

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 U.S.C. § 1319(g)

PREHEARING EXCHANGE

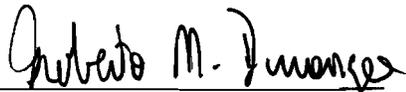
DOCKET NUMBER
CWA-02-2009-3460

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REGION 2
2009 SEP -3 PM 12: 32
REGIONAL HEARING
CLERK

COMPLAINANT'S INITIALPREHEARING EXCHANGE

Pursuant to the Order Setting Prehearing Procedures, dated July 6, 2009, directing the Parties to simultaneously make their initial prehearing exchanges by Friday, September 4, 2009, Complainant hereby files its Initial Prehearing Exchange for the above-captioned matter.

Respectfully submitted, in San Juan, Puerto Rico this 2nd day of September 2009.



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In compliance with this Court's Prehearing Order under Section 22.19 of the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits" (the Rules), directing each party to file with the Regional hearing Clerk and to serve on the opposing party and on the Presiding Judge, Complainant hereby files the following prehearing information:

1. Witnesses; Documents and Exhibits

- a. *Each Party shall submit a list of all expert and other witnesses it intends to call with a brief narrative summary of their expected testimony;*

Complainant expects to call the following persons as witnesses at the hearing:

- i. **José A. Rivera (Expert Witness)**
Environmental Engineer
Regional Storm Water Program Specialist
Multimedia Permits and Compliance Branch
U.S. Environmental Protection Agency
Caribbean Environmental Protection Division, Region 2

Mr. José A. Rivera has been working with the U.S. Environmental Protection Agency since September 9, 1990, where he started as an Environmental Engineer in the Water Permit and Compliance Branch, Water Management Division, Region 2. Mr. Rivera currently is the NPDES Regional Storm Water Program Specialist with office located at the Caribbean Environmental Protection Division, EPA, Region 2, in San Juan, Puerto Rico. Mr. Rivera holds a B.S. in Civil Engineering from the University of Puerto Rico where he graduated in 1990.

Mr. Rivera will testify about the NPDES Permit and Enforcement Programs, and how they apply to Respondent's facility.

Mr. Rivera will testify about the factual basis of this matter and will render his opinion as to the NPDES program violations, the violations of the CWA, and the pertinent regulations, as they apply to the Respondent. Mr. Rivera will testify as to the Agency's determination to seek the maximum statutory penalty against Respondent (including Respondent's economic benefit), and the appropriateness of the penalty.

In addition, Mr. Rivera will testify about Respondent's past history of violations under the Clean Water Act.

- ii. **Pedro A. Modesto, P.E. (Expert Witness)**
Environmental Engineer
Municipal Program Specialist
U.S. Environmental Protection Agency
Caribbean Environmental Protection Division, Region 2

Mr. Pedro A. Modesto has been working with EPA, Region 2, CEPD, since 1984, where he started as an Environmental Engineer in the Caribbean Branch, Water Management Division, Region 2. Mr. Modesto currently is the Regional Municipal Programs Specialist at the Caribbean Environmental Protection Division, EPA, Region 2, in San Juan, Puerto Rico. Mr. Modesto holds a B.S. in Civil Engineering from the University of Puerto Rico where he graduated in 1984 and a Masters Degree in Engineering Management from the Polytechnic University of Puerto Rico, where he graduated from in 1995. Mr. Modesto is also a licensed engineer and active member of the Puerto Rico Association of Professional Engineers and Land Surveyors.

Mr. Modesto will testify about the factual basis of this matter and render his opinion as to, among other things, Respondent's failure to properly operate the facility's wastewater treatment plant prior to and during the illegal discharges of process wastewater through the Facility's outfall 002, which occurred at relevant times, as alleged in the Complaint. He will also testify about the alternatives Respondent had to address the process wastewater during the relevant rain events of September 2008.

In addition, Mr. Modesto will render his opinion as to Respondent's NPDES program violations, the violations of the CWA, and the pertinent regulations, as they apply to the Respondent. Mr. Modesto will also testify about the assessed penalty included in the Complaint, and the appropriateness of the penalty.

- iii. **Mr. Luis A. Torres Pérez (Factual Witness)**

Mr. Luis A. Torres Pérez possesses a license in wastewater treatment plant operation and a license in drinking water plant operation issued by the Puerto Rico Department of State. Mr. Torres holds an Associate Degree in Industrial processes from Turabo University in Caguas, Puerto Rico, where he graduated from in 2008. Mr. Torres worked at Respondent's facility from October 28, 2002 to October 22, 2008, as a licensed wastewater treatment plant operator.

Mr. Torres will testify about his duties at the plant, the process and operating condition of the wastewater treatment plant prior, during and after the pertinent dates of September 2008.

Mr. Torres will testify about the facts and circumstances leading up to and including the violations alleged in the Complaint.

iv. **Mr. Edsel Llaurador Arroyo (Factual Witness)**

Mr. Edsel Llaurador Arroyo will testify about his duties at the facility and plant, the process and operation condition of the wastewater treatment plant prior, during and after the pertinent dates of September 2008.

Mr. Llaurador will testify about the facts and circumstances leading up to and including the violations alleged in the Complaint.

v. **Mr. Raúl Martínez González (Factual Witness)**

Mr. Raúl Martínez González will testify about his duties at the facility and plant, the process and operation condition of the wastewater treatment plant prior, during and after the pertinent dates of September 2008.

Mr. Martínez will testify about the facts and circumstances leading up to and including the violations alleged in the Complaint.

Complainant reserves the right, and nothing herein is intended or is to be construed to prejudice or waive any such right, to call or not to call any of the aforementioned potential witnesses, and to expand or otherwise modify the scope, extent and/or areas of the testimony of any of the above-named potential witnesses, where appropriate. In addition, Complainant reserves the right to list and to call additional potential hearing witnesses, including expert witnesses, to answer and/or rebut evidence (testimonial or documentary) listed by Respondent in its prehearing exchange or on matters arising as a consequence of such evidence.

b. *Each Party shall submit copies of all documents and exhibits it intends to introduce into evidence at the hearing. The exhibits should include a resume for each proposed expert witness.*

i. ***Complainant's Exhibit 1***—Administrative Complaint, Docket No. CWA-02-2009-3460, dated May 5, 2009; Certificate of Service, ***Complainant's Exhibit 1a***; Letter addressed to Mr. Ricardo Zayas, Vice President, Wyeth Pharmaceuticals Company, Inc., dated May 6, 2009, ***Complainant's Exhibit 1b***, and Certified Mail Receipt, ***Complainant's Exhibit 1c***.

ii. ***Complainant's Exhibit 2***—Respondent's Answer to the Administrative Complaint and Request for Hearing, dated June 10, 2009.

iii. ***Complainant's Exhibit 3***— Letter addressed to Mrs. Wanda García, Acting Director of the Water Quality Area, PR

Environmental Quality Board (EQB), dated May 6, 2009; and Certified Mail Receipt, ***Complainant's Exhibit 3a***.

- iv. ***Complainant's Exhibit 4***—Penalty Memorandum dated August 27, 2009, prepared by Mr. José A. Rivera, Docket CWA-02-2009-3460; EPA's Guidance on Administrative Penalty Pleading in the Water Enforcement Programs, ***Complainant's Exhibit 4a***; EPA's General Enforcement Policies known as GM-21 and GM-22, a guidance document for medium specific penalties in support of the penalty calculation ***Complainant's Exhibit 4b*** and ***Complainant's Exhibit 4c***; Annual Comprehensive Site Inspection, dated February 11, 2009 ***Complainant's Exhibit 4d***; Rain Gauge Monthly Report, September 2008, ***Complainant's Exhibit 4e***; Recording Device Chart, September 2008, ***Complainant's Exhibit 4f***; Event Notification Report, dated October 3, 2008, ***Complainant's Exhibit 4g***; Discharge Monitoring Report—September 22, 2008, dated October 21, 2008, with Log Book, ***Complainant's Exhibit 4h***; and Report Analysis, prepared by Beckton Environmental Laboratories, Inc., and accompanying Chain of Custody Record, ***Complainant's Exhibit 4i***.
- v. ***Complainant's Exhibit 5***—Compliance Evaluation Inspections Letter addressed to Mr. Ricardo Zayas, Vice President, Wyeth Pharmaceuticals Company, Inc., dated September 5, 2008; and Water Compliance Inspection Report, dated August 18, 2008, ***Complainant's Exhibit 5a***.
- vi. ***Complainant's Exhibit 6***—Receiving Waters Map.
- vii. ***Complainant's Exhibit 7***—PRASA Pretreatment Permit, dated August 26, 2005.
- viii. ***Complainant's Exhibit 8***—Notice of Issuance of Final Permit Decision, dated October 4, 2005, issuing NPDES Permit No. PR0024724 to Wyeth Pharmaceuticals Company.
- ix. ***Complainant's Exhibit 9***—Mr. José A. Rivera's Resume
- x. ***Complainant's Exhibit 10***—Mr. Pedro Modesto's Resume

Complainant reserves the right, and nothing herein is intended or should be construed to prejudice such right, to supplement or add, subject to notice to the Court and Respondent, documentary evidence to Complainant's prehearing exchange submission in order to respond to and/or rebut, or otherwise to address an issue arising as a

consequence of, evidence Respondent submits in its prehearing exchange or otherwise to update this prehearing exchange.

2. **The Complainant shall submit a statement explaining in detail how the proposed penalty was determined, including a description of how the specific provisions of any EPA penalty or enforcement policies or guidelines were applied in calculating the penalty.**

The proposed civil penalty for this case has been determined after taking into account the applicable factors identified at Section 309(g)(3) of the Act, 33 U.S.C. § 1319(g)(3). EPA has taken into account the nature, circumstances, extent and gravity of the violations, and Respondent's prior history of violations, degree of culpability, economic benefit or savings accruing to Respondent by virtue of the violations, and Respondent's ability to pay the proposed penalty. The Agency has also taken into account EPA's General Enforcement policies known as GM-21 and GM-22, which provide guidance about the development of a medium-specific penalty. The particular facts and circumstances of this case were also considered.

Complainant proposes, subject to receipt and evaluation of further relevant information from the Respondent, that Respondent be assessed a civil penalty in the amount of **\$157,500** for the violations alleged in the Complaint. A penalty memorandum and narrative explanation supporting the penalty figure for the violations cited in the Complaint is included in **Complainant's Exhibit 4** and its contents are incorporated herein by reference.

3. **The Respondent is directed to clarify whether its defense admits liability but challenges the appropriateness of the penalty sought by EPA.**

This section of the Prehearing Order does not apply to the Complainant.

4. **If the Respondent intends to take the position that it is unable to pay the proposed penalty, or that payment will have an adverse effect on Respondent's ability to continue in business, Respondent shall furnish supporting documentation such as a financial statement or tax returns.**

This section of the Prehearing Order does not apply to the Complainant.

5. **The Complainant shall submit a statement regarding whether the Paperwork Reduction Act of 1980 (PRA), 44 U.S.C. § 3501 et seq., applies to this proceeding, whether there is a current Office of Management and Budget Control number involved herein and whether the provisions of Section 3512 of the PRA are applicable in this case.**

Complainant believes that the Paperwork Reduction Act (PRA) does not apply to the alleged violations in this proceeding. Sections 301(a) and 308(a) of the Act, 33 U.S.C. §§ 1311(a) and 1318(a), requirements are independently enforceable regardless of the PRA. Section 3512, the public protection provision of the PRA, does not preclude the Agency from seeking enforcement directed at statutory mandates. See, 5 C.F.R. § 1320.6(e) (1997). Courts construing the PRA have held that it does not apply to requirements imposed by statute. See, Gossner Foods, Inc. v. EPA, 918 F. Supp. 359 (D. Utah 1996). The violations in this matter are statutorily mandated. There is no applicable NOI Form OMB Number for the Final NPDES General Permit for Storm Water Discharges from Small MS4's. Complainant believes that Section 3512 of the PRA does not apply to the violations alleged in this proceeding.

- 6. Each Party shall submit its views on the place for the hearing pursuant to §§ 22.21(d) and 22.19(d) of the Rules. Each party should also indicate when they would be available for the hearing, and give an estimate of the time needed to present its direct case.**

Pursuant to 40 CFR §§ 22.21(d) and 22.19(d), the hearing should be held in the county where the Respondent conducts business which the hearing concerns, in the city in which the relevant Environmental Protection Agency Regional office is located, or in Washington, D.C. Complainant requests that the hearing be held in San Juan, where the relevant Environmental Protection Agency Regional office is located. This location is convenient for both parties and witnesses than the Municipality where the events that gave rise to this action occurred. The Complainant can assist by providing the Regional Hearing Clerk with information on facilities which may be available for purposes of holding the hearing. Complainant is available for a hearing at this Court's discretion. Complainant estimates it will need four days to present its direct case.

Respectfully submitted, in San Juan, Puerto Rico this 2nd day of September 2009.



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**DOCKET NUMBER
CWA-02-2009-3460**

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing **Prehearing Exchange**, dated September 2, 2009, and bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and copy by **Federal Express** to:

Karen Maples
Regional Hearing Clerk
Region 2
U.S. Environmental Protection Agency
290 Broadway, 16th Floor
New York, NY 10007-1866.

Copy by **Certified Mail** to:

Attorney for Respondents:

Karín G. Díaz-Toro, Esquire
Counsel, Wyeth Pharmaceuticals Company, Inc.
705 Fernández Juncos Avenue
San Juan, Puerto Rico 00907-4226

Original **Federal Express** to:

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, D.C. 20460
Ph: 202.564.6255 / Fax (202) 565-0044

 Aileen Song 7/2/09