limitations), we prefer to take the conservative approach to these matters.

During the week of September 21 through 27, 2008, Puerto Rico experienced one of the biggest rain events in the island's

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<sup>3</sup> Documents for which exhibit numbers are provided under both Complainant and Respondent were duplicated in the parties' respective Prehearing Exchanges.

history. The Guayama area, where WPC is located, registered almost twenty (20) inches of rain.

WPC undertook the operation of draining collected rainwater from an inactive wastewater treatment lagoon to the storm water retention system. These operations were performed periodically from September 22 through 27, 2008. On Saturday, September 27, 2008, it came to the attention of WPC that the [South L]agoon might have received, as a result of overflows caused by the rain, wastewater from an active treatment lagoon. An investigation was immediately commenced by WPC and it was determined that water from the active wastewater lagoon apparently overflowed into the inactive lagoon as a result the extraordinary rain event [sic]. It is estimated that, overall, **approximately 120,000 – 180,000 gallons of water was pumped from the inactive lagoon into the storm water retention system during the September 22 through September 27 time frame. The storm water retention system includes a 3 million gallon retention pond.**

(Emphasis supplied.)

It is important to note that **neither the active North Lagoon nor the inactive South Lagoon is connected to Outfall 002**. See, Respondent's Exhibits 16 and 17. Moreover, Wyeth-Pharma's WWTP Log Book, which contains the official record of wastewater treatment plant operational incidents, does not include any evidence of overflowing of the North Lagoon into the South Lagoon during the dates that Complainant alleges the discharge of industrial waste; that is, **there is no evidence of such overflows in the WWTP Log Book entries for September 22, 23 and 24, 2008, the dates on which Wyeth-Pharma had discharges through Outfall 002 and which correspond to Claims 1, 2 and 3 of the Complaint**. See Respondent's Exhibit 10. Even if there was an overflow from one lagoon into the other (which Wyeth-Pharma

denies), the mere act of overflowing does not necessarily result in a violation of the NPDES Permit, and Complainant's mere assertions to the contrary are not supported by any evidence that has been proffered.

It thus came as a surprise to Wyeth-Pharma when, after following the conservative approach and responsibly making a protective report of a non-reportable event which occurred during an extraordinary rain event, it was served with a Notice of Assessment of a Class II Administrative Penalty (hereinafter referred to as the "Complaint") for the maximum statutory amount (\$157,500.00) in connection with such event.

### **Discussion**

The United States Environmental Protection Agency ("EPA")'s Consolidated Rules of Practice state that "the complainant has the burdens of presentation and persuasion that the violation occurred as set forth in the complaint and that the relief sought is appropriate." 40 CFR § 22.24(a). The standard of proof under the Rules of Practice is a preponderance of the evidence. 40 CFR § 22.24(b). Therefore, at this point, Complainant has the burden of demonstrating by a preponderance of the evidence the Respondent's liability on all claims set forth in the Complaint and the appropriateness of its proposed penalty in regard to all such claims. See, In Re Service Oil, Inc., Docket No. CWA-08-2005-0010 (Susan J. Biro, Chief Administrative Law Judge), issued on August 3, 2007.

We respectfully submit that Complainant's prehearing exchange does not support the allegations and claims set forth in the Complaint, as will be discussed in more detail below.

1. Claims No. 1, 2 and 3 (alleged discharge of industrial waste mixed with storm water on September 22, 23 and 24, respectively) are not supported by the evidence submitted by Complainant.

In order to establish a prima facie case, Complainant must prove by a preponderance of the evidence that there was a "discharge of pollutants" "through a point source" into "waters of the United States." The term "discharge of pollutants" is statutorily defined to mean "any addition of any pollutant to navigable waters from any point source." Section 502(12)(A) of the Clean Water Act ("CWA"), 33 USC § 1362(12)(A). In turn, the term "point source" is defined as "any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged." CWA Section 502(14), 33 USC § 1362(14). Hence, Complainant must prove by a preponderance of the evidence that "pollutants" (alleged industrial wastes) gained access to the south detention pond, from which they could be drop discharged into the sump denominated Outfall 002 (the "point source"), so that they could be discharged through the underground discharge line from Respondent's facility to Las Mareas Bay on September 22, 23 and 24, 2008.

- a. Complainant cites the October 3, 2008 protective voluntary report (Complainant's Exhibit 4g/Respondent's Exhibit 9) as evidence of the allegations set forth in Claims 1, 2 and 3 of the Complaint regarding the discharge of "industrial waste mixed with storm water." See, Complainant's

Exhibit 4, at page 3 of 8. Notwithstanding, the October 3, 2008 report clearly states that there was a **discharge of water into the storm water retention system** (i.e., the earthen area around the North Lagoon). **Complainant has not provided any evidence whatsoever of a discharge of industrial waste through Outfall 002, especially in light of the fact that neither the North Lagoon nor the South Lagoon is connected to Outfall 002.** See Respondent's Exhibits 16 and 17.

b. There is no evidence in the WWTP Log Book entries for September 22, 23 and 24, 2008, the dates on which Wyeth-Pharma had discharges through Outfall 002, of any overflows from the North Lagoon into the South Lagoon. See Respondent's Exhibit 10. The notations for those days merely reflect that the levels of both lagoons were high.

2. Claim No. 4 (failure to inspect and provide maintenance to the Outfall 002 underground discharge pipeline at least once per year) is not supported by any regulatory, NPDES Permit, or SWPP Plan provision.

a. Part I, Special Condition 11 of the NPDES Permit (Respondent's Exhibit 3<sup>4</sup>) requires that Wyeth-Pharma, as permittee, must "...comply with the terms and conditions included in the SWPP Plan as approved by the EQB on June 12, 2002, and its subsequent revisions as approved by EQB." NPDES Permit, at

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<sup>4</sup> Although both Respondent and Complainant includes copies of the NPDES Permit as exhibits to their respective prehearing exchanges (Complainant's Exhibit 8 and Respondent's Exhibit 3), the copy of the NPDES Permit included as Complainant's Exhibit 8 omitted all even-numbered pages. Hence, when referencing the NPDES Permit, we shall only refer to Respondent's Exhibit 3.

page 6 of 25. In turn, the approved SWPP Plan contemplates comprehensive site inspections of all areas that drain through Outfall 002, for evidence of (or the potential for) pollutants entering into the drainage system, good operation of storm water management measures, and equipment needed to implement the SWPP Plan. Section 5.1.3 of the SWPP Plan, Respondent's Exhibit 4, at page 28. The approved SWPP Plan does not mention or contemplate inspecting the underground discharge pipeline located outside of the facility's property line.<sup>5</sup>

- b. Part II.B.5 of the NPDES Permit, cited by Complainant in its Exhibit 4 (page 2 of 8), requires that "[t]he permittee shall at all times operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems, installed by the permittee, when the operation is necessary to achieve compliance with the conditions of this permit." NPDES Permit, at page 15 of 25 (emphasis supplied). Nevertheless, this permit provision refers to the operation and maintenance of a wastewater treatment system, which is not applicable to the storm water runoff discharge system at hand. Moreover, this

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<sup>5</sup> At this time, it is unclear whether the requested inspection (a camera survey) of the underground discharge pipeline located outside of Wyeth-Pharma's property line is technically practicable or feasible.

provision does not apply to the actual underground discharge pipe, as it is not “installed or used by the permittee to achieve compliance with the conditions of this permit.” To allow Complainant’s alleged inspection requirement is an arbitrary and capricious exercise of an inspector’s interpretation that results in a *de facto* modification of the NPDES Permit without fair notice to, and opportunity to comment by, Respondent and which further results in a deprivation of Respondent’s due process rights.

c. By letter dated September 5, 2008 (about two weeks prior to the September 2008 rain event), Complainant notified Respondent that “[t]he results of the CEIs [Compliance Evaluation Inspection] revealed that WPC [Wyeth-Pharma and Wyeth-OTC] is in compliance with its NPDES permit and MSGP.” **No mention was made therein with respect to the purported “requirement” to inspect the actual underground discharge pipe at Wyeth-Pharma.** See, Complainant’s Exhibit 5/Respondent’s Exhibit 14.

d. Moreover, the annual comprehensive site inspection report included as **Complainant’s Exhibit 4d does not correspond to Wyeth-Pharma and the NPDES Permit.** Rather, it corresponds to the annual comprehensive site inspection conducted at Wyeth-OTC pursuant to the MSGP.

3. Claim No. 5 (failure to comply with the NPDES sampling protocol) is likewise not supported by the evidence submitted by Complainant.

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- a. Table A-1 of the NPDES Permit requires sampling “when flow occurs (WFO)”. In turn, Part I, Special Condition 13 of the NPDES Permit defines WFO as “[f]or our purposes mean[ing] when flow occurs during normal business hours fo [sic] the facility but not more than one rainfall runoff per month.” It must be borne in mind that Wyeth-Pharma does not discharge storm water runoff through Outfall 002 upon each and every rain event. Rather, the Wyeth-Pharma facility is designed to discharge storm water runoff through Outfall 002 only when its retention capacity is exceeded. Hence, WFO at Wyeth-Pharma is not tied to “rainfall” runoff.
- b. Part I, Special Condition 13(B) of the NPDES Permit provides that, for discharges occurring after the 15<sup>th</sup> day of the month, the permittee may sample “**any**” discharge event: “In the event that the permittee is unable to satisfy the above condition<sup>6</sup> during the first fifteen (15) days of the month, beginning on the sixteenth (16<sup>th</sup>) day of the month, **the permittee shall sample any storm water discharge which occurs** during normal business hours for the facility”. (Emphasis supplied). Respondent’s Exhibit 3, at page 6 of 25. The NPDES Permit does not establish specific requirements as to which

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<sup>6</sup> Part I, Special Condition 13(A) defines the sampling protocol for discharges occurring during the first half of the month as follows: “During the first fifteen (15) days of the month, sampling shall be as follows: A minimum period of 48 hours without measurable precipitation (measurable precipitation being rainfall greater than 0.1 inch) shall precede the storm event to be sampled. For parameters that require grab samples, the sample shall be taken during the first thirty (30) minutes of the storm water discharge.” This latter requirement of taking the sample during the first thirty (30) minutes of the storm water discharge is not included in the sampling protocol for the second half of the month [Part I, Special Condition 13(B)]. Moreover, since by design Wyeth-Pharma does not discharge storm water runoff upon the occurrence of each individual rain event, this protocol must necessarily be tempered to reflect this particular.

discharge must be sampled to comply with the sampling protocol during the second half of the month. Cf. Part I, Special Condition 13(A) of the NPDES Permit.

- c. During the month of September 2008, there were no storm water runoff discharges through Outfall 002 until September 22, 2008 (i.e., the second half of the month). Hence, in this case, Wyeth-Pharma was free to sample the discharge of storm water runoff flowing through Outfall 002 at any time, pursuant to the provisions of Part I, Special Condition 13(B) of the NPDES Permit.
- d. Although Complainant's penalty justification memorandum makes reference to "relevant pages of the log book" (Complainant's Exhibit 4, at page 4 of 8), such "relevant pages" were not and have not been provided by Complainant.
- e. In contrast, the "relevant pages" of the WWTP log book (Respondent's Exhibit 10) clearly indicate that the storm water samples were taken on September 22, 2008, and picked up by Beckton Laboratories (external laboratory analyzing the samples) on September 23, 2009. See, Respondent's Exhibit 10.

- 4. The evidence provided in support of Complainant's proposed penalty does not justify the amount assessed.

In determining the amount of any administrative penalty assessed under CWA Section 309, the statute provides that the following factors must be taken into account: "...the nature, circumstances, extent and gravity of the violation, or violations, and, with respect

to the violator, ability to pay, any prior history of such violations, the degree of culpability, economic benefit or savings (if any) resulting from the violation, and such other matters as justice may require.” CWA Section 309(g)(3), 33 USC § 1319(g)(3). We respectfully submit that the proposed penalty in the present action (\$157,500.00, which represents the maximum statutory amount) does not properly take into account such statutory factors, as evidenced by the penalty justification memorandum prepared for the present case and submitted by Complainant as Exhibit 4 of its Prehearing Exchange.

- a. The penalty justification memorandum (Complainant’s Exhibit 4) was **prepared after the Complaint was issued**. The Complaint was issued on May 6, 2009; while the penalty justification memorandum is dated August 27, 2009, almost three months after the Complaint was issued.
- b. Complainant has not taken into account the extraordinary nature of the rain event experienced in the Guayama, Puerto Rico area on September 22, 2008 when twenty inches (20”) of rainfall were recorded in one day – while the monthly average for September is around nine inches (9”) -- (see, Respondent’s Exhibit 11), and which was beyond Wyeth-Pharma’s control.
- c. Complainant has not taken into account that the Wyeth-Pharma facility is designed to retain rather than discharge storm water runoff during storm events; and only discharges storm water runoff through Outfall 002 when the storm water accumulation in its detention ponds exceeds their 4,000,000-gallon combined holding capacity. See, Respondent’s Exhibit 4, at page 15. **In fact,**

**in almost four (4) years since the current NPDES Permit became effective (i.e., December 1, 2005), Wyeth-Pharma has only discharged through Outfall 002 in October 2007 and in September 2008.** See, Respondent's Exhibit 6.

- d. The purported evidence of "prior history of violations" (Complainant's Exhibit 4, at page 7 of 8) does not correspond to Wyeth-Pharma, and neither is it related to the NPDES Permit. Rather, the case mentioned in the penalty justification memorandum refers to an action brought against Wyeth-OTC, back in March of 2000, for the alleged failure to file a Notice of Intent to obtain coverage under the MSGP.
- e. Complainant has not met its burden of proof in proving "knowing" and "willful" violations to assess the maximum degree of culpability in its penalty calculation. On the contrary, Respondent's protective voluntary oral report to the NRC and subsequent written report dated October 3, 2008 evidence good faith and responsible corporate behavior, intent to comply, and cooperation with the agency.
- f. Complainant has not taken into account the prior compliance history of Respondent, as evidenced by its own Compliance Evaluation Inspection report dated September 5, 2008 (Complainant's Exhibit 5/Respondent's Exhibit 14), informing Respondent that it is in compliance with the NPDES Permit.

5. The factual witnesses proffered by Complainant do not have personal knowledge of the facts surrounding the alleged violations.
  - a. Mr. Luis Torres was off-duty at Wyeth-Pharma on September 22, September 23, and September 24 – the days of the alleged violations. See, Respondent's Exhibit 10. Hence, he does not have any personal knowledge of the facts surrounding such alleged violations.
  - b. Mr. Edsel Llaurador's and Mr. Raul Martinez' duties at Wyeth-Pharma were not exclusively related to the wastewater treatment plant or the storm water discharge. Neither did their duties include environmental compliance matters at the facility. Rather, their duties comprised supervision (Llaurador) and operation after normal business hours (third shift, from 10:00 pm to 6:00 am on the days of the alleged violations) (Martínez) of the facility's utilities, including but not limited to boilers, water purification systems, emergency generators, and similar duties.
6. The expert witnesses proffered by Complainant are either factual witnesses or are not qualified to testify as experts.
  - a. Eng. José A. Rivera has been the agency inspector with respect to storm water regulatory compliance for both Wyeth-Pharma and Wyeth-OTC for a number of years. Hence, if at all, he would be a factual witness.
  - b. Eng. Pedro Modesto, who presumably is being proffered by Complainant as a wastewater treatment plant expert, does not have any wastewater treatment

plant operational experience. Neither does he have any design experience with respect to pharmaceutical manufacturing facility wastewater treatment systems; rather, his experience is circumscribed to municipal wastewater treatment systems. See, Complainant's Exhibit 10. Hence, he would not be qualified to testify as an expert with respect to a pharmaceutical manufacturing wastewater treatment system.

Contrary to what Complainant has attempted to imply, this case does not involve improper operation of a wastewater treatment system, which system discharges to a publicly owned treatment works through an outfall separate from Outfall 002 at hand and is authorized pursuant to a permit issued by the Puerto Rico Aqueduct and Sewer Authority ("PRASA"). In that respect, Complainant's Exhibit 7, the industrial wastewater discharge permit issued to Wyeth-Pharma by PRASA, is irrelevant and of little probative value. See, 40 CFR § 22.22(a)(1).

Rather, this case involves the responsible actions undertaken by Respondent Wyeth-Pharma during a record-breaking rain event, when twenty (20) inches of rain fell on Guayama in just one day. Hence, Respondent denies that any violations to the provisions of its storm water discharge permit occurred from September 22 to 24, 2008, in the aftermath of a force majeure event: a record-breaking rain event (as recognized by NOAA) in the Guayama, Puerto Rico area. Moreover, Respondent contends that the penalty has been proposed by EPA, notwithstanding the representation made by the agency in the Complaint, without any good faith consideration of the statutory factors,

including the compliance record of the facility, the lack of economic benefit, the lack of health or environmental harm, and other factors.

WHEREFORE, Respondent respectfully requests that the present Complaint be dismissed with prejudice.

**RESPECTFULLY SUBMITTED.**

In San Juan, Puerto Rico, this 23<sup>rd</sup> day of October, 2009.

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

In the Matter of:

**WYETH PHARMACEUTICALS  
COMPANY, INC.**

State Road 3, Km. 142.1  
Guayama, Puerto Rico 00784

**RESPONDENT**

Proceeding pursuant to Section  
309(g)(2)(B) of the Clean Water Act, 33  
USC § 1319(g)

PROCEEDING TO ASSESS A CLASS II  
CIVIL PENALTY

DOCKET NUMBER CWA-02-2009-3460

**CERTIFICATE OF SERVICE**

I CERTIFY that, on the date noted below, I caused to be submitted a copy of the foregoing Respondent's Motion to Dismiss to the following persons, at the addresses listed below, and in the manner specified below:

**Original and one copy via Federal Express:**

Karen Maples  
Regional Hearing Clerk  
U.S. Environmental Protection Agency – Region 2  
290 Broadway – 16<sup>th</sup> Floor  
New York, NY 10007

**Copy via Federal Express:**

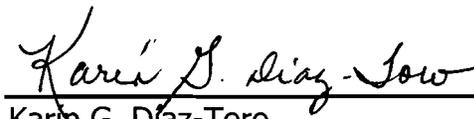
Judge William B. Moran  
U.S. Environmental Protection Agency  
Office of Administrative Law Judges  
Franklin Court Building  
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Washington DC 20460

**Copy via certified mail, return receipt requested –**  
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In San Juan, Puerto Rico, this 4<sup>th</sup> day of September, 2009.

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