

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
Philadelphia, Pennsylvania 19103**

IN THE MATTER OF:)	DOCKET NO.: RCRA-03-2022-0049
)	
KVK Tech, Inc.)	
)	
Respondent,)	EXPEDITED SETTLEMENT AGREEMENT AND FINAL ORDER
)	
)	
KVK Tech, Inc.)	Proceeding under Section
110 Terry Drive)	3008(a) and (g) of the Resource
Newtown, PA 18940,)	Conservation and Recovery Act, as
)	amended, 42 U.S.C. § 6928(a) and (g)
Facility)	
)	
)	
)	

EXPEDITED SETTLEMENT AGREEMENT

1. KVK Tech, Inc. (“Respondent”), and the Director, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region III (“Complainant”) enter into this Expedited Settlement Agreement (“Agreement”) pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act (“RCRA”), as amended, 42 U.S.C § 6928(a) and (g), and the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (“Consolidated Rules of Practice”), 40 C.F.R. Part 22 (with specific reference to 40 C.F.R. §§ 22.13(b), 22.18(b)(2), and (3)). The Administrator has delegated the authority to enter into this Agreement to the Regional Administrator who, in turn, has delegated it to the Complainant.
2. The U.S. Environmental Protection Agency, Region III (“EPA”) has jurisdiction over this matter pursuant to Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), and 40 C.F.R. §§ 22.1(a)(4) and 22.4 of the Consolidated Rules of Practice.
3. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), EPA has authorized the Commonwealth of Pennsylvania to administer a hazardous waste management program in lieu of the federal hazardous waste management program established under RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g. The provisions of the current authorized (revised) Commonwealth of Pennsylvania Hazardous Waste Management Regulations, codified at 25 Pa. Code Chapters 260a-266a, 266b, and 268a-270a (“PAHMWR”), have thereby become requirements of RCRA Subtitle C and are enforceable by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).
4. On December 8, 2021, EPA sent a letter to Pennsylvania, through the Pennsylvania Department of Environmental Protection (“PADEP”), giving prior notice of this enforcement action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. §

6928(a)(2).

5. At its facility, located at 110 Terry Drive in Newtown, Pennsylvania (“Facility”), Respondent manufactures and develops FDA-approved generic pharmaceuticals. On November 01, 2004, Respondent submitted a notification to PADEP that the Facility was a small quantity generator (“SQG”) of hazardous waste at the Facility, and PADEP assigned RCRA ID No. PAR000512343 to the Facility. Respondent does not have a RCRA permit or interim status for the treatment, storage or disposal of hazardous waste at the Facility.
6. Complainant alleges that, at all times relevant to the allegations described in this Agreement, Respondent was and continues to be a corporation organized under the laws of the Commonwealth of Pennsylvania and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and 25 Pa. Code § 260a.10, and at all times relevant to the allegations in this Agreement was the “operator” and the “owner” of a “facility,” described in Paragraph 5, as the terms “facility”, “owner” and “operator” are defined in 25 Pa. Code § 260a.10.
7. At all times relevant to the allegations described in this Agreement, Respondent was a “generator” of, and has engaged in the “storage” in “containers” at the Facility of materials described below that are “solid wastes” and “hazardous wastes”, as those terms are defined in 40 C.F.R. § 260.10, as incorporated by reference by 25 Pa. Code § 260a.1, with the exception of the term “storage”, which is defined in 25 Pa. Code § 260a.10.
8. On March 25, 2021, EPA sent an information request letter to the Respondent pursuant to RCRA, requesting information about the Facility regarding its compliance with the applicable hazardous waste regulations. On May 27, 2021, Respondent provided a response to EPA’s information request.
9. Based on information obtained during EPA’s records review of the Facility, Respondent identified the Facility as a RCRA “Small Quantity Generator”. However, according to e-Manifest data and the Uniform Hazardous Waste Manifests submitted by Respondent to EPA for review, the Facility generated hazardous waste in quantities greater than 1,000 kilograms per calendar month, which indicates that it is a “Large Quantity Generator,” as established under the authorized regulations.
10. Based on the review of information gathered from the Facility’s response to the EPA request for information letter, dated March 25, 2021, Complainant alleges and finds that Respondent failed to comply with specific requirements of Subtitle C of RCRA, 42 U.S.C. §§ 6921 et seq., its implementing regulations at 40 C.F.R. Parts 262, 264, 265, and the federally-authorized Commonwealth of Pennsylvania hazardous waste management regulations set forth in the 25 Pa. Code Ch. 260a-266a, 266b, 268a and 270a et seq.
11. Complainant has identified the following violations at the Facility:
 - a. Respondent failed to submit a 2019 biennial report to EPA by March 1, 2020. The certified mail receipt document provided by the Facility for the 2019 biennial report was dated May 12, 2021, showing that the report was submitted after March 1, 2020, in

- violation of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.41(a).
- b. Respondent failed to maintain job titles for the Environmental Health and Safety Manager, the Lab Technician, and the Group Leader. The written job descriptions of the jobs positions at the Facility provided by Respondent on May 27, 2021 failed to describe any duties related to hazardous waste management, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.16(d)(2).
 - c. Respondent failed to have a contingency plan designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water. On May 27, 2021, the Respondent submitted for review a contingency plan, dated June 2021. Facility personnel stated this is the completion date of the plan. According to Facility personnel, there was no contingency plan at the Facility previous to this date. Therefore, from June 2019 through May 27, 2021, Respondent failed to have a contingency plan, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.51(a).
 - d. Respondent failed to notify the State of a change in generator status in 2019. Based on information obtained during EPA’s records review of e-Manifest data, in 2019, the Facility generated hazardous waste in quantities greater than 1,000 kilograms per calendar month, which indicates the Facility was a “Large Quantity Generator” as established under the authorized regulations. The “United States Environmental Protection Agency RCRA Subtitle C Site Identification Form” provided to by the Respondent was signed by a Facility representative on May 12, 2021. The certified mail receipt provided by the Facility as proof the form was submitted was dated May 12, 2021. Respondent failed to notify the state of a change in generator status, in violation of 25 Pa. Code § 262a.18(1)(v).
12. Complainant and Respondent agree that settlement of this matter for a total penalty of **SIX THOUSAND TWO HUNDRED AND FIFTY DOLLARS (\$6,250)** is in the public interest. In calculating this amount, Complainant considered the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and with specific reference to EPA’s October 1990 RCRA Civil Penalty Policy, as revised in June 2003 (“RCRA Penalty Policy”), and the 2021 RCRA Expedited Settlement Agreement Pilot.
13. Respondent agrees that, within 30 days of the effective date of this Agreement, Respondent shall make a payment of six thousand two hundred and fifty dollars (\$6,250) by one of four methods: 1) electronic funds transfer (“EFT”), 2) Automated Clearinghouse, 3) Pay.gov, or 4) a cashier’s check or certified check made out to “**United States Treasury**” with the case name, address and docket number of this Agreement (RCRA-03-2022-0049), for the amount specified above:
- a. Payment of the penalty amount by EFT:

Federal Reserve Bank of New York

ABA 021030004
Account 68010727
SWIFT address FRNYUS33
33 Liberty Street
New York, NY 10045
Beneficiary: Environmental Protection Agency

b. Payment of the penalty amount by Automated Clearinghouse (“ACH”):

U.S. Treasury REX/Cashlink ACH Receiver

ABA: 051036706
Account Number: 310006, Environmental Protection Agency

CTX Format Transaction Code 22- Checking

Physical Location of the U.S. Treasury Facility
5700 Rivertech Court
Riverdale, MD 20737

Remittance Express (REX): 1-866-234-5681

c. Payments made through Pay.gov:

Payers can use their credit or debit cards (Visa, MasterCard, American Express & Discover) as well as checking account information to make payments. Follow these steps to make a payment:

- (1) You **DO NOT** need a username and password or account.
- (2) Enter **SFO 1.1** in the form search box on the top left side of the screen.
- (3) Open the form and follow the on-screen instructions.
- (4) Select your method of payment from the “Type of Payment” drop down menu.
- (5) Based on your selection, the corresponding line will open and no longer be shaded grey.
- (6) Enter the docket number of this Agreement into the field.

d. Payment of the penalty amount by regular U.S. Postal Service shall be sent via **certified mail** to:

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

e. Payment of the penalty amount by overnight mail (FedEx or other non-U.S. Postal Service express mail) shall be sent to:

U.S. Environmental Protection Agency
Government Lock Box - Cincinnati Finance Center Box 979077
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63101

- f. A list of the payment methods is also provided at this website
<https://www.epa.gov/financial/makepayment>.
14. Within 24 hours of payment, Respondent shall also send proof of payment (a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer), by electronic mail to:

Stephen Forostiak, Environmental Scientist (3ED22)
U.S. EPA, Region III
forostiak.stephen@epa.gov

and

Regional Hearing Clerk (3RC00)
U.S. EPA, Region III
R3_Hearing_Clerk@epa.gov

15. In signing this Agreement, Respondent: admits the jurisdictional allegations in this Agreement; neither admits nor denies the specific factual allegations in this Agreement, except as provided in the jurisdictional admission above; agrees not to contest EPA's jurisdiction with respect to the execution of this Agreement, the issuance of the attached Final Order, or the enforcement the Agreement; expressly waives its right to a hearing on any issue of law or fact in this Agreement and any right to appeal the accompanying Final Order; consents to the issuance of the Agreement and agrees to comply with its terms; agrees to bear its own costs and attorney's fees; and agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.
16. By its signature below, Respondent certifies, subject to civil and criminal penalties for making a false submission to the United States Government, that (1) the alleged violations have been corrected, and (2) any documentation or information provided to EPA was true and accurate.
17. This Agreement and the attached Final Order constitute a settlement by EPA of its claims for civil penalties for the violations alleged in this Agreement.
18. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Sections 22.18(c) and 22.31(a) of the Consolidated Rules of Practice. Further, EPA reserves any rights and remedies available to it under the RCRA, the RCRA

regulations promulgated, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this Agreement, following its filing with the Regional Hearing Clerk.

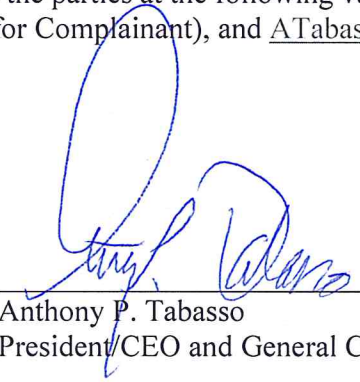
19. Late payment of the agreed upon penalty may subject Respondent to interest, administrative costs and late payment penalties in accordance with 40 C.F.R. § 13.11.
20. This Agreement is effective upon filing, in accordance with 40 C.F.R. § 22.31(b).
21. The undersigned representative certifies that she/he is fully authorized to execute this Agreement and to legally bind KVK Tech, Inc.
22. As permitted under 40 CFR § 22.6, the Regional Hearing Clerk will serve copies of this Agreement and Final Order by e-mail to the parties at the following valid e-mail addresses: forostiak.stephen@epa.gov (for Complainant), and ATabasso@kvktech.com (for Respondent).

For Respondent: KVK Tech, Inc.

Date:

03/03/22

By:



Anthony P. Tabasso
President/CEO and General Counsel

For Complainant: U.S. Environmental Protection Agency, Region III

After reviewing the Agreement and other pertinent matters, I, the undersigned Director of the Enforcement and Compliance Assurance Division of the United States Environmental Protection Agency, Region III, agree to the terms and conditions of this Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

Date: _____

By: _____

Karen Melvin, Director
Enforcement & Compliance Assurance Division

provisions of Subtitle C of the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6921 et seq., and the regulations promulgated thereunder.

The effective date of the foregoing Expedited Settlement Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

Date: _____

By: _____

Joseph J. Lisa
Regional Judicial and Presiding Officer
U.S. EPA Region III

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029**

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KVK Tech, Inc.)	EXPEDITED SETTLEMENT
110 Terry Drive)	AGREEMENT AND FINAL ORDER
Newtown, PA 18940,)	
)	
Facility)	

CERTIFICATE OF SERVICE

I certify that on _____, the original and one (1) copy of the foregoing Consent Agreement and Final Order, were filed with the EPA, Region III, Regional Hearing Clerk. I further certify that on the date set forth below, I served a true and correct copy of the foregoing to each of the following persons, in the manner specified below, at the following addresses:

Copy served via Electronic Delivery to:

Anthony P. Tabasso
President/CEO and General Counsel
KVK Tech, Inc.
110 Terry Drive
Newtown, PA 18940
ATabasso@kvktech.com

Copy served via Electronic Delivery to:

Stephen Forostiak
Compliance Officer
U.S. EPA Region III
forostiak.stephen@epa.gov

Dated: _____

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region III

TRACKING NUMBER(S): _____