

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2009 MAY 08 AM 9:20  
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 U.S.C. § 1319(g)

**PROCEEDING TO ASSESS A  
CLASS II CIVIL PENALTY**

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

**COMPLAINT, FINDINGS OF VIOLATION, NOTICE OF PROPOSED  
ASSESSMENT OF A CIVIL PENALTY, AND  
NOTICE OF OPPORTUNITY TO REQUEST A HEARING**

**I. STATUTORY AUTHORITY**

1. This Administrative Complaint, Findings of Violation, Notice of Proposed Assessment of an Administrative Penalty, and Notice of Opportunity to Request a Hearing ("Complaint") is issued under the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by Section 309(g)(2)(B) of the Clean Water Act (the "Act" or "CWA"), 33 U.S.C. § 1319(g)(2)(B). The Administrator of EPA has delegated this authority to the Regional Administrator of EPA, Region 2, who in turn has delegated it to the Director, Caribbean Environmental Protection Division of EPA, Region 2 ("Complainant").
2. Pursuant to Section 309(g)(2)(B) of the Act, and in accordance with 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" ("CROP"), 40 CFR § 22, a copy of which is attached, Complainant hereby requests that the Regional Administrator assess a civil penalty against Wyeth Pharmaceuticals Company ("Respondent" or "permittee"), as a result of Complainant's determination that the Respondent violated Section 301 of the Act, 33 U.S.C. § 1311, for its unauthorized discharges of pollutants into a water of the United States, and for its failure to comply with the National Pollutant Discharge Elimination System ("NPDES") Permit (the "NPDES Permit") Number PR0024724 concerning monitoring and operation and maintenance of a discharge pipeline.

**Complaint against Wyeth Pharmaceuticals Company, Inc.  
Docket Number CWA-02-2009-3460**

3. Section 301(a) of the Act, 33 U.S.C. § 1311(a), provides in part that "except as in compliance with this Section and Sections . . . 402, and 404 of the Act, the discharge of any pollutant by any person shall be unlawful."
4. Section 308 of the Act, 33 U.S.C. § 1318, provides, in relevant part, that the Administrator of EPA may require the owner or operator of any point source to, among other things: maintain such records; make such reports; install, use and monitor such equipment; sample such effluents; and provide such other information as may reasonably be required in order to carry out Section 402 of the Act, 33 U.S.C. § 1342.
5. Section 402 of the Act, 33 U.S.C. § 1342, authorizes the Administrator of EPA to issue a NPDES permit for the discharge of any pollutant, or combination of pollutants, subject to certain requirements of the Act and such conditions as the Administrator determines are necessary.
6. The Act and its implementing regulations contain the following definitions:
  - a) "Navigable waters" means the waters of the United States and territorial seas, pursuant to Section 502(7) of the Act, 33 U.S.C. § 1362(7).
  - b) "Pollutant" means, but is not limited to, solid waste, dredged spoil, rock, sand, cellar dirt, sewage, sewage sludge, and industrial, municipal and agricultural waste discharged into water, pursuant to Section 502(6) of the Act, 33 U.S.C. § 1362(6).
  - c) "Point source" means "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, ..." pursuant to Section 502(14) of the Act, 33 U.S.C. § 1362(14).
  - d) "Discharge of a pollutant" means any addition of any pollutant to navigable waters from any point source, pursuant to Section 502(12) of the Act, 33 U.S.C. § 1362(12).
  - e) "Person" means, but is not limited to, an individual, corporation, partnership or association, pursuant to Section 502(5) of the Act, 33 U.S.C. § 1362(5).
  - f) "Owner or Operator" means the owner or operator of any facility or activity subject to regulation under the NPDES program.
  - g) "NPDES" means a National Pollutant Discharge Elimination System pursuant to Section 402 of the Act, 33 U.S.C. § 1342.

## II. JURISDICTIONAL BASIS

### With Respect to the Person

7. Respondent is a corporation organized under the laws of the Commonwealth of Puerto Rico.
8. Respondent is a person pursuant to Section 502(5) of the CWA, 33 U.S.C. § 1362(5).

### With Respect to the Facility

9. Respondent owns and operates a manufacturing facility (the "Facility").
10. The Facility is located at State Road 3, Km. 142.1, Guayama, Puerto Rico 00784.
11. The manufacturing, fabrication, and processing activities at the Facility are primarily associated with drugs in pharmaceutical preparations for human use.

### With Respect to the Point Sources and the Discharge of Pollutants

12. Respondent owns and operates an Industrial Wastewater Treatment Plant ("IWWTP") located at the Facility.
13. The IWWTP primarily treats industrial waste which originates from the manufacturing, fabrication, and processing of drugs from the Facility's buildings and premises.
14. The treated industrial waste is discharged through an underground pipeline into a point of connection of a Puerto Rico Aqueduct and Sewer Authority ("PRASA") Sanitary Collection System ("SCS"), under the PRASA Pretreatment Permit Number GDA-02-507-040.
15. The IWWTP discharge point into the SCS is known as outfall serial number 001.
16. This SCS discharges into the PRASA Guayama Regional Sanitary Treatment Plant located in Guayama, Puerto Rico.
17. The PRASA Guayama Regional Sanitary Treatment Plant is authorized to discharge pollutants into the Caribbean Sea under the NPDES Permit Number PR0025445.
18. Respondent owns and operates a storm water collection, storage, sampling, and discharge system ("SW System") which receives storm water from the Facility's premises.

19. The SW System discharges through an underground pipeline into Las Mareas Bay.
20. The SW System discharge point into Las Mareas Bay is known as outfall serial number 002.
21. The sampling point for outfall serial number 002 has a flow measurement device and flow recording device.
22. The Facility was and is, at relevant times, a point source pursuant to 502(14) of the Act, 33 U.S.C. § 1362(14).

With Respect to the Navigable Waters

23. Las Mareas Bay and the Caribbean Sea are navigable waters of the United States pursuant to Section 502(7) of the Act, 33 U.S.C. § 1362(7).

With Respect to the Facility's NPDES Permit

24. On September 15, 2005, EPA re-issued an NPDES Permit to Respondent.
25. The NPDES Permit authorizes Respondent to discharge water composed entirely of storm water through outfall serial number 002 into Las Mareas Bay.
26. The NPDES Permit became effective on December 1, 2005.
27. The NPDES Permit will expire on November 30, 2010.
28. Special Condition 10 of the NPDES Permit indicates that Respondent "should keep daily records of rain, indicating the date and duration of the events, and that copy of these records shall be submitted monthly to EQB" [Environmental Quality Board of Puerto Rico].
29. Special Condition 12 of the NPDES Permit indicates that Respondent "shall comply at all times with the provisions, measures or practices included in the SWPP Plan (Special Condition 11) approved by EQB.
30. Special Condition 13.B of the NPDES Permit includes the term "When Flow Occurs" ("WFO") monitoring protocol that Respondent shall follow when sampling a storm water discharge at outfall serial number 002 sampling point. The Permit states:

"WFO - For our purposes means when flow occurs during normal business hours fo[r] the facility but not more often than one rainfall runoff per month.

A. First Half of Month

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.

B. Second Half of Month

In the event that the permittee is unable to satisfy the above condition 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.

C. General Requirements

The permittee must report in a cover letter attached to each Discharge Monitoring Report (DMR), detailing the conditions under which the storm water samples were taken, the date of sampling.

Alternatively, if no samples are taken during the month, the permittee will be considered to have met its sampling requirement if the permittee certifies that it was not possible to meet the specified sampling protocol during the first fifteen (15) days of the month and that there was no appreciable discharge of storm water during normal business hours for the facility from the sixteenth (16<sup>th</sup>) day of the month to the last day of the month."

31. Part I.B.2.b. of the NPDES Permit states that the "Monitoring results obtained during the previous month shall be summarized and reported in a Discharge Monitoring Report Form (EPA No. 3320-1), postmarked no later than the 28th day of the month following the completed reporting period.
32. Part II.B.1.a of the NPDES Permit states that "The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act and is grounds for enforcement action; for permit termination, revocation and re-issuance, or modification; or for denial of a permit renewal application."

33. Part II.B.3 of the NPDES Permit states that "It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
34. Part II.B.4 of the NPDES Permit states that "The permittee shall take all reasonable steps to minimize or prevent any discharge in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment."
35. Part II.B.5 of the NPDES Permit states that "The permittee shall at all times properly 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 the permit."

With Respect to Jurisdiction under the Act

36. Based on the paragraphs above, Respondent is subject to the Provisions of the Act.

**III. FINDINGS OF VIOLATIONS**

37. The outfall serial number 002 recording device recorded the following data for the week of September 21, 2008.
  - a. The graphic paper of the recording device recorded a discharge event ("1<sup>st</sup> Event") that began on September 22, 2008 (on or about 3:00 p.m.) and ended on September 23, 2008 (on or about 3:00 p.m.).
  - b. The graphic paper of the recording device recorded another discharge event ("2<sup>nd</sup> Event") that began on September 23, 2008 (on or about 7:30 p.m.) and ended on September 24, 2008 (on or about 5:00 p.m.).
38. Respondent submitted a written notification to Complainant, dated October 3, 2008, in which Respondent admitted that industrial waste from the IWWTP North Lagoon overflowed into the IWWTP South Lagoon on or about September 22, 2008 to September 27, 2008.
39. The written notification, dated October 3, 2008, also indicated that approximately 120,000 – 180,000 gallons of industrial waste and storm water from the IWWTP South Lagoon were discharged into the SW System from September 22, 2008 to September 27, 2008.

40. On September 26, 2008, a Respondent IWWTP operator (Mr. Luis Torres) wrote in the IWWTP's Log Book that the IWWTP North Lagoon was overflowing into the IWWTP South Lagoon.
41. On September 27, 2008, a Respondent IWWTP operator (Mr. Luis Torres) wrote in the IWWTP's Log Book that the IWWTP South Lagoon was discharging into the SW System.
42. **CLAIM 1 – Unauthorized Discharge of Pollutants (September 22, 2008)**
- a. Complainant re-alleges and incorporates by reference paragraphs 1-41 above.
  - b. On September 22, 2008, Respondent discharged industrial waste mixed with storm water through outfall serial number 002 into Las Mareas Bay, a navigable water of the Unites States, without an NPDES permit.
  - c. The unauthorized discharge of industrial waste mixed with storm water through the outfall 002 into Las Mareas Bay, without an NPDES permit, constitutes a violation of Section 301 of the Act, 33 U.S.C. § 1311.
  - d. Respondent is charged for **one (1) day of violation** of Section 301 of the Act, 33 U.S.C. § 1311.
43. **CLAIM 2 – Unauthorized Discharge of Pollutants (September 23, 2008)**
- a. Complainant re-alleges and incorporates by reference paragraphs 1-41 above.
  - b. On September 23, 2008, Respondent discharged industrial waste mixed with storm water through outfall serial number 002 into Las Mareas Bay, a navigable water of the Unites States, without an NPDES permit.
  - c. The unauthorized discharge of industrial waste mixed with storm water through the outfall 002 into Las Mareas Bay, without an NPDES permit, constitutes a violation of Section 301 of the Act, 33 U.S.C. § 1311.
  - d. Respondent is charged for **one (1) day of violation** of Section 301 of the Act, 33 U.S.C. § 1311.
44. **CLAIM 3 – Unauthorized Discharge of Pollutants (September 24, 2008)**
- a. Complainant re-alleges and incorporates by reference paragraphs 1-41 above.

- b. On September 24, 2008, Respondent discharged industrial waste mixed with storm water through outfall serial number 002 into Las Mareas Bay, a navigable water of the United States, without an NPDES permit.
- c. The unauthorized discharge of industrial waste mixed with storm water through the outfall 002 into Las Mareas Bay, without an NPDES permit, constitutes a violation of Section 301 of the Act, 33 U.S.C. § 1311.
- d. Respondent is charged for **one (1) day of violation** of Section 301 of the Act, 33 U.S.C. § 1311.

**45. CLAIM 4 – Lack of Inspection & Maintenance of Outfall 002 Discharge Pipeline**

- a. Complainant re-alleges and incorporates by reference paragraphs 1-36 above.
- b. Respondent has not inspected and provided maintenance to the outfall serial number 002 underground discharge pipeline for the last five (5) years.
- c. At a minimum, Respondent should have inspected the outfall serial number 002 underground discharge pipeline at least once per year during the Annual Storm Water Comprehensive Compliance Evaluation Inspection performed by Wyeth, as established in the Storm Water Pollution Prevention Plan, dated August 2007.
- d. Respondent's failure to inspect and provide maintenance to the outfall serial number 002 underground discharge pipeline constitutes a violation of Part II.B.5 of the NPDES Permit.
- e. A violation of an NPDES permit requirement constitutes a violation of Section 301 of the Act, 33 U.S.C. § 1311.
- f. Respondent is charged for **five (5) days of violation** of Section 301 of the Act, 33 U.S.C. § 1311.

**46. CLAIM 5 – Sampling did not Comply with Sampling for September 2008**

- a. Complainant re-alleges and incorporates by reference paragraphs 1-36 above.
- b. Respondent submitted a Discharge Monitoring Report ("DMR") dated October 10, 2008, and supporting documents ("Rain Gauge Daily Record Log for September 2008, Laboratory Report of Analytical Chemistry Services, Inc. dated October 10, 2008, and Laboratory Report of Analytical Chemistry Services, Inc. dated October 10, 2008") to the Department of Environmental Services, San Francisco, California, on October 10, 2008.



- c. The Chain of Custody Record includes conflicting dates because it indicates in one part that the sample date was September 22, 2008 and, in another part, it indicates September 23, 2008.
- d. The IWWTP log book indicates that the storm water sample was taken on September 21, 2008.
- e. The IWWTP log book for September 23, 2008 indicates that personnel from the Private Laboratory [Beckton] received the storm water samples collected on September 22, 2008.
- f. Based on the WFO Protocol in Special Condition 13.B of the NPDES Permit, Respondent should have sampled the storm water discharge that began on or about September 22, 2008, at approximately 3:30 pm.
- g. Respondent's DMR and supporting documents did not comply with Special Condition 13.B of the NPDES Permit and 40 CFR §136.
- h. Respondent did not comply with the September 2008 monitoring requirements established in Table A-1 of the permit for Chemical Oxygen Demand, Color, Oil and Grease, pH, Temperature, Total Suspended Solids, Turbidity and Zinc.
- i. A violation of an NPDES permit requirement constitutes a violation of Section 301 of the Act, 33 U.S.C. § 1311.
- j. Respondent is charged with **eight (8) violations** of Section 301 of the Act, 33 U.S.C. § 1311.

#### **IV. NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY**

- 47. Based on the foregoing Findings of Violation, and pursuant to the authority of Section 309(g) of the Act, 33 U.S.C. § 1319(g), and the Debt Collection Improvement Act of 1996, EPA, Region 2 hereby proposes to issue a Final Order Assessing Administrative Penalties (Final Order) to Respondent assessing a penalty of **\$157,500**.
- 48. EPA determined the proposed penalty after taking into account the applicable factors identified at Section 309(g)(3) of the Act, 33 U.S.C. § 1319(g)(3). They are: the nature, circumstances, extent and gravity of the violation (or violations), and Respondent's prior compliance history, degree of culpability, economic benefit or savings accruing to Respondent by virtue of the violations, and Respondent's ability to pay the proposed penalty.

49. EPA may issue the Final Order Assessing Administrative Penalties thirty (30) days after Respondent's receipt of this Notice, unless Respondent within that time files an Answer to the Complaint and requests a Hearing on this Notice pursuant to the following section.

**V. PROCEDURES GOVERNING THIS ADMINISTRATIVE ACTION**

50. The rules of procedure governing this civil administrative litigation have been set forth in the CROP, 40 CFR § 22. A copy of these rules accompanies this Complaint.

**a. Answering the Complaint**

51. Where Respondent intends to contest any material fact upon which the Complaint is based, to contend that the proposed penalty is inappropriate or to contend that Respondent is entitled to judgment as a matter of law, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written Answer to the Complaint, and such Answer must be filed within thirty (30) days after service of the Complaint, per 40 CFR § 22.15(a).

52. The address of the Regional Hearing Clerk of EPA, Region 2, is:

**Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 2  
290 Broadway, 17th floor  
New York, New York 10007-1866**

53. Respondent shall also then serve one copy of the Answer to the Complaint upon Complainant and any other party to the action, per 40 CFR § 22.15(a).
54. Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations that are contained in the Complaint and with regard to which the Respondent has any knowledge, per 40 CFR § 22.15(b).
55. Where Respondent lacks knowledge of a particular factual allegation and so states in the Answer, the allegation is deemed denied, per 40 CFR § 22.15(b).
56. The Answer shall also set forth:
- a) the circumstances or arguments that are alleged to constitute the grounds of defense,
  - b) the facts that Respondent disputes (and thus intend to place at issue in the proceeding),

c) the basis for opposing the proposed relief and (4) whether Respondent requests a Hearing, per 40 CFR § 22.15(b).

57. Respondent's failure to affirmatively raise in the Answer facts that constitute or that might constitute the grounds of a defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a Hearing.

**b. Opportunity to Request a Hearing**

58. If requested by Respondent in its Answer, a Hearing upon the issues raised by the Complaint and Answer may be held, per 40 CFR § 22.15(c).

59. If, however, Respondent does not request a Hearing, the Presiding Officer (as defined in 40 CFR § 22.3) may hold a Hearing if the Answer raises issues appropriate for adjudication, per 40 CFR § 22.15(c).

60. Any Hearing in this proceeding will be held at a location determined in accordance with 40 CFR § 22.21(d).

61. A Hearing of this matter will be conducted in accordance with the applicable provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of 40 CFR Part 22.

62. Should Respondent request a Hearing on this proposed penalty assessment, members of the public, to whom EPA is obligated to give notice of this proposed action, will have a right under Section 309(g)(4)(B) of the Act, 33 U.S.C. § 1319(g)(4)(B), to be heard and to present evidence on the appropriateness of the penalty assessment.

63. Should Respondent not request a Hearing, EPA will issue a Final Order, and only members of the public who submit timely comment on this proposal will have an additional thirty (30) days to petition EPA to set aside the Final Order and to hold a Hearing thereon.

64. EPA will grant the petition and will hold a Hearing only if the petitioner's evidence is material and was not considered by EPA in the issuance of the Final Order.

**c. Failure to Answer**

65. If Respondent fails in any Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation, per 40 CFR § 22.15(d).

66. If Respondent fails to file a timely [i.e. in accordance with the 30-day period set forth in 40 CFR § 22.15(a)] Answer to the Complaint, Respondent may be found in default upon motion, per 40 CFR § 22.17(a).
67. Default by Respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations, per 40 CFR § 22.17(a).
68. Following a default by Respondent for a failure to timely file an Answer to the Complaint, any order issued therefore shall be issued pursuant to 40 CFR § 22.17(c).
69. Any penalty assessed in the default order shall become due and payable by Respondent without further proceedings thirty (30) days after the Default Order becomes final pursuant to 40 CFR § 22.27(c), per 40 CFR § 22.17(d).
70. If necessary, EPA may then seek to enforce such Final Order of Default against Respondent, and to collect the assessed penalty amount, in Federal court.

#### **VI. INFORMAL SETTLEMENT CONFERENCE**

71. Whether or not Respondent requests a formal Hearing, EPA encourages settlement of this proceeding consistent with the provisions of the Act and its applicable regulations, per 40 CFR § 22.18(b).
72. At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in this Complaint and Respondent may also provide whatever additional information is believed to be relevant to the disposition of this matter, including:
  - a) actions Respondent has taken to correct any or all of the violations herein alleged,
  - b) any information relevant to Complainant's calculation of the proposed penalty,
  - c) the effect the proposed penalty would have on Respondent's ability to continue in business and/or
  - d) any other special facts or circumstances Respondent wishes to raise.
73. Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant or to dismiss any or all of the charges, if Respondent can

demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. Respondent is referred to 40 CFR § 22.18.

74. Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to the EPA attorney named in Section VIII Paragraph 94 below.
75. The parties may engage in settlement discussions irrespective of whether Respondent has requested a Hearing, per 40 CFR § 22.18(b)(1).
76. Respondent's requesting a formal Hearing does not prevent Respondent from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure.
77. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a Hearing as specified in 40 CFR § 22.15(c).
78. A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 CFR § 22.15.
79. No penalty reduction, however, will be made simply because an informal settlement conference is held.
80. Any settlement that may be reached as a result of an informal settlement conference shall be embodied in a written Consent Agreement, per 40 CFR §22.18(b)(2).
81. In accepting the Consent Agreement, Respondent waives any right to contest the allegations in the Complaint and waive any right to appeal the Final Order that is to accompany the Consent Agreement, per 40 CFR § 22.18(b)(2).
82. In order to conclude the proceeding, a Final Order ratifying the parties' agreement to settle will be executed, per 40 CFR § 22.18(b)(3).
83. Entering into a settlement through the signing of such Consent Agreement and complying with the terms and conditions set forth in such Consent Agreement and Final Order terminates this administrative litigation and these civil proceedings against Respondent (note that a new enforcement action may be initiated based on continued non-compliance).
84. Entering into a settlement agreement does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all

applicable statutory and regulatory requirements, and to maintain such compliance.

**VII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE**

85. Instead of filing an Answer, Respondent may choose to pay the total amount of the proposed penalty **(\$157,500)** within thirty (30) days after receipt of the Complaint, provided that Respondent files with the Regional Hearing Clerk, Region 2 (at the address noted above), a copy of the check or other instrument of payment, per 40 CFR § 22.18(a).
86. A copy of the check or other instrument of payment should be provided to the EPA attorney named in Section VIII Paragraph 94 below.
87. Payment of the penalty assessed should be made by sending a cashier's or certified check payable to the "Treasurer, United States of America," in the full amount of the penalty assessed in this complaint to the following addressee:

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P. O. Box 979077  
St. Louis, MO 63197-9000

88. Pursuant to 40 CFR §22.18(a)(3), if Respondent elects to pay the full amount of the penalty proposed in the Complaint within thirty (30) days of receiving the Complaint, then, upon EPA's receipt of such payment, the Regional Administrator of EPA, Region 2 (or, if designated, the Regional Judicial Officer), shall issue a Final Order in accordance with 40 CFR §22.18(a)(3).
89. In accordance with 40 CFR §22.45(c)(3), no Final Order shall issue until at least ten (10) days after the close of the comment period on this Complaint.
90. Issuance of a Final Order terminates this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint (note that a new enforcement action may be initiated based on continued non-compliance).
91. Further, pursuant to 40 CFR §22.18(a)(3), the making of such payment by Respondent shall constitute a waiver of Respondent's right both to contest the allegations made in the Complaint and to appeal said Final Order to Federal court.
92. Such payment does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

**VIII. FILING OF DOCUMENTS**

93. The Answer and any Hearing Request and all subsequent documents filed in this action should be sent to:

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

94. A copy of the Answer, any Hearing Request and all subsequent documents filed in this action shall be sent to:

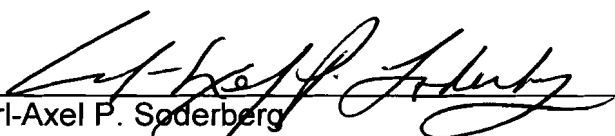
Roberto Durango, Esq.  
Assistant Regional Counsel  
Caribbean Team  
Office of Regional Counsel  
U.S. Environmental Protection Agency, Region 2  
1492 Ponce de Leon Avenue, Suite 417  
San Juan, PR 00907  
Telephone (787) 977-5822  
Fax: (787) 729-7748

**IX. GENERAL PROVISIONS**

95. Respondent has a right to be represented by an attorney at any stage of these proceedings.
96. This Complaint does not constitute a waiver, suspension or modification of the requirements of the Act, regulations promulgated thereunder, or any applicable permit.

97. Neither assessment nor payment of an administrative civil penalty pursuant to Section 309(g) of the Act will affect Respondent's continuing obligation to comply with the Act, and with any separate Compliance Order issued under Section 309(a) of the Act, 33 U.S.C. §1319(a), for the violations alleged herein.

ISSUED THIS 5<sup>th</sup> DAY OF May, 2009.

  
\_\_\_\_\_  
Carl-Axel P. Soderberg  
Director, Caribbean Environmental Protection Division  
U. S. Environmental Protection Agency - Region 2  
Centro Europa Building, Suite 417  
1492 Ponce de León Avenue  
San Juan, Puerto Rico 00907

ATTACHMENT

cc: Wanda García, EQB (w/ Complaint)



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)

**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 mailed a copy of the foregoing Complaint to the following persons, at the addresses listed below and in the following manner:

**Original and copy for filing**

**Fed Ex:**

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

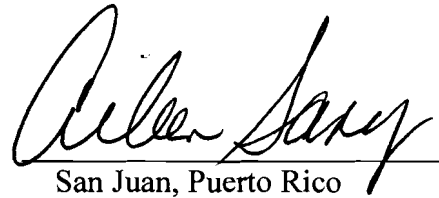
**Copy by Certified Mail /**

**Return Receipt Requested:**

Mr. Ricardo Zayas  
Vice President  
Wyeth Pharmaceuticals Company, Inc.  
Call Box 10012  
Guayama, Puerto Rico 00785

Ms. Wanda Garcia  
Director  
Water Quality Area  
Environmental Quality Board  
P.O. Box 11488  
Santurce, Puerto Rico 00910

Date: 05/06/09

A handwritten signature in black ink, appearing to read "Allen Sanchez", written over a horizontal line.

San Juan, Puerto Rico  
Office of Regional Counsel - CT