

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2**

U.S. ENVIRONMENTAL
PROTECTION AGENCY
2009 OCT 30 PM 1:17
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

OPPOSITION TO MOTION FOR ADDITIONAL DISCOVERY

TO THE HONORABLE ADMINISTRATIVE LAW JUDGE:

COMES NOW Respondent, Wyeth Pharmaceuticals Company, Inc. – Guayama Operations (“Wyeth-Guayama”), through its undersigned attorneys, and, pursuant to the provisions of 40 CFR § 22.16(b) and for the reasons set forth below, respectfully sets forth and prays as follows:

1. On October 26, 2009, Wyeth-Guayama received a Motion for Additional Discovery filed by Complainant, dated October 23, 2009. Wyeth-Guayama objects to this motion, which is basically a “fishing expedition” in an attempt to cure Complainant’s failure to state a prima facie case in its Notice of Assessment of a Class II Administrative Penalty, dated May 5, 2009 (hereinafter referred to as the “Complaint”).
2. Complainant adduces that its July 21, 2009 letter requesting additional information was a “request for discovery,” when in fact the letter references

the initial settlement conference held by the parties on June 17, 2009. See, Attachment 1. Moreover, the Prehearing Exchange was not due until September 4, 2009, pursuant to the Prehearing Order issued on July 6, 2009. Complainant also conveniently fails to note that it has not yet provided the information requested by Respondent by letter dated June 22, 2009. See, Attachment 2.

3. Notwithstanding the foregoing, and without waiving its objections in this matter, with respect to the information requested in the July 21, 2009 letter, Wyeth-Guayama informs as follows:
 - a. There are no videos and/or photographs of the facility's WWTP and nearby areas on September 22-24, 2008. A photograph of the North aeration lagoon and nearby areas, dated September 27, 2008 (copy of which Wyeth-Guayama delivered to Complainant during the initial settlement conference held on June 17, 2009), is a still image from a video taken by the facility's closed circuit security camera (CCTV) system on that date by the facility's security personnel. Notwithstanding, the CCTV system does not customarily take images of the WWTP and its nearby earthen area, as it is used to monitor security at the facility's perimeters. In any event, the CCTV videos are only stored for approximately 30 to 45 days in the system's digital video recorder servers, after which time the system records over previous videos.

- b. Respondent has already provided Complainant with copies of the WWTP daily log book entries for August 20 - September 27, 2008 and for September 27 – October 31, 2008, which documents were voluntarily delivered by Wyeth-Guayama to Complainant on April 21, 2009, prior to issuance of the Complaint. (See, Attachment 3, items 7 and 8). In any event, since the claims of violation as set forth in the Complaint only comprise September 22, 23 and 24, 2008 (as acknowledged by Complainant's counsel in his July 21, 2009 letter), Wyeth-Guayama has already provided copies of the pertinent log book pages as Exhibit 10 of Respondent's Prehearing Exchange.
- c. The WWTP Process Control Log Sheets for September 15 through September 28, 2008, are not available, as they could not be located in the company's files. Nevertheless, and for illustrative purposes only, we attach a copy of the Process Control sheet for September 29, 2008 (Attachment 4). This illustrates that the requested sheets are intended to record internal operational data regarding the facility's active wastewater treatment system, and have no bearing upon the storm water discharge system which is the object of the Complaint. Hence, these Process Control Log Sheets are irrelevant, immaterial and of little probative value to the present proceeding.

- d. Information in connection with the sampling activities conducted during September 2008 is included at pages 211 and 213 of the WWTP daily log book (Respondent's Exhibit 10 of its Prehearing Exchange). Laboratory results and chain of custody records were submitted to the agency with the corresponding discharge monitoring report, and were included as Complainant's Exhibit 4h/Respondent's Exhibit 7 to the respective Prehearing Exchanges. These documents speak for themselves. As pointed out in Wyeth-Guayama's Motion to Dismiss, it is important to note that, in accordance with Part I, Special Condition 13(B) of its NPDES permit, Wyeth-Guayama is free to sample "any" storm water discharge during the second half of the month (i.e. beginning on the 16th day of each month). NPDES permit number PR0024724 (Respondent's Exhibit 3 of its Prehearing Exchange), at page 6 of 25.
4. With respect to the "additional items of evidence" requested in paragraph 4 of Complainant's Motion, and without waiving its objections in this matter, Wyeth-Guayama informs as follows:
 - a. An aerial photograph of the Wyeth-Guayama facility, showing the WWTP and nearby areas, taken on September 18, 2008, was included as Respondent's Exhibit 15 of its Prehearing Exchange.
 - b. A photograph of the WWTP and nearby areas, showing the "discharge" discovered by Wyeth-Guayama personnel on September 27, 2008 (which

“discharge” prompted the oral report to the National Response Center on that date and the subsequent October 3, 2008 written report), was delivered to Complainant during the initial settlement conference on June 17, 2009. For the convenience of the court, we include herewith copy of such photograph (Attachment 5). It must be noted that both Complainant and Respondent agree that there were no storm water discharges through Outfall 002 from September 25 through September 27, 2009, as evidenced by Complainant’s July 21, 2009 letter and by the pertinent flow recorder graph (Complainant’s Exhibit 4f/Respondent’s Exhibit 12 of their respective Prehearing Exchanges). Hence, Respondent’s request for additional discovery with respect to a date not included in the claims set forth in the Complaint (i.e., September 22, 23 and 24, 2008) must fail as it is irrelevant, immaterial and of little probative value to the present proceeding.

- c. The October 3, 2008 event notification report (Complainant’s Exhibit 4g/Respondent’s Exhibit 9 of the respective Prehearing Exchanges) speaks for itself.
- d. A copy of the requested Storm Water Pollution Prevention Plan was included as Respondent’s Exhibit 4 of its Prehearing Exchange.
- e. A request for “interviews” of Wyeth-Guayama employees is tantamount to a request for depositions. Granting such a request at this juncture, when the hearing is scheduled to commence in a little over one month, will most

certainly unreasonably delay the proceeding and unreasonably burden Wyeth-Guayama. See, 40 CFR § 22.19(e)(1)(i). Moreover, the three individuals identified in Complainant's Motion were not announced as witnesses in Complainant's Prehearing Exchange, and the relevance of the information to be presumably provided by them has not been established by the agency.

The EPA Consolidated Rules of Practice provide for "other discovery", that is, discovery other than that provided for in the prehearing exchange, only upon determination by the Presiding Officer: (i) That such discovery will not in any way unreasonably delay the proceeding or unduly burden the non-moving party; (ii) That the information to be obtained is not otherwise obtainable; and (iii) That such information has significant probative value. 40 CFR § 22.19(e)(1). See, *e.g.*, Order on Motions for Discovery, In re Mark Fastow and Fiberglass Specialties, Inc., Docket No. EPCRA-09-97-0013 (Susan L. Biro, Chief Administrative Law Judge), retrieved from <http://www.epa.gov/oalj/orders/fastow.htm>. As discussed above, Wyeth-Guayama respectfully submits that Complainant's Motion for Additional Discovery further evidences the fact that the agency's prehearing exchange does not support the allegations and claims set forth in the Complaint. Rather, Complainant now wishes to engage in a "fishing expedition" for evidence to support its allegations.

Moreover, **most of the information requested by Complainant has already been delivered by Respondent, either voluntarily or as Exhibits to its**

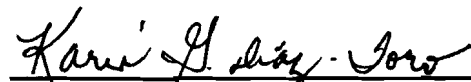
Prehearing Exchange. Hence, Complainant has not established that the information to be obtained “has not been provided voluntarily” by Respondent. Neither has Complainant established that taking depositions at this time, when the hearing is scheduled to commence in a little over one month, will not “unreasonably delay” this proceeding. In consequence, Complainant has not met the criteria set forth at 40 CFR § 22.19(e) to allow additional discovery.

WHEREFORE, Respondent respectfully requests that the Motion for Additional Discovery filed by Complainant be denied in its entirety; and that its Motion to Dismiss filed on October 23, 2009 be granted.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 29th day of October, 2009.

TORRES & GARCIA, P.S.C.
Attorneys for Wyeth Pharmaceuticals
Company, Inc.
PO Box 19539
San Juan, Puerto Rico 00910-1539
Tel. 787-721-8220
Fax 787-721-8223



Karín G. Díaz-Toro
E-mail: kdiaz@envirolawpr.com

**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 Opposition to Motion for Additional Discovery 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:

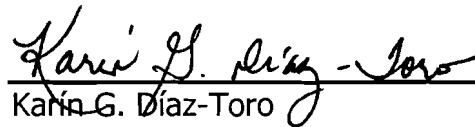
Judge William B. Moran
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Franklin Court Building
1099 14th Street N.W. Suite 350
Washington DC 20460

Copy via certified mail, return receipt requested –
7008 3230 0000 1298 6829:

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 29th day of October, 2009.

TORRES & GARCIA, P.S.C.
Attorneys for Wyeth Pharmaceuticals
Company, Inc.
PO Box 19539
San Juan, Puerto Rico 00910-1539
Tel. 787-721-8220
Fax 787-721-8223


Karin G. Diaz-Toro
E-mail: kdiaz@envirolawpr.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF REGIONAL COUNSEL
CENTRO EUROPA BUILDING, SUITE 207
1492 PONCE DE LEON AVENUE, STOP 22
SAN JUAN, PR 00907-4127

RECEIVED

JUL 27 2009

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

July 21, 2009

Ms. Karín Díaz-Toro, Esq.
Torres & García, P.S.C.
PO Box 19539
San Juan, PR 00910-1539

**Re: Notice Assessment of a Class II Civil Penalty
Wyeth Pharmaceuticals, Inc.
Gauyama, Puerto Rico
Docket Number CWA-02-2009-3460**

Dear Ms. Diaz:

This letter addresses the June 22, 2009 letter that you submitted on behalf of Wyeth Pharmaceuticals, Inc. (Respondent), referencing the informal settlement conference held on June 17, 2009 and communications held thereafter.

In response, EPA's Enforcement Team also believes that there are major discrepancies between the company records that were reviewed in preparing Respondent's Answer to the Complaint and those that should have been reviewed and provided to EPA in order to adequately address the allegations and claims set forth in the Complaint. Specifically, during the June 17 conference Respondent provided EPA with a photograph of the Wastewater Treatment Plant (WWTP) and nearby storm water retention lagoon, which was taken on September 27, 2008.

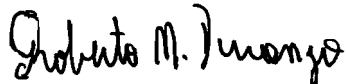
In the Complaint, however, EPA does not allege that there were unauthorized discharges on such date. Therefore, in order to clarify that major discrepancy in the records Respondent reviewed and submitted, EPA requests that Respondent provide the video and/or photographs, depicting the Facility's WWTP and nearby storm water retention lagoon between September 22 and September 24, 2009—the dates on which EPA claims that there were unauthorized discharges of pollutants.

In addition, EPA reiterates the request it made during the June 17 conference. That is, EPA requests, prior to reaching an expeditious settlement to this matter, that Respondent submit the following information:

1. The WWTP Process Control Log Sheet records from Monday, September 15 to Monday, September 29, 2008;
2. The WWTP Log Sheet records from Monday, September 15 to Monday, September 29, 2008; and
3. A detailed explanation and description of the sampling procedures undertaken by Respondent relating to the sampling activities performed in order to comply with the monitoring and reporting requirements contained in Respondent's NPDES permit for the month of September 2008. Please include a copy of the chain of custody records, all available written documentation, including electronic correspondence, and sworn statements from those individuals who conducted the monitoring activities.

Upon receiving such information, EPA's Enforcement Team will continue to engage in informal discovery, in a good-faith effort to reach a prompt, amicable resolution to this matter, pursuant to Agency policies.

Best regards,



Roberto M. 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

TORRES & GARCÍA, P.S.C.
ATTORNEYS AND COUNSELORS AT LAW
ENVIRONMENTAL, NATURAL RESOURCES, AND LAND USE

FRANCIS TORRES-FERNÁNDEZ
BRAULIO GARCÍA-JIMÉNEZ
KARÍN G. DÍAZ-TORO
RAÚL NEGRÓN-CASASNOVAS
EUGENE SCOTT-AMY

PO Box 19539
SAN JUAN, PUERTO RICO 00910-1539

705 FERNÁNDEZ JUNCOS AVENUE
SAN JUAN, PUERTO RICO 00907-4226
TELEPHONE 787-721-8220
TELECOPIER 787-721-8223
HTTP://WWW.ENVIROLAWPR.COM

Ref. 7040-003

**PRIVILEGED AND CONFIDENTIAL –
FOR SETTLEMENT PURPOSES ONLY**

June 22, 2009

BY MESSENGER

Mr. Roberto Durango, Esq.
Assistant Regional Counsel
Region II
United States Environmental Protection Agency
Caribbean Environmental Protection Division
Centro Europa Building – Suite 417
1492 Ave. Ponce de León
San Juan, Puerto Rico

Re: Notice of Assessment of Class II Penalty
Wyeth Pharmaceuticals, Inc.
Guayama, Puerto Rico
Docket No. CWA-02-2009-3460

Dear Mr. Durango:

We make reference to our meeting on June 17, 2009, and to our subsequent telephone conference on June 19, 2009, regarding settlement negotiations with respect to the above referenced Notice of Assessment of Class II Penalty against our client, Wyeth Pharmaceuticals, Inc. – Guayama Operations ("Wyeth-Guayama"). As discussed, in keeping with its corporate commitment to environmental compliance, Wyeth-Guayama is interested in achieving an expeditious settlement of the above referenced administrative action. Nevertheless, during our meeting on June 17, 2009 it became apparent that there are major discrepancies between the information found in the official company records, which were reviewed during the preparation of Wyeth-Guayama's Answer to the Complaint filed on June 10, 2009; and the information to which Mr. José A. Rivera, Civil and Environmental Engineer, referred during the meeting as constituting the foundation for the findings of violation, allegations and claims set forth in the aforementioned Complaint.

DEPT. ENV. PROT. AGENCIA
2009 JUN 22 PM 3:29
DEPT-DIRECTOR OFFICE

**PRIVILEGED AND CONFIDENTIAL –
FOR SETTLEMENT PURPOSES ONLY**

WYETH GUAYAMA – LETTER TO R. DURANGO

JUNE 22, 2009

PAGE 2 OF 2

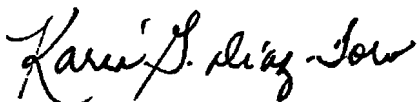
Hence, for Wyeth-Guayama to responsibly assess the findings of violation, allegations and claims set forth in the Complaint and responsibly and reasonably submit a settlement proposal, we must be able to review all information available to the agency with respect to such findings of violation and claims. Therefore, Wyeth-Guayama respectfully requests that the agency provide to us any and all information and/or documentation that provides 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 South inactive lagoon
4. Alleged discharges of industrial waste into storm water retention ponds
5. So-called "infiltration" problems
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.

Once Wyeth-Guayama has the opportunity to review the aforementioned information, it will be in a better position to submit a reasonable and responsible settlement proposal.

We look forward to continuing working with you towards achieving an expeditious resolution of this matter. Should you require further information, please contact the undersigned at your convenience at 787-721-8220 and/or by electronic mail at kdiaz@envirolawpr.com.

Cordially yours,



Karín G. Díaz-Toro

c: Edwin Gómez – Wyeth Guayama
Ronald Schott, Esq. – Wyeth

Wyeth

Call Box 10012
Guayama, PR 00785

EHS DEPARTMENT

TO: Sr. Jose Rivera/Environmental Protection Agency
FROM: Ruben Soto
DATE: April 21, 2009

This to certify that the following document is being received.

Article Number	Description	Amount (some double sites)
1	All day logs for "Wastewater Treatment Plant" Log Sheet & Effluent Calculation Job Aid" from: • Sep 29,2008, Oct 05-10,2008	7 pages
2	Recording Sheet for flow measurement at 002 from Oct 13, 2007 to Oct 19, 2007, Oct 27, 2007 to Nov 2, 2007	2 pages
3	Logbook pages from Oct 23, 2007 to Oct 31, 2007	16 pages
4	Daily Precipitation for Sep 2008 and Oct 2007 & Raw Data	4 pages
5	PRASA Discharge Permit	16 pages
6	2008 PRASA Discharge File	57 pages
7	Waste treatment "WWTP Daily Log Book" pages 161-218, Aug.20, 2008 – Sept 27, 2008	58 pages
8	Waste treatment "WWTP Daily Log Book" pages 43-98	56 pages

RECEIVED BY

DATE

WASTE WATER TREATMENT PLANT

1. Q-INFLUENT SECONDARY CLARIFIER Q-QWAS
2. AERATION TANK
3. EFFLUENT

PROCESS CONTROL LOG SHEET

DATE: 29 Sep, 08

SAMPLE LOCATION	1	2	3	FREQUENCY	TYPE
FLOW				CR	-
BOD				W	C
COD	201	914	22	D/W	G/C
SUSPENDE SOLIDS TOTAL				D/W	G/C
SUSPENDE SOLIDS VOLATILE				W	C
NITROGEN - KJELDAHL				W	G
AMMONIA				W	C
NITRITE				W	G
NITRATE			.8	W	G
PHOSPHORUS				W	G
30 MIN. SETTLING		100		D/W	G/C
D.O.		1.6	1.2	D	G
PH	7.84	7.52	7.41	D	G
TEMPERATURE	27.6	27.3	27.9	D	G
SLUDGE BLANKET	11.7		7.3	3/D	
MICROSCOPIC EXAMINATION				W	G

FORM/PROCESS.DOC

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