

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2**

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In the Matter of :
 :
Baxter Healthcare SA, :
 :
Respondent. :
 :
Proceeding Under Section 3008 of the :
Solid Waste Disposal Act, as amended. :
-----X

**CONSENT AGREEMENT AND
FINAL ORDER**

Docket No. RCRA-02-2012-710

**U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG.11
2012 SEP 28 A 7 25
REGIONAL HEARING
CLERK**

PRELIMINARY STATEMENT

This administrative proceeding was instituted pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by various statutes including the Resource Conservation and Recovery Act of 1976 and the Hazardous and Solid Waste Amendments of 1984 ("HSWA"), 42 U.S.C. § 6908 (collectively these statutes referred to as "RCRA" or the "Act").

Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the Administrator to enforce violations of the Act and the regulations promulgated pursuant to it. Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance ("Complainant") of the U.S. Environmental Protection Agency, Region 2 ("EPA") has been duly delegated the authority to institute this action.

Pursuant to Section 22.13 of the Consolidated Rules of Practice, 40 Code of Federal Regulations ("C.F.R.") § 22.13(b), where parties agree to settlement of one or more causes of action before the filing of a Complaint, a proceeding may simultaneously be commenced and concluded by the issuance of a Consent Agreement and Final Order ("CA/FO") pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3).

It has been agreed by the parties that settling this matter by entering into this CA/FO pursuant to 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) is an appropriate means of resolving specified claims against Respondent without further litigation. To that end, the parties met on September 6, 2012. This CA/FO is being issued pursuant to said provisions of 40 C.F.R. Part 22. No formal findings of fact or conclusions of law, in either an administrative or judicial forum, have been adjudicated. The following constitute EPA's Findings of Fact and accompanying Conclusions of Law based on information of which Complainant was aware as of September 1, 2012.

EPA FINDINGS OF FACT

1. Respondent is Baxter Healthcare SA, a corporation formed under the laws of Switzerland, and it has been authorized to do business in Puerto Rico since at least March 2006.

2. Respondent is and has been since April 2006 the owner and operator of a pharmaceutical manufacturing business located at PR-3 km 142.5 in Guayama, Puerto Rico (hereinafter the "Baxter facility").

3. Respondent does business in Puerto Rico as Baxter Healthcare of Puerto Rico.

4. On or about August 18, 1983, Respondent's predecessor-in-interest, Anaquest, Inc., requested from EPA an identification number for activities generating "hazardous waste" (as that term has been defined in Section 1004(5) of the Act, 42 U.S.C. § 6903(27), and 40 C.F.R. §261.3) at the Baxter facility.

5. In response to the aforementioned request, EPA, on or about September 19, 1983, provided Anaquest, Inc., with EPA Identification Number PRD000692525.

6. Subsequent to its issuance of the EPA Identification Number, EPA transferred said number to Respondent's name.

7. At the Baxter facility, Respondent has manufactured (and continues to manufacture) pharmaceuticals used in medical practices and in surgery, and in the course of such pharmaceutical manufacturing operations, Respondent has generated (and continues to generate) organic hazardous waste, including the following (as each is defined in 40 C.F.R. Part 261, Subparts C and D): **a**) characteristic wastes ("D wastes"); **b**) wastes from non-specific sources ("F wastes"); and **c**) acute hazardous waste ("P wastes"); and **d**) discarded commercial chemical products, which include manufacturing chemical intermediates ("U wastes").

8. The aforementioned (¶ 7, above) hazardous waste that Respondent has generated (and continues to generate) consists primarily of spent solvent, and said waste has been (and continues to be) stored in two hazardous waste storage tanks.

9. The aforementioned (¶ 8, above) organic hazardous waste stored in said tanks has a Volatile Organic Concentration above 500 parts per million (by weight), and said organic hazardous waste, as transported in the equipment attached to the storage tank system, has an organic concentration of more than 10% by weight.

10. As of (at least) April 2009, there existed at the Baxter facility, *inter alia*, 49 valves that were used to transport hazardous waste with more than 10% organics.

11. The aforementioned (¶ 10, above) 49 valves were “in light liquid service” (as defined in 40 C.F.R. § 264.1031 and cross-referenced in 40 C.F.R. § 265.1081).¹

12. Since at least April 2009, Respondent has generated at the Baxter facility at least 1,000 kilograms of hazardous waste in each calendar month.

13. Respondent has stored since at least April 2009 (and continues to store) hazardous waste at the Baxter facility.

14. Respondent has never submitted to EPA an application to obtain a RCRA permit for the treatment, storage or disposal of hazardous waste at the Baxter facility, nor has Respondent ever obtained for said facility “interim status” (within the meaning of that term as used in 40 C.F.R. Part 270).

15. On each of the following dates, duly designated representatives of EPA conducted an inspection of the Baxter facility for the purpose of determining Respondent’s compliance with the requirements of RCRA and its implementing regulations in its operation of said facility: **a)** March 31, 2010, and **b)** April 19, 2012.

16. On each of the following dates, EPA issued to Respondent a Request for Information Letter (“IRL”) pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927: **a)** September 12, 2011; and **b)** May 18, 2012 (together with a Notice of Violation).

17. Respondent submitted its response to the September 2011 IRL on or about November 22, 2011, and Respondent submitted its response to the May 2012 IRL on or about July 24, 2012.

18. Between at least April 2009 and May 2012, Respondent failed to conduct monthly monitoring of the aforementioned (¶ 10, above) 49 valves in accordance with Reference Method 21 of 40 C.F.R. Part 60, as required by 40 C.F.R. § 265.1063(b)(1).

19. For each of calendar years 2009 and 2011, Respondent failed to conduct annual inspections of the fixed roof and the closure devices of the aforementioned (¶ 8, above) two hazardous waste storage tanks.

20. As of the date of the April 19, 2012 inspection, Respondent had failed to document in its operating record a determination of the maximum organic vapor pressure for the organic hazardous waste stored in the aforementioned (¶ 8, above) two hazardous waste storage tanks.

¹ While not defining the words “in light liquid service,” 40 C.F.R. § 265.1081 cross-references other sections of the RCRA regulations: “As used in this subpart, all terms not defined herein shall have the meaning given them in the Act and parts 260 through 266 of this chapter.” Forty C.F.R. § 264.1031 expressly defines “[i]n light liquid service.”

EPA CONCLUSIONS OF LAW

1. Respondent is a "person" as that term is defined in Section 1004(15) of the Act, 42 U.S.C. § 6903(15), and 40 C.F.R. § 260.10.
2. The Baxter facility is a "facility" as that term is defined in 40 C.F.R. § 260.10.
3. Respondent has been and remains the "owner" and "operator," as those terms are defined in 40 C.F.R. § 260.10, of the Baxter facility.
4. Respondent has been and remains a "generator," as that term is defined in 40 C.F.R. § 260.10, of hazardous waste at the Baxter facility.
5. Each of the aforementioned (¶ 15 of the "EPA Findings of Fact" section, above) inspections was conducted to evaluate Respondent's compliance with the applicable regulatory requirements for organic air emissions found at 40 C.F.R. Part 265, Subparts BB and CC.
6. For a period of time that includes the time period between April 2009 and June 2012, Respondent, at the Baxter facility, has been (and continues to be) a "large quantity generator" of hazardous waste.
7. Pursuant to 40 C.F.R. §265.1057(a), Respondent was required to perform monthly emissions monitoring of valves in light liquid service by methods specified in 40 C.F.R. § 265.1063(b), and pursuant to 40 C.F.R. § 265.1063(b)(1), such monitoring was to comply with Reference Method 21.
8. Since at least April 2009, Respondent was required to conduct monthly monitoring of each valve in light liquid service at the Baxter facility using Reference Method 21, *i.e.* the aforementioned (¶ 10 of the "EPA Findings of Fact" section, above) valves were subject to the requirements set forth in 40 C.F.R. Part 265, Subpart BB.
9. Respondent's failure between April 2009 and May 2012 to conduct monthly monitoring of the 49 valves in accordance with Reference Method 21 of 40 C.F.R. Part 60, as required by 40 C.F.R. § 265.1063(b)(1), as set forth in paragraph 18 of the "EPA Findings of Fact" section, above, constitutes a violation of 40 C.F.R. § 265.1057(a).
10. Pursuant to 40 C.F.R. § 262.34(a)(1)(ii), to be exempt from the permitting requirements, a generator of hazardous waste must, *inter alia*, manage all hazardous waste placed in tanks in accordance with the applicable requirements of 40 C.F.R. §§ 265.1030 - 265.1090.
11. Pursuant to 40 C.F.R. § 265.1085(c)(4)(ii), the owner/operator of a tank in which hazardous waste is stored is required to perform an annual inspection of the fixed roof and the

closure device to check for defects that could result in air pollutant emissions.

12. Respondent's failure in calendar years 2009 and 2011 to conduct an annual inspection of the fixed roof and its closure devices for each of the two hazardous waste storage tanks, as set forth in paragraph 19 of the "EPA Findings of Fact" section, above, constitutes a violation of 40 C.F.R. § 265.1085(c)(4)(ii).

13. Pursuant to 40 C.F.R. § 265.1090 (b)(2), Respondent was required, as a consequence of it having stored hazardous waste with volatile organic-concentration of over 500 parts per million in a level one tank, to record the determination of the maximum organic vapor pressure in its operating record.

14. Each of the aforementioned (¶ 8 of the "EPA Findings of Fact" section, above) storage tanks constituted a level one tank.

15. Respondent's failure as of the date of the April 2012 inspection to document a determination of the maximum organic vapor pressure, as set forth in paragraph 20 of the "EPA Findings of Fact" section, above, constitutes a violation of 40 C.F.R. § 265.1090(b)(2).

16. Each of the following provisions constitutes a requirement of Subchapter III of RCRA, 42 U.S.C. §§ 6921 - 6939e:

- a) 40 C.F.R. § 265.1057(a);
- b) 40 C.F.R. § 265.1085(c)(4)(ii); and
- c) 40 C.F.R. § 265.1090(b)(2).

17. For a violation of each of the aforementioned (¶ 16 of this section, above) provisions, Respondent is liable pursuant to Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3).

CONSENT AGREEMENT

Based upon the foregoing, and pursuant to Section 3008 of RCRA and the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits" (40 C.F.R. Part 22), it is hereby agreed by and between Complainant and Respondent, as follows:

1. For the purpose of this proceeding and in the interest of an expeditious resolution of this matter, pursuant to 40 C.F.R. § 22.18(b)(2), Respondent: **a)** admits the EPA has jurisdiction pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, to commence a civil administrative proceeding for the violations alleged in the "EPA Conclusions of Law" section, above; **b)** neither admits nor denies the EPA Findings of Fact and EPA Conclusions of Law set forth in this Consent Agreement; **c)** consents to the assessment of the civil penalty as set forth below; **d)**

consents to the issuance of the Final Order accompanying this Consent Agreement; and e) waives its right to contest or seek judicial review of the attached Final Order in any forum.

2. Pursuant to 40 C.F.R. § 22.31(b), the effective date of this CA/FO shall be the date when such document is filed with the Regional Hearing Clerk of the United States Environmental Protection Agency, Region 2.

3. Commencing on the effective date of this CA/FO, Respondent shall maintain compliance with applicable provisions of 40 C.F.R. § 262.34 and 40 C.F.R. Part 265, including that Respondent shall maintain compliance, as follows: a) continue to conduct required monitoring and inspections of any valves in light liquid hazardous waste service that are subject to the organic air emission requirements of 40 C.F.R. Part 265, Subpart BB; b) conduct annual inspections and meet other prescribed operating requirements in accordance with the provisions of 40 C.F.R. Part 265, Subpart CC; and c) document determination of the maximum organic vapor pressure of tanks in which hazardous waste is stored in accordance with the applicable requirements of 40 C.F.R. Part 265, Subpart CC. The actions required by this paragraph include Respondent, in its operations of the Baxter facility, complying with the requirements of each of the following applicable regulatory provisions (and maintaining such compliance as long as the requirements remain applicable):

- a) 40 C.F.R. § 265.1057(a);
- b) 40 C.F.R. § 265.1085(c)(4)(ii); and
- c) 40 C.F.R. § 265.1090(b)(2).

4. Respondent hereby certifies that, as of the time of its signature to this Consent Agreement, to the best of its knowledge and belief, it is in compliance with all applicable requirements of 40 C.F.R. Part 265, Subparts BB and CC.

5. This Consent Agreement is neither intended nor to be construed to waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of federal, Commonwealth, or local law governing the generation, handling, treatment, storage, transport and disposal of hazardous waste at or from the Baxter facility, and to maintain such compliance.

6. Respondent shall pay, by cashier's or certified check, a civil penalty in the total amount of **FIFTY THOUSAND (\$50,000.00) DOLLARS**. Payment shall be made payable to the "Treasurer of the United States of America" and shall be mailed to EPA, Region 2 (Regional Hearing Clerk), P.O. Box 360188M, Pittsburgh, Pennsylvania 15251. The check shall be identified with a notation of the name and docket number of this case as follows: *In re Baxter Healthcare SA*, Docket. No. RCRA-02-2012-7107.

The instrument of payment shall be mailed to the following address:

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

Alternatively, if Respondent chooses to make each installment payment by EFT, Respondent shall then provide the following information to its remitter bank for each of the two payments:

- a. Amount of Payment
- b. SWIFT address: **FRNYUS33, 33 Liberty Street, New York, New York 10045**
- c. Account Code for Federal Reserve Bank of New York receiving payment: **68010727**
- d. Federal Reserve Bank of New York ABA routing number: **021030004**
- e. Field Tag 4200 of the Fedwire message should read: **D 68010727 Environmental Protection Agency**
- f. Name of Respondent: **Baxter Healthcare SA**
- g. Case docket number: **RCRA-02-2012-7107**

Payment shall be received (if made by check) or effected (if implemented by EFT) on or before forty-five (45) calendar days after the effective date of this CA/FO. Respondent shall also send a copy of the check (or evidence of payment by EFT) to both:

Lee A. Spielmann
Assistant Regional Counsel,
United States Environmental Protection Agency
290 Broadway, 16th Floor
New York, New York, 10007-1866

and

Karen Maples,
Region 2 Regional Hearing Clerk,
United States Environmental Protection Agency
290 Broadway, 16th Floor
New York, New York, 10007-1866

- a. Failure to pay the penalty in full according to the above provisions may result in the referral of this matter to the United States Department of Justice or

Department of the Treasury for collection or other appropriate action.

b. Further, if timely payment is not received, interest will be assessed, at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of \$15.00 will be assessed for each thirty (30) day period following the due date in which the balance remains unpaid.

c. A 6% per annum penalty also will be applied on any principal amount not paid within 90 days of the due date.

d. Complainant shall endeavor to provide Respondent with timely notice of the filing of this CA/FO with the Regional Hearing Clerk of the EPA, Region 2.

7. The civil penalty Respondent shall pay, as set forth in this section, constitutes a penalty within the meaning of 26 U.S.C. § 162(f).

8. This Consent Agreement is being voluntarily and knowingly entered into by the parties in full and final settlement of the civil liability that might have attached under Section 3008 of RCRA, 42 U.S.C. § 6928, as a result of the violations set forth in Paragraphs 9, 12 and 15 of the "EPA Conclusions of Law" section, above.

9. Respondent's payment of the penalty in accordance with the requirements set forth in this document and any action taken in compliance with or otherwise in connection with this Consent Agreement shall not affect the right of the EPA or the United States to pursue appropriate injunctive or otherwise seek equitable relief or criminal sanctions for any violation(s) of law resulting from or pertaining to Respondent's management of hazardous waste at the Baxter facility.

10. Respondent has read the Consent Agreement, understands its terms, voluntarily consents to its issuance and its terms and conditions, including payment of the full amount of the civil penalty in accordance with the terms set forth above. Respondent also consents to the issuance of the accompanying Final Order.

11. Respondent waives its right to request and/or obtain a hearing on this Consent Agreement, or the accompanying Final Order, including any right to contest any of the EPA Findings of Fact and EPA Conclusions of Law set forth in said Consent Agreement and any right to contest any of the terms or conditions set forth in said Consent Agreement.

12. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with and to reply to any memorandum or communication addressed to the Regional Administrator, the Deputy Regional Administrator or the Regional Judicial Officer where the purpose of such discussion, memorandum, or communication is to

discuss a proposed settlement of this matter or to recommend that such official accept this Consent Agreement and issue the attached Final Order.

13. Respondent consents to service of a copy of the executed Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.

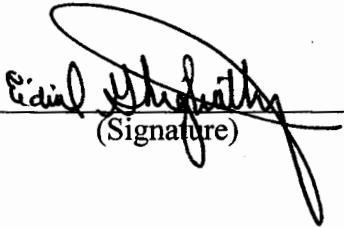
14. This Consent Agreement and any provision herein shall not be construed as an admission of liability in any adjudicatory or administrative proceeding, except in an action, suit or proceeding to enforce this CA/FO or any of its terms and conditions.

15. The signatory for the Respondent certifies that: a) he or she is duly and fully authorized to enter into and ratify this Consent Agreement and all the terms, conditions and requirements set forth in this Consent Agreement, and b) he or she is duly and fully authorized to bind the party on behalf of which he or she is entering this Consent Agreement to comply with and abide by all the terms, conditions and requirements of this Consent Agreement.

16. Each party hereto shall bear its own costs and fees in this matter.

RESPONDENT:

Baxter Healthcare SA

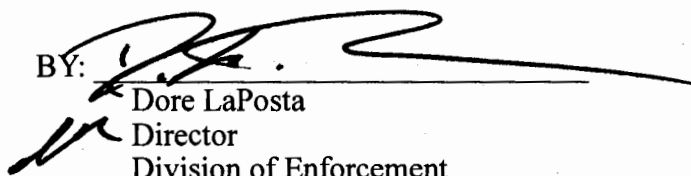
BY: 
(Signature)

NAME: EIDIOL GHIGLIOTTI
(PLEASE PRINT)

TITLE: GENERAL MANAGER

DATE: 18-Sep-2012

**COMPLAINANT: United States Environmental Protection Agency
Region 2**

BY: 
Dore LaPosta
Director
Division of Enforcement
and Compliance Assistance
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 21st floor
New York, New York 10007

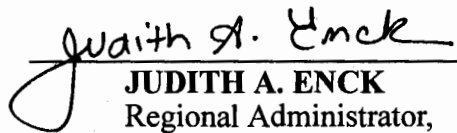
DATE: 9/21/12

In re Baxter Healthcare SA
Docket Number RCRA-02-2012-7107

FINAL ORDER

The Regional Administrator of EPA, Region 2 concurs in the foregoing Consent Agreement in the case of *In the Matter of Baxter Healthcare SA*, bearing Docket Number RCRA-02-2012-7107. Said Consent Agreement, having been duly accepted and entered into by the parties, shall be, and hereby is, ratified and incorporated into this Final Order, which is hereby issued and shall take effect when filed with the Regional Hearing Clerk of EPA, Region 2. 40 C.F.R. § 22.31(b). This Final Order is being entered pursuant to the authority of 40 C.F.R. § 22.18(b) (3) and shall constitute an order issued under authority of Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

DATED: September 25, 2012
New York, New York



JUDITH A. ENCK
Regional Administrator,
United States Environmental Protection
Agency, Region 2

In re Baxter Healthcare SA
Docket No. RCRA-02-2012-7107

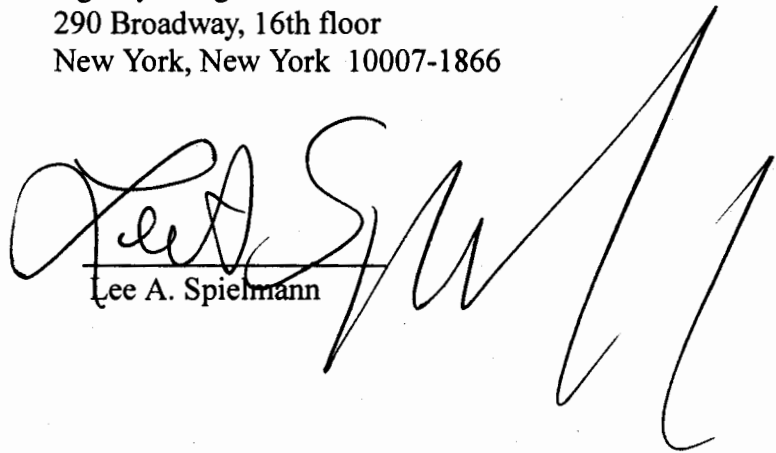
CERTIFICATE OF SERVICE

I hereby certify that I have this day caused to be sent the foregoing "CONSENT AGREEMENT AND FINAL ORDER," said Final Order having been executed by the Regional Administrator of the United States Environmental Protection Agency, Region 2, on September 25, 2012, in the above-referenced proceeding in the following manner to the addressee listed below:

Original and One Copy
By Inter-Office Mail:

Office of Regional Hearing Clerk
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

Dated: September 27, 2012
New York, New York



Lee A. Spielmann