

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2009 JUN 11 AM 11:48  
REGIONAL HEARING  
CLERK

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

**ANSWER TO THE COMPLAINT AND REQUEST FOR  
HEARING**

TO THE HONORABLE ADMINISTRATIVE LAW JUDGE:

NOW COMES Respondent, Wyeth Pharmaceuticals Company, Inc. – Guayama Operations ("Wyeth-Guayama"), through its undersigned attorneys, and for its Answer to the Administrative Complaint, Findings of Violation, Notice of Proposed Assessment of a Civil Penalty, and Notice of Opportunity to Request a Hearing issued by the U. S. Environmental Protection Agency, Region II ("EPA") by letter dated May 6, 2009 (hereinafter, the "Complaint"), and received by Respondent on May 11, 2009, admits, denies and alleges as follows:

1. The averments contained in paragraphs 1, 2, 3, 4, 5, and 6 require no responsive pleadings insofar as they recite provisions of law. To the

extent that they might be deemed allegations of fact, such allegations are denied.

2. The averments contained in paragraphs 7 and 8 are admitted.
3. The averments contained in paragraphs 9, 10 and 11 are admitted.
4. The averments contained in paragraphs 12, 13, 14, 15, 16 and 17 are objected as irrelevant, as they refer to a pretreatment system and pretreatment permit which are not the object of the present Complaint.
5. The averments contained in paragraph 18 are denied as drafted. It is clarified that Respondent's facility has two (2) detention ponds with a holding capacity of almost 4,000,000 gallons (3,000,000 in the south detention pond and 930,000 gallons in the east detention pond), which receive storm water during rain events. It is further clarified that Respondent'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.
6. The averments contained in paragraph 19 are denied as drafted. It is affirmatively alleged that Respondent discharges storm waters from the detention ponds through an underground pipeline which eventually reaches Las Mareas Bay.
7. The averments contained in paragraph 20 are denied as drafted. It is affirmatively alleged that Respondent's discharge point into the

underground pipeline which eventually reaches Las Mareas Bay is known as Outfall 002.

8. The averments contained in paragraphs 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35 and 36 are admitted.
9. The averments contained in paragraph 37(a) are denied as drafted. It is affirmatively alleged that there was a discharge through Outfall 002 around 10:00 am on September 22, 2008. It is affirmatively alleged that the Outfall 002 flow meter was offline from September 21, 2008 (2:00 – 10:00 pm shift) through September 22, 2008 (6:00 am - 2:00 pm shift).
10. The averments contained in paragraph 37(b) are denied as drafted. It is affirmatively alleged that the discharge on September 24, 2008 concluded around 5:30 am.
11. The averments contained in paragraph 38 are denied as drafted. It is affirmatively alleged that Respondent's October 3, 2008 letter constitutes a protective filing regarding the occurrence of an extraordinary storm event occurring in Guayama during the period from September 21 through September 27, 2008, when almost twenty inches (20") of rain were registered in Guayama.
12. The averments contained in paragraph 39 are denied as drafted. It is affirmatively alleged that the October 3, 2008 notification indicated that 120,000 – 180,000 gallons of "water" were discharged into the south

retention pond area during the period from September 22 through September 27, 2008. It is affirmatively alleged that there was no discharge through Outfall 002 from September 24, 2008 (after 5:30 am) to September 27, 2008, as evidenced by Outfall 002's flow recording device.

13. The averments contained in paragraph 40 are admitted. It is affirmatively alleged that there was no discharge from Outfall 002 on September 26, 2008, as evidenced by Outfall 002's flow recording device.
14. The averments contained in paragraph 41 are denied as drafted. It is affirmatively alleged that the notation in the log book indicates that there was a discharge from the South Lagoon to the "landfield," i.e., the south retention pond area with a 3,000,000-gallon holding capacity. It is affirmatively alleged that there was no discharge through Outfall 002 on September 27, 2008, as evidenced by Outfall 002's flow recording device.
15. The averments contained in paragraph 42(a) do not require a responsive pleading and/or are denied.
16. The averments contained in paragraph 42(b) are denied. In the alternative, the amount of process wastewater from an open aeration lagoon which might have been discharged as part of the discharge of

storm water during a *force majeure* event (major rain storm depositing over 20" of rain during the course of a week), if any, was insignificant.

17. The averments contained in paragraph 42(c) do not require a responsive pleading insofar as they are conclusions of law and/or are denied.
18. The averments contained in paragraph 42(d) are denied.
19. The averments contained in paragraph 43(a) do not require a responsive pleading and/or are denied.
20. The averments contained in paragraph 43(b) are denied. In the alternative, the amount of process wastewater from an open aeration lagoon which might have been discharged as part of the discharge of storm water during a *force majeure* event (major rain storm depositing over 20" of rain during the course of a week), if any, was insignificant.
21. The averments contained in paragraph 43(c) do not require a responsive pleading insofar as they are conclusions of law and/or are denied.
22. The averments contained in paragraph 43(d) are denied.
23. The averments contained in paragraph 44(a) do not require a responsive pleading and/or are denied.
24. The averments contained in paragraph 44(b) are denied. In the alternative, the amount of process wastewater from an open aeration lagoon which might have been discharged as part of the discharge of

storm water during a *force majeure* event (major rain storm depositing over 20" of rain during the course of a week), if any, was insignificant.

25. The averments contained in paragraph 44(c) do not require a responsive pleading insofar as they are conclusions of law and/or are denied.
26. The averments contained in paragraph 44(d) are denied.
27. The averments contained in paragraph 45(a) do not require a responsive pleading and/or are denied.
28. The averments contained in paragraph 45(b) are denied as drafted. It is affirmatively alleged that the Storm Water Pollution Prevention Plan ("SWPP") for Wyeth-Guayama, dated August 2007, does not require Respondent to inspect the Outfall 002 underground discharge pipeline.
29. The averments contained in paragraph 45(b) are denied as drafted. It is affirmatively alleged that the SWPP for Wyeth-Guayama, dated August 2007, does not require Respondent to inspect the Outfall 002 underground discharge pipeline. It is affirmatively alleged that, by letter dated September 5, 2008, Complainant certified that Respondent was in compliance with the NPDES permit and the SWPP.
30. The averments contained in paragraph 45(c) are denied. It is affirmatively alleged that the SWPP for Wyeth-Guayama, dated August 2007, does not require Respondent to inspect the Outfall 002 underground discharge pipeline. It is affirmatively alleged that, by

letter dated September 5, 2008, Complainant certified that Respondent was in compliance with the NPDES permit and the SWPP.

31. The averments contained in paragraph 45(d) are denied.
32. The averments contained in paragraph 45(e) do not require a responsive allegation insofar as they are conclusions of law. To the extent that they may be deemed allegations of fact, they are denied.
33. The averments contained in paragraph 45(f) are denied.
34. The averments contained in paragraph 46(a) do not require a responsive allegation and/or are denied.
35. The averments contained in paragraph 46(b) are admitted.
36. The averments contained in paragraph 46(c) are denied. It is affirmatively alleged that the Chain of Custody record indicates that the sample date was September 22, 2008 at 10:00 am.
37. The averments contained in paragraph 46(d) are denied as drafted. It is affirmatively alleged that the log book for September 21, 2008 indicates that a rain sample ("*muestra de lluvia*") was taken. It is affirmatively allege that the log book for September 22, 2008 indicates that storm water sampling was conducted and the samples were taken to EHS ("*Se tomaron muestras de stormwater y se llevaron a EHS*").
38. The averments contained in paragraph 46(e) are admitted.
39. The averments contained in paragraph 46(f) are denied. It is affirmatively alleged that, pursuant to the WFO Protocol in Special

Condition 13.B of the NPDES Permit, Respondent must sample “any storm water discharge which occurs during normal business hours for the facility.” It is affirmatively alleged that, in compliance with the aforementioned Special Condition 13.B, Respondent sampled a storm water discharge which occurred on or around 10:00 am on September 22, 2008.

40. The averments contained in paragraphs 46(g) and 46 (h) are denied.
41. The averments contained in paragraph 46(i) do not require a responsive allegation insofar as they are recite provisions of law. To the extent that they might be deemed allegations of fact, such allegations are denied.
42. The averments contained in paragraph 46(j) are denied.
43. The averments contained in Section IV of the Complaint (paragraphs 47, 48, and 49) set forth the relief requested therein and require no response. To the extent a response is required, Respondent denies that the relief requested is appropriate.
44. The averments contained in Sections V, VI, VII, VIII and IX of the Complaint do not require a responsive pleading, since they refer to statutory, regulatory and procedural requirements.
45. Respondent denies any and all allegations not specifically admitted herein.



### **Affirmative Defenses**

1. The Complaint fails to state a claim upon which relief can be granted.
2. The proposed civil penalty is excessive, unreasonable and is not supported by the individual facts and circumstances present in this matter, including but not limited to the existence of mitigating factors which must be taken into consideration.
3. Complainant's allegations constitute agency action that is arbitrary and capricious, and an abuse of discretion under the Administrative Procedure Act, 5 U.S.C. §§553 and 706.
4. We reiterate and incorporate by reference herein each and every affirmative allegation included in the response to each specific averment of the Complaint stated above.
5. Respondent expressly reserves the right to raise additional affirmative defenses which may arise during discovery or under other procedures associated with the present Complaint.

### **Informal Settlement Conference**

Respondent respectfully informs that the parties have scheduled an informal settlement conference for June 17, 2009, at 9:30 am.

### **Request for Hearing**

Respondent hereby requests a hearing upon the issues raised by the Complaint and its Answer as included herein, pursuant to CWA § 309 and the Consolidated Rules of Practice, 40 CFR §22.15.

**WHEREFORE**, Respondent respectfully requests that the present Complaint be dismissed and/or that the relief requested in the Complaint be denied, including the proposed civil penalty amount assessed; that Respondent be granted a hearing on this matter; and/or that Respondent be granted any other remedy deemed fit and proper.

**RESPECTFULLY SUBMITTED.**

In San Juan, Puerto Rico, this 10<sup>th</sup> day of June, 2009.

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Karin G. Díaz-Toro

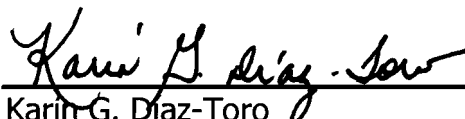
E-mail: [kdiaz@envirolawpr.com](mailto:kdiaz@envirolawpr.com)

**Copy by regular mail:**

Eng. Wanda García  
Manager, Water Quality Area  
P.R. Environmental Quality Board  
PO Box 11488  
San Juan, PR 00910-1488

In San Juan, Puerto Rico, this 10<sup>th</sup> day of June, 2009.

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

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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 Answer to the Complaint to the following persons, at the addresses listed below, and in the manner specified below:

**Original and copy for filing 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 by messenger:**

Roberto Durango, Esq.  
Assistant Regional Counsel  
U.S. Environmental Protection Agency –  
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