

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2**

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II
2009-07-08 PM 1:23
REGIONAL HEARING
CLERK

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

RESPONDENT'S PREHEARING EXCHANGE

TO THE REGIONAL HEARING CLERK:

COMES NOW Respondent, Wyeth Pharmaceuticals Company, Inc. – Guayama Operations ("Wyeth-Guayama"), through its undersigned attorneys, and in accordance with the Prehearing Order dated July 6, 2009, issued by the Honorable William B. Moran, Administrative Law Judge, submits the following prehearing exchange. The sequence and numbering of this document correspond to the sequence and numbering of the procedure set forth in the Prehearing Order.

- 1. (A) Respondent's list of all expert and other witnesses intended to be called at hearing, with a brief narrative summary of their expected testimony.**

Respondent anticipates that it will call the following witnesses:

- a. Rubén Soto, EHS Director for Wyeth-Guayama. Mr. Soto supervises and is in charge of all environmental matters at the facility, including but not limited to compliance, recordkeeping, employee training, implementation of plans and pollution prevention controls, construction and improvements at the facility, about which he will testify. Mr. Soto will also testify about the characteristics

of the storm water retention system at the Wyeth-Guayama facility. He is also expected to testify about the incidents regarding the storm event occurring in September 2008, the measures taken by the company to ensure compliance with its storm water discharge permit, and the preventive notification made to the National Response Center on September 28, 2008.

- b. Juan Enrique Negrón, Principal EHS Specialist I for Wyeth-Guayama. Mr. Negrón is expected to testify about the preparation and implementation of the Storm Water Pollution Prevention Plan (SWPPP) for the facility, and about storm water sampling protocols and procedures.

On June 21, 2009, and as part of settlement negotiations, Respondent requested from Complainant EPA copies of information and/or documentation that provided the foundation for the findings of violation, allegations and claims stated in the Complaint; specifically with respect to the following:

1. Alleged discharges of storm water mixed with industrial waste occurring on September 22, 23 and 24, 2008,
2. Information on storm water sampling pertaining to September 21, 22 and 23, 2008,
3. Alleged discharges of industrial waste into the South inactive lagoon,
4. Alleged discharges of industrial waste into storm water retention ponds,
5. So-called "infiltration" problems, and

6. Other enforcement actions against facilities located in Guayama for storm water discharges occurring during the period from September 21 through September 28, 2008, inclusive.

As of the date of this document, the documents and information requested have not been provided to Respondent. Therefore, Respondent anticipates that it may need to call additional witnesses to address issues which may arise out of the examination of the documents produced by Complainant, or which may be raised by Complainant in its Prehearing Exchange and any supplements thereto. If necessary, Respondent will move for additional discovery, in compliance with 40 C.F.R. §22.19(e) and §22.22. Respondent respectfully reserves the right to supplement its witness list and to call additional witnesses on its behalf upon adequate notice to Complainant and the Administrative Law Judge in accordance with 40 C.F.R. §22.19(e).

1. (B) Copies of all documents and exhibits intended to be introduced by Respondent into evidence.

Respondent intends to offer into evidence the following documents, copies of which are annexed as Respondent's Exhibits 1 - 17:

- a. Respondent's Exhibit 1 - Administrative Complaint CWA-02-2009-3460, dated May 6, 2009 (the "Complaint").
- b. Respondent's Exhibit 2 – Respondent's response to the Complaint, dated June 10, 2009
- c. Respondent's Exhibit 3 – NPDES Permit No. PR0024724, effective December 1, 2005, and expiring on November 30, 2010.

- d. Respondent's Exhibit 4 - Storm Water Pollution Prevention Plan (SWPPP) for Wyeth-Guayama.
- e. Respondent's Exhibit 5 -- Source Location and Storm Sewer Site Plan (included as Figure 4.1 in Respondent's Exhibit 4).
- f. Respondent's Exhibit 6 -- Summary of monthly precipitation data and discharge history for Wyeth-Guayama (January 2005 -- August 2009)
- g. Respondent's Exhibit 7 -- Discharge Monitoring Report for the month of September 2008, dated October 21, 2008 (including copy of laboratory sampling report and corresponding chain of custody document).
- h. Respondent's Exhibit 8 -- Rain Gauge Monthly Report for the month of September 2008, dated October 8, 2008
- i. Respondent's Exhibit 9 -- Letter to Patrick H. Harvey (USEPA) from Rubén Soto (Wyeth-Guayama), dated October 3, 2008, regarding Event Notification Report No. 885-549 (written report regarding preventive notification to the National Response Center made on September 28, 2008).
- j. Respondent's Exhibit 10 -- Wastewater Treatment Plant (WWTP) log book entries from September 22 through September 24, 2008.
- k. Respondent's Exhibit 11 -- Information on precipitation in Guayama area from September 20 through September 26, 2008 [National Oceanic and Atmospheric Administration ("NOAA")]
- l. Respondent's Exhibit 12 -- Copy of Outfall 002 flow meter graph for the period from September 20 through September 26, 2008.

- m. Respondent's Exhibit 13 – Outfall 002 flow meter specifications
- n. Respondent's Exhibit 14 – Letter from Tere Rodríguez (EPA-CEPD) to Ricardo Zayas (Wyeth-Guayama), dated September 5, 2008, regarding results of NPDES Compliance Evaluation Inspection
- o. Respondent's Exhibit 15 – Aerial photograph of Wyeth-Guayama facility, dated September 18, 2008
- p. Respondent's Exhibit 16 – Drawing of the Wyeth-Guayama outside piping – underground system (Sheet No. 100-M3-101)
- q. Respondent's Exhibit 17 – Drawing of the Wyeth-Guayama outside piping- underground system (Sheet No. 100-M3-101A)

Respondent anticipates that it may need to introduce further evidence to address issues which may arise out of the examination of documents produced by Complainant or in reply to issues which may be raised in Complainant's Prehearing Exchange and any supplements thereto. Respondent respectfully reserves the right to supplement its exhibit list upon adequate notice to Complainant and the Administrative Law Judge. Additional discovery, if necessary, will be requested by Respondent in compliance with 40 C.F.R. §22.19(e) and §22.22. In addition, Respondent may request the Administrative Law Judge to take official notice of appropriate matters in accordance with 40 CFR § 22.22(f).

3. Respondent's clarification whether its defense admits liability but challenges the appropriateness of the penalty sought by EPA.

Respondent is challenging not only the appropriateness of the penalty sought by EPA, but also the determination of liability made by the agency.

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 record-breaking storm event (as recognized by NOAA) in the Guayama, Puerto Rico area. Moreover, Respondent contends that the penalty proposed by EPA in the present case is the maximum allowable statutory amount, without any consideration for the compliance record of the facility, the lack of economic benefit, the lack of health or environmental harm, and other factors that, notwithstanding the representation made by EPA in the Complaint, were apparently not considered by the agency.

4. Respondent's position regarding ability to pay or to continue in business

Respondent does not intend to take the position that it is unable to pay the proposed penalty, or that payment thereof will materially affect its ability to continue in business. Nevertheless, Respondent vigorously challenges the proposed penalty as excessive, arbitrary, and as being in contravention of EPA's CWA penalty policy.

6. Respondent's view on hearing location and date, and time needed to present its direct case

Pursuant to 40 C.F.R. §§ 22.19(d), 22.21(d), Respondent respectfully requests that the hearing be held in San Juan, Puerto Rico, at the offices of the Puerto Rico Environmental Quality Board, where there are adequate facilities for this type of administrative hearing; or at the offices of the U.S. Environmental Protection Agency, Region II, Caribbean Environmental Protection Division. In support of this request, Respondent notes that all the witnesses that will be called by Respondent work and reside in Puerto Rico.

Respondent submits that holding the hearing in Puerto Rico, the location where the Respondent resides and conducts its business, would pose no particular hardship for Complainant, since Complainant maintains an office in Puerto Rico with a considerable amount of employees and resources.


In order to allow the parties to continue meaningful settlement negotiations, to attempt to reach a settlement of these proceedings without the need for a formal hearing, Respondent respectfully requests that the hearing be scheduled for late January or February 2010.

As of this date, Respondent estimates that the time needed to present its case would be five (5) to eight (8) hours.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 4th day of September, 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
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RESPONDENT

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

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CERTIFICATE OF SERVICE

I CERTIFY that, on the date noted below, I caused to be submitted a copy of the foregoing Respondent's Prehearing Exchange 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 – 16th Floor
New York, NY 10007

Copy via Federal Express:

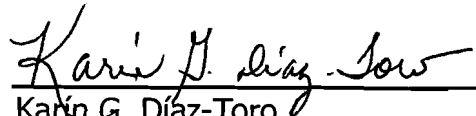
Judge William B. Moran
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Franklin Court Building
1099 14th Street N.W. Suite 350
Washington DC 20460

Copy via certified mail, return receipt requested –
7008 3230 0002 0840 7183:

Roberto Durango, Esq.
Assistant Regional Counsel
U.S. Environmental Protection Agency –
Caribbean Environmental Protection Division
Centro Europa Bldg. – Suite 417
1492 Ave. Ponce de León
San Juan, Puerto Rico 00907

In San Juan, Puerto Rico, this 4th day of September, 2009.

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