IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 24-CR-00069**
KVK RESEARCH	:	

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(B), the government, the defendant KVK Research, Inc. ("RESEARCH"), and defendant RESEARCH's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Consumer Protection Branch of the Department of Justice.

1. Defendant RESEARCH agrees to plead guilty to Counts One and Two of an information charging it with two counts of introducing adulterated drugs into interstate commerce, a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1), and not to contest forfeiture as set forth in the notice of forfeiture seeking forfeiture of $1,000,000 in substitute assets, in lieu of the drugs which were deemed adulterated and are no longer available, all arising from defendant RESEARCH's delivery for introduction into interstate commerce of: (1) hydroxyzine hydrochloride ("hydroxyzine") tablets manufactured with Active Pharmaceutical Ingredient ("API") manufactured in Morales, Mexico; and (2) Sodium Polystyrene Sulfonate 15 mg tablets manufactured by codefendant KVK-Tech, Inc. ("KVK") in or about 2019 with insufficient controls exercised over computer and related systems, both of which

were adulterated as a matter of federal law in the United States. Defendant RESEARCH further acknowledges its waiver of rights, as set forth in Attachment A to this agreement.

2. This agreement is conditioned upon the following: (a) codefendant KVK entering a Deferred Prosecution Agreement ("DPA") attached as Attachment C, for Counts One and Two of the information, and (b) acceptance of that DPA and factual statement by a United States District Judge. If codefendant KVK does not satisfy these two conditions, or subsequently seeks to withdraw from the DPA, the government, in its sole discretion, will be released from all its obligations under this guilty plea agreement. At the time of sentencing for defendant RESEARCH, the government will:

a. Move to dismiss Counts One and Two of the Superseding Indictment in Criminal No. 21-132. The defendant waives the statute of limitations as to all counts to be dismissed under this agreement and agrees that if codefendant KVK withdraws from, or successfully challenges, the DPA and/or Statement of Facts entered under this agreement, or if these counts are otherwise reinstated under the terms of this agreement, neither the statute of limitations nor the Double Jeopardy Clause will bar prosecution on any of the dismissed counts.

b. Recommend a sentence consistent with paragraph 3 below.

3. The parties agree that this plea agreement is made pursuant to Federal Rule of Criminal Procedure 11(c)(1)(B) and that the following specific sentence is the joint recommendation of the parties, although not binding on the Court, and is an appropriate disposition of this case. This agreed joint recommendation sentence is as follows:

a. Defendant RESEARCH agrees to pay the special assessment in the amount of $250 on the date of sentencing.

b.e Defendant RESEARCH agrees that as a result of its acts or omissions, thee property that is subject to forfeiture, that is the drugs deemed adulterated, are no longer available for forfeiture as the drugs cannot be located or have been transferred, sold to, or deposited with, a third party, or otherwise disposed of, within the meaning of federal law, and that the government is entitled to the forfeiture of substitute assets pursuant to 21 U.S.C. § 853(p). As a result, defendant RESEARCH agrees to forfeit $1,000,000 as a substitute asset, to the entry of a forfeiture money judgment in the amount of $1,000,000, and to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of $1,000,000 as substitute assets for the pertinent drugs. Defendant RESEARCH agrees that, on the day of sentencing, defendant RESEARCH will make payment to the United States, by means of a wire transfer to the United States Marshal's Service or check payable to same, in the amount of $1,000,000, this amount representing substitute assets of the offenses for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

c.e Defendant RESEARCH further agrees to pay a criminal fine of $500,000 one the day of sentencing.

d.e Defendant RESEARCH and the government agree that this fine and forfeituree represent a fair and just resolution of all issues associated with the fine and forfeiture calculations.

e.e The parties agree that a period of probation for defendant RESEARCH is note needed as codefendant KVK will have entered into a DPA that includes a three-year period of corporate monitoring which would serve the same purpose as a court-supervised probationary period.

4.e Defendant RESEARCH waives any and all defenses and objections in thise

matter which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment resulting from any forfeiture imposed in this case and/or any pending or completed administrative or civil forfeiture actions and stipulates that such forfeiture is not grossly disproportionate to its criminal conduct.

5. The parties agree that to avoid unduly complicating and prolonging the sentencing process, the appropriate disposition of this case should not include a restitution order.

6. Defendant RESEARCH understands, agrees, and has had explained to it by counsel that the offenses to which it is pleading guilty carry the following statutory maximum sentence: a fine of at least approximately $4,000,000, which represents twice the gross gain that was realized from the sale of adulterated hydroxyzine; a special assessment of $250; forfeiture of approximately $1,000,000; and a period of probation, the terms and conditions of which may be changed, and extended, by the Court if any of the terms and conditions of such court-ordered supervision are violated.

7. With respect to defendant RESEARCH's conduct, defendant RESEARCH accepts and acknowledges responsibility for its conduct and that of its officers, employees, and agents as set forth in the Statement of Facts attached as Attachment B and incorporated herein by reference (the "Statement of Facts").

8.e Defendant RESEARCH waives any claim under the Hyde Amendment, 18e U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

9.e Defendant RESEARCH agrees to waive the statute of limitations, and any othere time-related defense, to the charges to which it is agreeing to plead guilty under this plea agreement, provided that the guilty plea is accepted by the Court.

10.e Defendant RESEARCH understands and agrees that, should it withdraw itse plea or if defendant RESEARCH's guilty plea is not accepted by the Court for whatever reason, defendant RESEARCH may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, notwithstanding the expiration of any applicable statute of limitations between the time period when defendant RESEARCH signed this plea agreement and either defendant RESEARCH's withdrawal of its plea or the Court's rejection of its plea. In that event, RESEARCH agrees that it will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of any tolling agreement between the parties, and this paragraph.

11.e Defendant RESEARCH will acknowledge acceptance of this guilty pleae agreement by the signature of its counsel and of an authorized corporate officer. Defendant RESEARCH shall provide to the government for attachment as Attachment D to this plea agreement a notarized resolution by defendant RESEARCH's Board of Trustees authorizing the corporation to enter a plea of guilty and authorizing a corporate officer to execute this agreement.

12.e In exchange for the promises made by the government in entering this pleae

agreement, the defendant voluntarily and expressly waives all rights to file any appeal, any collateral attack, or any other writ or motion that challenges the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such an appeal, collateral attack, or other writ or motion arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. As part of this knowing and voluntary waiver of the right to challenge the conviction and sentence, the defendant expressly waives the right to raise on appeal or on collateral review any argument that: (1) the statute to which the defendant is pleading guilty is unconstitutional; and (2) the admitted conduct does not fall within the scope of the statute.

a. Notwithstanding the waiver provision above, if the government appeals from the sentence, then defendant RESEARCH may file a direct appeal of its sentence.

b. If the government does not appeal, then notwithstanding the waiver provision set forth in this paragraph, defendant RESEARCH may file a direct appeal or petition for collateral relief but may raise only a claim, if otherwise permitted by law in such a proceeding:

i. that the defendant's sentence on any count of conviction exceeds the statutory maximum for that count as set forth in paragraph 6 above;

ii. challenging a decision by the sentencing judge to impose an "upward departure" pursuant to the Sentencing Guidelines;

iii. challenging a decision by the sentencing judge to impose an "upward variance" above the final Sentencing Guideline range determined by the Court; and

iv. that an attorney who represented the defendant during the course of this criminal case provided constitutionally ineffective assistance of counsel.

If the defendant does appeal or seek collateral relief pursuant to this subparagraph, no issue may be presented by the defendant in such a proceeding other than those described in this subparagraph.

13. The defendant acknowledges that filing an appeal or any collateral attack waived in either of the two preceding paragraphs may constitute a breach of this plea agreement. The government promises that it will not declare a breach of the plea agreement on this basis based on the mere filing of a notice of appeal but may do so only after defendant RESEARCH or its counsel thereafter states, either orally or in writing, a determination to proceed with an appeal or collateral attack raising an issue the government deems barred by the waiver. The parties acknowledge that the filing and pursuit of an appeal constitutes a breach only if a court determines that the appeal does not present an issue that a judge may reasonably conclude is permitted by an exception to the waiver stated in the preceding paragraph or constitutes a "miscarriage of justice" as that term is defined in applicable law.

14. Defendant RESEARCH also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

15. Defendant RESEARCH is satisfied with the legal representation provided by its lawyers; RESEARCH and its lawyers have fully discussed this guilty plea agreement; and RESEARCH is agreeing to plead guilty because RESEARCH admits that it is guilty of the misdemeanor violations described in Paragraph 1.

16. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements, or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements, or understandings will be entered into unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division
United States Department of Justice

AMANDA LISKAMM
Digitally signed by AMANDA LISKAMM
Date: 2024.01.19 12:62:44 -05'00'

AMANDA N. LISKAMM
Director
Consumer Protection Branch United States Department of Justice

ROSS S. GOLDSTEIN
Assistant Director
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JACQUELINE C. ROMERO
United States Attorney
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for the Eastern District of Pennsylvania

RICHARD P. BARRETT
Chief, Criminal Division

M. BETH LEAHY
PATRICK J. MURRAY
Assistant United States Attorneys

DATE: Jan 26, 2024

SIGNATURE FOR KVK RESEARCH

DATE: 02/05/2024

03/06/2024

ANTHONY TABASSO, ESQ.
President and Chief Executive Officer
KVK Research

SIGNATURE OF KVK RESEARCH'S ATTORNEY

DATE: 2/22/2024

3/6/2024

JACK W. PIROZZOLO, ESQ.
JEFFREY M. SENGER, ESQ.
Sidley Austin LLP
Counsel for Defendant KVK Research

ATTACHMENT A

SIGNATURE FOR KVK RESEARCH

DATE: 02/05/2024

ANTHONY TABASSO, ESQ.
President and Chief Executive Officer
KVK Research

03/06/2024

SIGNATURE OF KVK RESEARCH'S ATTORNEY

DATE: 2/22/2024

JACK W. PIROZZOLO, ESQ.
Sidley Austin LLP
Counsel for Defendant KVK Research

03/06/2024

ATTACHMENT A

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 24-**
KVK RESEARCH	:	

ACKNOWLEDGMENT OF RIGHTS

I hereby acknowledge, on behalf of the defendant, that the defendant has certain rights that it will be giving up by pleading guilty.

1. I understand that the defendant does not have to plead guilty.

2. The defendant may plead not guilty and insist upon a trial before a United States Federal Magistrate Judge.

3. At that trial, I understand

a. that the defendant is charged with a Class A misdemeanor and may have the right to be tried by a jury on these misdemeanor charges and if so the jury would be selected from the Eastern District of Pennsylvania and that along with its attorney, the defendant would have the right to participate in the selection of that jury;

b. that the jury could only convict the defendant if all 12 jurors agreed that they were convinced of its guilt beyond a reasonable doubt;

c. that the government would have the burden of proving the defendant's guilt beyond a reasonable doubt and that the defendant would not have to prove anything;

d. that the defendant would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that the defendant was guilty;

e. that the defendant would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if the defendant could not afford to hire a lawyer, the court would appoint one for it free of charge;

f. that through its lawyer the defendant would have the right to confront and cross-examine the witnesses against it;

g. that the defendant could testify in its defense if it wanted to and could subpoena witnesses to testify in its defense if it wanted to; and

h. that the defendant would not have to present any defense if it did not want to and that if it did not present any evidence, the jury could not hold that against the defendant.

4. I understand that if the defendant pleads guilty, there will be no trial and the defendant would be giving up all of the rights listed above.

5. I understand that if I decide to enter a plea of guilty on behalf of the defendant, the judge will ask me questions under oath and that if I lie in answering those questions, I could be prosecuted for the crime of perjury, that is, for lying under oath.

6. I understand that if I enter a plea of guilty on behalf of the defendant, it will have given up its right to appeal, except as set forth in the appellate waiver provisions of its plea agreement.

7. Understanding that the defendant has all these rights and that by entry of a plea of guilty on behalf of the defendant, the defendant is giving them up, the defendant still wishes to plead guilty.

8. I acknowledge that no one has promised me or the defendant what sentence the Court will impose. I am aware and have discussed with the defendant's attorney that, at sentencing, the Court will calculate the Sentencing Guidelines range (including whether any departures apply), and then, in determining the defendant's sentence, will consider the Guideline range and all relevant policy statements in the Sentencing Guidelines, along with other sentencing factors set forth in 18 U.S.C. § 3553(a), including

(1) the nature and circumstances of the offense and the defendant's history and characteristics;

(2) the need for the sentence imposed--(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; and (C) to protect the public from further crimes of the defendant.;

(3) the kinds of sentences available;

(4) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and

(5) the need to provide restitution to any victims of the offense.

ATTACHMENT B

STATEMENT OF STIPULATED FACTS

The following Statement of Facts is incorporated by reference as part of the Guilty Plea Agreement (the "Agreement") between the United States Department of Justice, Consumer Protection Branch, and the Office of the United States Attorney for the Eastern District of Pennsylvania (collectively, the "Offices") and defendant KVK Research ("RESEARCH"). RESEARCH hereby agrees and stipulates that the following information is true and accurate. RESEARCH admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents, including those of its affiliate KVK Tech, Inc.("KVK"), as set forth below. The following facts took place in or about and between October 2010 and April 2019 (the "relevant time period"), unless otherwise noted, and RESEARCH agrees that these facts establish beyond a reasonable doubt the charges set forth in the criminal Information attached to this Agreement.

1. KVK, located in Newtown, Pennsylvania, was a manufacturer of generic pharmaceuticals and distributed those products to wholesalers and retail chains throughout the United States. RESEARCH was an affiliate of KVK used to communicate with vendors and regulators. RESEARCH, formed on or about February 19, 2010, was owned by the same three trusts that owned KVK. Among the pharmaceutical products that KVK manufactured and distributed was hydroxyzine tablets, a prescription drug intended and commonly used for the treatment of anxiety and allergic conditions. Accordingly, KVK's hydroxyzine tablets were drugs within the meaning of section 321(g)(1) of Title 21, United States Code.

2. The part of a drug that produces the intended effect is called the "active pharmaceutical ingredient" or "API." The API in KVK's hydroxyzine tablets was the chemical,

hydroxyzine hydrochloride ("hydroxyzine HCl").

3. On or about June 21, 2006, KVK filed abbreviated new drug applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to distribute hydroxyzine tablets in various dosage strengths. In these ANDAs, KVK stated that the drugs would be produced with API manufactured by Supplier 1 at its facility located in Braine-l'Alleud, Belgium. On or about March 20, 2007, FDA approved KVK's ANDAs. Around the same time as FDA's approval of the ANDAs, Supplier 1 ceased production of API at its Belgium facility.

4. On or about May 31, 2008, KVK notified FDA that it intended to obtain API for its hydroxyzine tablets from Supplier 2, manufactured at its plant located in Ciserano, Italy, which was not specified in the FDA-approved ANDAs. Because this change was considered a major change under FDA regulations (21 C.F.R. § 314.70), FDA required KVK to file a "prior approval supplement" ("PAS") and obtain FDA's approval prior to distributing hydroxyzine tablets made with API not approved in the ANDAs. On or about December 3, 2008, FDA approved KVK's PAS for hydroxyzine, permitting KVK to distribute hydroxyzine tablets containing API manufactured by Supplier 2 at its Italian facility, in addition to hydroxyzine with API manufactured by Supplier 1 in Belgium.

5. Supplier 3 was a pharmaceutical company with a manufacturing facility located in Morales, Mexico. Between about November 6, 2010, through about November 11, 2010, FDA conducted an inspection of Supplier 3's Mexico facility. Following that inspection, FDA issued a Warning Letter to Supplier 3 that API manufacturing in its Mexico facility was adulterated and, on or about July 7, 2011, FDA issued an import alert for API manufactured by Supplier 3 at its Mexico facility. This alert authorized any API manufactured by Supplier 3 in Mexico and

imported into the United States after that date to be detained. The alert remained in effect until on or about July 12, 2012.

6. On or about October 29, 2010, RESEARCH purchased a commercial quantity of hydroxyzine API from Supplier 3's facility in Mexico for use in KVK's hydroxyzine tablets. When KVK submitted its ANDAs for hydroxyzine tablets to FDA, it had not listed the SUPPLIER 3 facility as a manufacturing site. The first shipment of Supplier 3's API was accepted by Research on or about January 4, 2011. KVK failed to notify FDA or take any steps to submit supplemental filings to their approved applications to use the SUPPLIER 3 API before accepting the first shipment.

7. In January, March, and May of 2011, RESEARCH received additional shipments of hydroxyzine API manufactured at Supplier 3's Mexico facility and used it to manufacture KVK's hydroxyzine tablets for distribution in the United States.

8. Between in or about January 2011 and October 2013, RESEARCH and KVK introduced, and caused to be introduced into interstate commerce at least one lot of 10mg hydroxyzine tablets, 34 lots of 25mg hydroxyzine tablets, and 27 lots of 50mg hydroxyzine tablets that were manufactured using API manufactured at Supplier 3's facility in Mexico without notifying or seeking approval from FDA to change the manufacturing facility of the raw material API from those contained within the FDA-approved ANDAs. Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) ("FDCA"), FDA promulgated regulations, including regulations requiring drug manufacturers to adhere to current good manufacturing practices ("cGMP") to assure the identity, strength, quality, and purity of drug products. These regulations required drug manufactures such as KVK to adequately control manufacturing operations to control risks to public health. Those regulations, located at 21

C.F.R. part 211, required that RESEARCH and KVK maintain a quality control unit whose responsibilities and procedures were required to be in writing and which procedures were required to be followed. 21 C.F.R. § 211.22.

9. Between in or about January 2011 and October 2013, RESEARCH and KVK failed to have quality control procedures in writing to ensure the rejection of raw material and API that was not manufactured at a facility identified in the FDA-approved ANDAs. These failures were violations of the cGMP regulations located at 21 C.F.R. § 211.22(d).

10. As a result, because the methods used in, and the facilities and controls used for their manufacture did not conform to the cGMP regulations, the hydroxyzine tablets manufactured by KVK with API from Supplier 3, purchased by RESEARCH, were deemed to be adulterated as a matter of law pursuant to section 351(a)(1)(B) of Title 21, United States Code.

11. Between in or about January 2011 and October 2013, KVK shipped to customers, and thereby introduced and delivered for introduction into interstate commerce and caused to be introduced and delivered for introduction into interstate commerce, at least 62 batches of hydroxyzine tablets that were deemed to be adulterated drugs.

12. Between about April 9, 2019, and April 16, 2019, FDA conducted an inspection of KVK's manufacturing facility. During that inspection, FDA found that KVK failed to comply with requirements of the Food, Drug, and Cosmetic Act and its associated regulations and it issued a Warning Letter, dated February 11, 2020, describing the violations. For example, FDA found that KVK failed to exercise appropriate controls over computer and related systems to assure that only authorized personnel institute changes in master production and control records as required by cGMP.

13. Specifically, data generated from KVK's laboratory testing system was not adequately protected from deletion or alteration. RESEARCH was included in the establishment of KVK's security protocols. Four quality assurance employees – three from KVK and one from RESEARCH- had unauthorized administrator access privileges to KVK's chromatographic testing software, which was used for high-performance liquid chromatography assays and impurity analyses of finished drug products. Additionally, it was possible for KVK's drug manufacturing data files to be modified or overwritten without being captured on audit trails on KVK's laboratory equipment.

14. The cGMP regulations promulgated under the FDCA required that appropriate controls be exercised over computer and related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. 21 C.F.R. § 211.68(b).

15. As a result, because the methods used in, and the facilities and controls used for, their manufacture did not conform to the cGMP regulations, the drug products manufactured by KVK with these insufficient controls were deemed to be adulterated as a matter of law pursuant to section 351(a)(1)(B) of Title 21, United States Code.

16. As a result, beginning on or about February 27, 2019, and continuing through about April 16, 2019, KVK shipped the prescription drug sodium polystyrene 15 mg tablets to customers, and thereby RESEARCH and KVK introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, drugs that were adulterated.

AUSA Mitchell Long
3/6/2024

ATTACHMENT C

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 24-**
KVK TECH, INC.	:	

DEFERRED PROSECUTION AGREEMENT

The United States Department of Justice, Consumer Protection Branch, and the Office of the United States Attorney for the Eastern District of Pennsylvania (collectively, the "Offices") and defendant KVK Tech, Inc. (the "Company"), pursuant to authority granted by the Company's Board of Directors reflected in Attachment B, enter into this Deferred Prosecution Agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Offices will file the attached two-count criminal Information in the United States District Court for the Eastern District of Pennsylvania charging the Company and its affiliate KVK Research, Inc. with introducing adulterated drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(1) (the "Information"). In so doing, the Company: (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, section 3161 of Title 18, United States Code, and Federal Rule of Criminal Procedure 48(b); (b) knowingly waives any applicable statute of limitations defenses in any prosecution relating to the conduct described in the Information or the Statement of Facts, attached hereto as Attachment A, ("Statement of Facts"); and (c) knowingly waives any objection with respect to venue to any charges by the United States arising out of

the conduct described in the Statement of Facts, and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Eastern District of Pennsylvania. The Offices agree to defer prosecution of the Company pursuant to the terms and conditions described below.

2.e The Company admits, accepts, and acknowledges that it is responsible under United Statese law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, effective as of the date the Company signs this Agreement, in any prosecution that is deferred by this Agreement and in prosecution of the individuals charged in the Superseding Indictment in Crim. No. 21-132 (E.D. Pa.), it will not dispute the Statement of Facts set forth in this Agreement and, in any such prosecution against the Company, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

3. The Company agrees that this Agreement is contingent on an affiliate of the Company, thate is, KVK Research, entering a plea of guilty to the two counts charged against it in the Information. Within 3 business days of sentencing KVK Research, Inc. on the two counts charged in the Information, the Government shall dismiss the charges against the Company contained in the Superseding Indictment in Crim. No. 21-132 (E.D. Pa.). If the affiliate does not enter a guilty plea as set forth above within 30 days of the date this Agreement is effective, this Agreement shall be deemed null and void, except: (a) the

provisions contained within Paragraph 2 of this Agreement; and (b) the statute of limitations waiver contained within Paragraph 1.

Term of the Agreement

4.e This Agreement is effective for a period beginning on the date on which the Information ise filed (the "Effective Date") and ending thirty-six (36) months from the later of the Effective Date or the date on which the independent compliance monitor (the "Monitor") is retained by the Company, as described in Paragraphs 14–17 below (the "Term"). The Company agrees, however, that, in the event the Offices determine, in their sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Offices, in their sole discretion, for up to an additional time period of one year, without prejudice to the Offices' right to proceed as provided in Paragraphs 20–23, below. Any extension of this Agreement extends all terms of this Agreement, including the terms of the reporting requirements and monitorship in Attachment D, for an equivalent period. Conversely, in the event the Offices find, in their sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirements and monitorship in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion oftime under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all provisions of this Agreement shall be deemed null and void, except: (a) the provisions contained within Paragraph 2 of this Agreement; and (b) the statute of limitations waiver contained within Paragraph 1.

Relevant Considerations

5.e The Offices enter into this Agreement based on the individual facts and circumstancese presented by this case and the Company, including:

a.e the Company did not voluntarily and timely disclose to the Offices the conducte

described in the Statement of Facts;

b. the Company has agreed to provide to the Offices all relevant facts known to it, including but not limited to information about the individuals involved in the conduct described in the Statement of Facts and conduct disclosed to the Offices prior to the Agreement;

c. the Company has committed to enhance its compliance program and internal controls, including ensuring that its compliance program satisfies the minimum elements set forth in Attachment C to this Agreement ("Corporate Compliance Program");

d. the Company has agreed to report to the Offices as set forth in Attachment D to this Agreement ("Compliance Reporting Requirements");

e. the Company has agreed to implement remedial measures including removing administrator access to certain quality assurance personnel and took certain steps to improve data integrity;

f. although the Company has engaged in some remedial measures, the Offices have determined that an independent compliance monitor is necessary to ensure that the Company's compliance program is operating effectively and is adequately evaluated to ensure that it meets the minimum requirements set forth in the Corporate Compliance Program;

g. the nature and seriousness of the offense conduct, including the distribution of adulterated drugs;

h. the Company has agreed to cooperate with the Offices in any ongoing investigation of the conduct of the Company and its officers, directors, employees, agents, business partners, distributors, and consultants relating to violations of the Federal Food, Drug, and Cosmetic Act;

i. the agreement by the Company and the Company's affiliate, KVK Research for the affiliate to plead guilty to the charges against it in the Information; and

j. after considering subparagraphs (a) though (i) above, the Offices believe that the appropriate resolution in this case as to the Company is a deferred prosecution agreement with the

Company, and the Company's agreement to report to the Offices as set forth in the Compliance Reporting Requirements and to engage an independent compliance monitor.

Future Cooperation and Disclosure Requirements

6. The Company shall cooperate fully with the Offices in any and all matters relating to the conduct described in this Agreement, the Statement of Facts, the Information, and other conduct related to: (a) current good manufacturing practices; and (b) applications for approval to market a new drug currently under investigation by the Offices. At the request of the Offices, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its subsidiaries or its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the above conduct. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Offices a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information with respect to its activities, those of its subsidiaries and affiliates, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Offices may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Offices, upon request, any document, record, or other tangible evidence about which the Offices may inquire of the Company. Upon request of the Offices, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Offices the information and materials described in this

Paragraph on behalf of the Company. It is further understood that the Company must at all times provide complete, truthful, and accurate information.

b. The Company shall use its best efforts to make available for interviews or testimony, as requested by the Offices, present or former officers, directors, employees, agents, and consultants of the Company. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

c. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Offices pursuant to this Agreement, the Company consents to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government of such materials as the Offices, in their sole discretion, shall deem appropriate.

Payment of Monetary Penalty

7. While the fine provisions of the United States Sentencing Guidelines ("U.S.S.G." or "Sentencing Guidelines") do not apply to organizational defendants for misdemeanor violations of the FDCA, see U.S.S.G. § 8C2.1, the Offices and the Company agree that application of the Sentencing Guidelines to determine an applicable fine range yields the following analysis:

a. The 2021 version of the U.S.S.G. is applicable to this matter.

b. Offense Level. Based upon U.S.S.G. §2N2.1, the base offense level, and the total offense level, is 6.

c. Base Fine. Under U.S.S.G. §8C2.4(a), the base fine is the greatest of the amount from the Offense Level Fine Table or the pecuniary gain or loss from the offense. Here, the

pecuniary gain is the greatest, and is approximately $2,000,000.

d.e Culpability Score. Based upon U.S.S.G. §8C2.5, the culpabilitye score is 7, calculated as follows:

(a)e	Base Culpability Score	5e
(b)(3)	The organization had 200 or more employees and ane individual within high-level personnel of the organizatione participated in, condoned, or was willfully ignorant of the offensee	+3e
(g)(3)	The organization clearly demonstrated recognition and affirmative acceptance of responsibility for its criminale conducte	-1e
TOTAL		7

e.e Calculation of Fine Range.e

Base Finee	$1,000,000
Multipliers (§8C2.6)e	1.4 (min) / 2.8 (max)
Fine Rangee	$ 1,400,000 to $2,800,000

8.e The Company and the Offices agree that a total penalty in the amount ofe $1,500,000 (the "Criminal Monetary Penalty") is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 5 of this Agreement. The Company agrees that its affiliate KVK Research will forfeit, and the Company will not contest the forfeiture of, $1,000,000 in substitute assets, in lieu of the drugs which were deemed adulterated and are no longer available, and a $500,000 fine on the day of sentencing, pursuant to payment instructions provided by the Offices in their sole discretion. Payment of the Criminal Monetary Penalties is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Offices that the Criminal Monetary Penalty is the maximum penalty that may be imposed in any future prosecution, and

the Offices are not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Offices agree that under those circumstances, the Offices will recommend to the Court that the Criminal Monetary Penalty paid by the Company pursuant to this Agreement be applied toward any fine that the Court might impose as part of its judgment. The Company acknowledges that such a recommendation will not be binding on the Court.

9.e The Company acknowledges that no tax deduction may be sought in connection with thee payment of any part of the Criminal Monetary Penalty. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the penalty amounts that the Company pays pursuant to this Agreement concerning the facts set forth in the Information and the Statement of Facts.

Conditional Release from Liability

10.e Subject to Paragraphs 20–23 the Offices agree, except as provided in this Agreement, thate they will not bring any new criminal case against the Company relating to any of the conduct described in the Statement of Facts or the Information filed pursuant to this Agreement. The Offices, however, may use any information related to the conduct described in the Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a.e This Agreement does not provide any protection against prosecution for any futuree conduct by the Company.

b.e In addition, this Agreement does not provide any protection against prosecution ofe any individuals, regardless of their affiliation with the Company.

Corporate Compliance Program

11.e The Company represents that it has implemented and will continue to implement ae

compliance and ethics program designed to prevent and detect violations of statutory and regulatory provisions relating to current good manufacturing practices and to applications for approval to market a new drug under the Federal Food, Drug, and Cosmetic Act, throughout its operations, including those of its subsidiaries, affiliates, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities relate to the Company's manufacturing and distribution of FDA-regulated products, including, but not limited to, the minimum elements set forth in Attachment C.

12. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FDCA, focusing on the Company's manufacturing processes. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program, including a system of internal controls, designed to effectively detect and deter violations of the Food, Drug, and Cosmetic Act. The compliance program, including the internal controls system will include, but not be limited to, the minimum elements set forth in Attachment C. In assessing the Company's compliance program, the Offices, in their sole discretion, may consider the Monitor's certification decision.

Corporate Compliance Reporting

13. The Company agrees that it will report to the Offices periodically during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with Attachment D.

Independent Compliance Monitor

14. Promptly after the Offices' selection pursuant to Paragraph 16 below, the Company agrees to retain a Monitor for the term specified in Paragraph 17. The Monitor's duties and authority, and the

obligations of the Company with respect to the Monitor and the Offices, are set forth in Attachment D. Within twenty (20) business days after the Effective Date of this Agreement, the Company shall submit a written proposal identifying three monitor candidates, and, at a minimum, providing the following:

a. a description of each candidate's qualifications and credentials in support of the evaluative considerations and factors listed below;

b. a written certification by the Company that it will not employ or be affiliated with the monitor for a period of not less than two years from the date of the termination of the monitorship;

c. a written certification by each of the candidates that he/she is not a current or recent (i.e., within the prior two years) employee, agent, or representative of the Company and holds no interest in, and has no relationship with, the Company, its subsidiaries, affiliates or related entities, or its employees, officers, or directors;

d. a written certification by each of the candidates that he/she has notified any clients that the candidate represents in a matter involving the Offices (or any other Department of Justice component) handling the monitor selection process, and that the candidate has either obtained a waiver from those clients, or, if an attorney has withdrawn as counsel in the other matter(s); and

e. a statement identifying the monitor candidate that is the Company's first, second, and third choice to serve as the monitor.

15. The Monitor candidates or their team members shall have, at a minimum, the following qualifications:

a. demonstrated experience and expertise with respect to current good manufacturing practices as they relate to the manufacturing of drugs;

b. experience designing and/or reviewing corporate compliance policies, procedures and internal controls, including those specific to maintaining compliance with the Federal Food, Drug, and Cosmetic Act and its associated regulations;

c.e the ability to access and deploy resources as necessary to discharge the Monitor'se duties as described in this Agreement; and

d.e sufficient independence from the Company to ensure effective and impartiale performance of the Monitor's duties as described in this Agreement.

16.e The Offices retain the right, in their sole discretion, to choose the Monitor from among thee candidates proposed by the Company. Any submission or selection of a monitor candidate by either the Company or the Offices shall be made without unlawful discrimination against any person or class of persons. If the Offices determine, in their sole discretion, that any or all of the three candidates lack the requisite qualifications, they shall notify the Company and request that the Company propose another candidate or candidates within twenty (20) business days. This process shall continue until a Monitor acceptable to both parties is chosen. The Offices and the Company will use their best efforts to complete the selection process within sixty (60) calendar days of the Effective Date of this Agreement. The Offices retain the right to determine that the Monitor should be removed if, in the Offices' sole discretion, the Monitor fails to conduct the monitorship effectively, fails to comply with this Agreement, or no longer meets the qualifications outlined in Paragraph 15 above. If the Monitor resigns, is removed, or is otherwise unable to fulfill his or her obligations as set out herein and in Attachment D, the Company shall within twenty (20) business days recommend a pool of three qualified Monitor candidates from which the Offices will choose a replacement, following the process outlined above.

17.e The Monitor's term shall be thirty-six (36) months from the date on which the Monitor ise retained by the Company, subject to extension or early termination as described in Paragraph 4. The Monitor's powers, duties, and responsibilities, as well as additional circumstances that may support an extension of the Monitor's term, are set forth in Attachment D. The Company agrees that it will not employ or be affiliated with the Monitor, or the Monitor's firm for a period ofnot less than two years from the date on which the Monitor's term expires, nor will the Company discuss with the Monitor or the

Monitor's firm the possibility of further employment or affiliation during the Monitor's term. Upon agreement by the parties, this prohibition will not apply to other monitorship responsibilities that the Monitor or the Monitor's firm may undertake in connection with resolutions with foreign or other domestic authorities.

Deferred Prosecution

18.e In consideration of the undertakings agreed to by the Company herein, the Offices agreee that any prosecution of the Company for the conduct set forth in the Statement of Facts or the Information be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts or the Information, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19.e The Offices further agree that if the Company fully complies with all of its obligationse under this Agreement, the Offices will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire, except as described in the last sentence of this Paragraph. Within three (3) months after the Agreement's expiration, the Offices shall seek dismissal with prejudice of the Information filed against the Company described in Paragraph 1 and agree not to file charges in the future against the Company based on the conduct described in the Statement of Facts or the Information. If, however, the Offices determine during this three-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Offices' ability to extend the Term, as described in Paragraph 4, or to pursue other remedies, including those described in Paragraphs 20–23 remains in full effect.

Breach of the Agreement

20.e If, during the Term, the Company: (a) commits any felony under U.S. federal law; (b)e provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (c) fails to

cooperate as set forth in Paragraph 6 of this Agreement; (d) fails to implement a compliance program as set forth in Paragraphs 11–12 of this Agreement and Attachment C; (e) fails to make any reports as set forth in Paragraph 13 of this Agreement and Attachment D; or (f) otherwise fails to completely perform or fulfill each of the Company's obligations under the Agreement, regardless of whether the Offices become aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Offices have knowledge, including, but not limited to, the charges in the Information described in Paragraph 1, which may be pursued by the Offices in the United States District Court for the Eastern District of Pennsylvania or in any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Offices' sole discretion. Any such prosecution may be premised on information provided by the Company or its personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Offices prior to the Effective Date of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the Effective Date and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of the laws of the United States that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Offices are made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Offices determine that the Company has breached this Agreement, the Offices agree to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty (30) calendar days of receipt of such notice, the Company shall have the opportunity to respond to the Offices in writing to explain the nature and

circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Offices shall consider in determining, in their sole discretion, whether to pursue prosecution of the Company.

22. In the event that the Offices determine that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Offices or to the Court, including in this Agreement, the Statement of Facts, and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Offices against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Offices.

23. The Company acknowledges that the Offices have made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

Sale, Merger, or Other Change in Corporate Form of Company

24. Except as may otherwise be agreed by the parties in connection with a particular

transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the Information and the Statement of Facts, as they exist as of the Effective Date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Offices' ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the Offices at least thirty (30) business days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Offices shall notify the Company prior to such transaction (or series of transactions) if they determine that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Offices may deem it a breach of this Agreement pursuant to Paragraph 20 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Offices.

Public Statements by Company

25.e The Company expressly agrees that it shall not, through present or future attorneys,e officers, directors, employees, agents or any other person authorized to speak for the Company make any

public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts or in the Information. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20–23 of this Agreement. The decision whether any public statement by any such person contradicting ae fact contained in the Statement of Facts or the Information will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Offices. If the Offices determine that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts or the Information, the Offices shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statemcnt contained in the Information or the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

26.e The Company agrees that if it or any of its direct or indirect subsidiaries or affiliates issuese a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Offices to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Offices and the Company; and (b)ewhether the Offices have any objection to the release.e

27.e The Offices agree, if requested to do so, to bring to the attention of law enforcement ande regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this

Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Offices are not agreeing to advocate on behalf of the Company, but rather are agreeing to provide facts to be evaluated independently by such authorities.

Publication

28. Within ten (10) business days of the Effective Date of this Agreement, the Company agrees to make the Information and this Agreement, including all Attachments, available to the public on its website in a conspicuous location to the Offices' reasonable satisfaction for twenty-four (24) months after the Effective Date of this Agreement.

Limitations on Binding Effect of Agreement

29. This Agreement is binding on the Company and the Offices but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Offices will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

Notice

30. Unless otherwise directed by the Offices in writing, any notice to the Offices under this Agreement shall be given by electronic mail to Consumer.Compliance@usdoj.gov and to any additional email addresses provided by the Offices. The subject line of the email must begin with the Company's name. In the event that electronic mail is unavailable, the notice may be sent by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail to an address provided by the Offices. Notice shall be effective upon actual receipt by the Offices.

31. Any notice to the Company under this Agreement shall be given by personal delivery,

overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Anthony Tabasso
President and CEO
KVK Tech, Inc.
110 Terry Drive
Newtown PA 18940

or by electronic mail to atabasso@kvktech.com or to other counsel or individuals identified to the Offices by the Company. Notice shall be effective upon actual receipt by the Company.

Complete Agreement

32. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Offices. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Offices, the attorneys for the Company, and a duly authorized representative of the Company.

AGREED:

SIGNATURES FOR THE UNITED STATES

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division
United States Department of Justice

AMANDA LISKAMM
Digitally signed by AMANDA LISKAMM
Date: 2024.01.19 12:20:06 -05'00'

AMANDA N. LISKAMM
Director
Consumer Protection Branch
United States Department of Justice

Digitally signed by ROSS GOLDSTEIN
DN: cn=US, o=U.S. Government, ou=Dept of Justice, ou=CIV, cn=ROSS GOLDSTEIN, 0.9.2342.19200300.100.1.1=15001001023022
Date: 2024.01.28 12:36:28 -05'00'

ROSS S. GOLDSTEIN
Assistant Director
ALISHA M. CROVETTO
Trial Attorney
Consumer Protection Branch
United States Department of Justice

Date: Jan 24, 2024

JACQUELINE C. ROMERO
United States Attorney
United States Attorney's Office
for the Eastern District of Pennsylvania

RICHARD P. BARRETT
Chief, Criminal Division

M. BETH LEAHY
PATRICK J. MURRAY
Assistant United States Attorneys

SIGNATURE FOR KVK TECH, INC.

Date: 02/05/2024

ANTHONY TABASSO, ESQ.
President and Chief Executive Officer
KVK Tech, Inc.

SIGNATURE OF KVK TECH, INC.'s ATTORNEY

Date: 2/22/2024

JACK W. PIROZZOLO, ESQ.
Sidley Austin LLP
Counsel for Defendant KVK Tech, Inc.

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for KVK Tech, Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the President and Chief Executive Officer for the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: 02/05/2024

By: _____
ANTHONY TABASSO, ESQ.
President and Chief Executive Officer
KVK Tech, Inc.

CERTIFICATE OF COUNSEL

I am counsel for KVK Tech, Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the President and Chief Executive Officer of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 2/22/2024

By: _____
JACK W. PIROZZOLO, ESQ.
Sidley Austin LLP

ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Consumer Protection Branch, and the Office of the United States Attorney for the Eastern District of Pennsylvania (collectively, the "Offices") and defendant KVK Tech, Inc. (the "Company" or "KVK"). The Company hereby agrees and stipulates that the following information is true and accurate. The Company admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Offices pursue the prosecution that is deferred by this Agreement, the Company agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts took place in or about and between October 2010 and April 2019 (the "relevant time period"), unless otherwise noted, and the Company agrees that these facts establish beyond a reasonable doubt the charges set forth in the criminal Information attached to this Agreement.

1. The Company was organized under the laws of Pennsylvania with its headquarters in Newtown, Pennsylvania. KVK was a manufacturer of generic pharmaceuticals and distributed those products to wholesalers and retail chains throughout the United States. Among the pharmaceutical products that KVK manufactured and distributed was hydroxyzine tablets, a prescription drug intended and commonly used for the treatment of anxiety and allergic conditions. Accordingly, KVK's hydroxyzine tablets were drugs within the meaning of section 321(g)(1) of Title 21, United States Code.

2. The part of a drug that produces the intended effect is called the "active pharmaceutical ingredient" or "API." The API in KVK's hydroxyzine tablets was the chemical, hydroxyzine hydrochloride

("hydroxyzine HCl").

3.e On or about June 21, 2006, the Company filed abbreviated new drug applicationse ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to distribute hydroxyzine tablets in various dosage strengths. In these ANDAs, KVK stated that the drugs would be produced with API manufactured by Supplier 1 at its facility located in Braine-l'Alleud, Belgium. On or about March 20, 2007, FDA approved KVK's ANDAs. Around the same time as FDA's approval of the ANDAs, Supplier 1 ceased production of API at its Belgium facility.

4.e On or about May 31, 2008, the Company notified FDA that it intended to obtain APIe for its hydroxyzine tablets from Supplier 2, manufactured at its plant located in Ciserano, Italy, which was not specified in the FDA-approved ANDAs. Because this change was considered a major change under FDA regulations (21 C.F.R. § 314.70), FDA required KVK to file a "prior approval supplement" ("PAS") and obtain FDA's approval prior to distributing hydroxyzine tablets made with API not approved in the ANDAs. On or about December 3, 2008, FDA approved the Company's PAS for hydroxyzine, permitting KVK to distribute hydroxyzine tablets containing API manufactured by Supplier 2 at its Italian facility, in addition to hydroxyzine with API manufactured by Supplier 1 in Belgium.

5. Supplier 3 was a pharmaceutical company with a manufacturing facility located in Morales, Mexico. Between about November 6, 2010, through about November 11, 2010, FDA conducted an inspection of Supplier 3's Mexico facility. Following that inspection, FDA issued a Warning Letter to Supplier 3 that API manufacturing in its Mexico facility was adulterated and, on or about July 7, 2011, FDA issued an import alert for API manufactured by Supplier 3 at its Mexico facility. This alert authorized any API manufactured by Supplier 3 in Mexico and imported into the United States after that date to be detained. The alert remained in effect until on or about July 12,

2012.

6.e On or about October 29, 2010, the Company purchased from Supplier 1 a commerciale quantity of hydroxyzine API that was manufactured at Supplier 3's facility in Mexico for use in the Company's hydroxyzine tablets. When the Company submitted its ANDAs for hydroxyzine tablets to FDA, it had not listed Supplier 3 facility as a manufacturing site. Supplier 1's first shipment of Supplier 3's API was accepted by the Company on or about January 4, 2011. The Company failed to notify FDA or take any steps to submit supplemental filings to their approved applications to use the Supplier 33 API before accepting the first shipment.

7.e In January, March, and May of 2011, the Company received additional shipmentse of hydroxyzine API manufactured at Supplier 3's Mexico facility and used it to manufacture KVK's hydroxyzine tablets for distribution in the United States.

8.e Between about January 2011 and October 2013, the Company introduced, and causede to be introduced into interstate commerce at least one lot of 10mg hydroxyzine tablets, 34 lots of 25mg hydroxyzine tablets, and 27 lots of 50mg hydroxyzine tablets that were manufactured using API manufactured at Supplier 3's facility in Mexico without notifying or seeking approval from FDA to change the manufacturing facility of the raw material API from those contained within the FDA-approved ANDAs. Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*) ("FDCA"), FDA promulgated regulations, including regulations requiring drug manufacturers to adhere to current good manufacturing practices ("cGMP") to assure the identity, strength, quality, and purity of drug products. These regulations required drug manufactures such as the Company to adequately control manufacturing operations to control risks to public health. Those regulations, located at 21 C.F.R. part 211, required that the Company maintain a quality control unit whose responsibilities and procedures were required to be in writing and which procedures were required to

be followed. 21 C.F.R. § 211.22.

9.e Between about January 2011 and October 2013, the Company failed to have qualitye control procedures in writing to ensure the rejection of raw material and API that were not manufactured at a facility identified in the FDA-approved ANDAs. These failures were violations of the cGMP regulations located at 21 C.F.R. § 211.22(d).

10.e As a result, because the methods used in, and the facilities and controls used fore their manufacture did not conform to the cGMP regulations, the hydroxyzine tablets manufactured by the Company with API from Supplier 3 were deemed to be adulterated as a matter of law pursuant to section 351(a)(2)(B) of Title 21, United States Code.

11.e Between about January 2011 and October 2013, the Company shipped to itse customers, and thereby introduced and delivered for introduction into interstate commerce and caused to be introduced and delivered for introduction into interstate commerce, at least 62 batches of hydroxyzine tablets that were deemed to be adulterated drugs.

12.e Between about April 9, 2019, and April 16, 2019, FDA conducted an inspection of thee Company's manufacturing facility. During that inspection, FDA found that KVK failed to comply with requirements of the FDCA and its associated regulations, and it issued a Warning Letter, dated February 11, 2020, describing the Company's violations. For example, FDA found that KVK failed to exercise appropriate controls over computer and related systems to assure that only authorized personnel institute changes in master production and control records as required by the cGMP regulations.

13.e Specifically, data generated from the Company's laboratory testing system was note adequately protected from deletion or alteration. Four of KVK's quality assurance employees had unauthorized administrator access privileges to the Company's chromatographic testing software,

which was used for high-performance liquid chromatography assays and impurity analyses of finished drug products. Additionally, it was possible for KVK's drug manufacturing data files to be modified or overwritten without being captured on audit trails on the Company's laboratory equipment.

14. The cGMP regulations promulgated under the FDCA required that appropriate controls be exercised over computer and related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. 21 C.F.R. § 211.68(b).

15. As a result, because the methods used in, and the facilities and controls used for, their manufacture did not conform to the cGMP regulations, drug products manufactured by the Company with these insufficient controls were deemed to be adulterated as a matter of law pursuant to section 351(a)(2)(B) of Title 21, United States Code.

16. As a result, beginning on or about February 27, 2019, and continuing through about April 16, 2019, the Company shipped the prescription drug sodium ploystyrene sufonate (15 mg) (Batch Number 15376) to its customers, and thereby introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, drugs that were adulterated.

ATTACHMENT B

CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, KVK Tech, Inc., (the "Company") has been engaged in discussions with the United States Department of Justice, Consumer Protection Branch, and the Office of the United States Attorney for the Eastern District of Pennsylvania (collectively, the "Offices") regarding issues arising in relation to violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"); and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Offices; and

WHEREAS, the Company's President and Chief Executive Officer, Anthony Tabasso, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Offices;

Therefore, the Board of Directors has RESOLVED that:

1.e The Company: (a) acknowledges the filing of the two-count Information charging thee Company with misdemeanor violations of the FDCA, namely the introduction of adulterated drugs into interstate commerce, in violation of sections 331(a) and 333(a)(1) of Title 21, United States Code; and (b)ewaives any right it might have had to indictment on such charges and enters into a Deferrede Prosecution Agreement (the "Agreement") with the Offices.

2.e The Company accepts terms and conditions of this Agreement, including, but note limited to: (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, section 3161 of Title 18, United States Code, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the

United States District Court for the Eastern District of Pennsylvania; and (c) a knowing waiver of any applicable statute of limitations defenses in any prosecution by the Offices relating to the conduct described in the Information, the Statement of Facts, or conduct known to the Offices prior to the Effective Date of this Agreement;

3. The President and Chief Executive Officer of Company, Anthony Tabasso, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Deferred Prosecution Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the President and Chief Executive Officer of Company Anthony Tabasso may approve;

4. The President and Chief Executive Officer of Company, Anthony Tabasso, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the President and Chief Executive Officer of Company, Anthony Tabasso, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 02/07/2024

By: _____
ANTHONY TABASSO, ESQ.
Chairman of the Board of Directors
KVK Tech, Inc.

ACKNOWLEDGMENT

COMMONWEALTH OF PENNSYLVANIA)
) SS
COUNTY OF BUCKS)

On this, the 7th day of February, 2024, before me, the undersigned Notary Public, personally appeared Anthony P. Tabasso who acknowledged himself to be the Chairman of the Board for KVK Tech, Inc., and he being authorized to do so, executed the within instrument, and acknowledged that he executed the same for the purposes therein contained.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

Notary Public
My commission expires:

Commonwealth of Pennsylvania - Notary Seal
SUSAN DICROCE - Notary Public
Bucks County
My Commission Expires Jul 25, 2024
Commission Number 1270745

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and its associated regulations, KVK Tech, Inc. (the "Company"), on behalf of itself and its subsidiaries and affiliates, agrees to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, compliance code, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance code, policies, and procedures, to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the FDCA and its associated regulations. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the FDCA and its associated regulations and the Company's compliance codes, and demonstrate rigorous adherence by example. The Company will also ensure that middle management, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the company.

Policies and Procedures

2. The Company will develop and promulgate a clearly articulated and visible corporate policy against violations of the FDCA and its associated regulations, which policy shall be memorialized in a written compliance code or codes.

3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the FDCA and its associated regulations and the Company's compliance code, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the FDCA and its associated regulations by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company. The Company will ensure that it has a system of procedures, including a system of internal controls, reasonably designed to ensure the maintenance of current good manufacturing practices. This system shall be designed to provide reasonable assurances that:

a. Active pharmaceutical ingredients ("API") for the drugs manufactured by the Company will meet its intended specifications for quality and purity, including assuring that finished drug products contain only API sourced from sites and facilities described in the Company's FDA-approved abbreviated new drug applications and comply with all other approved specifications;

b. Vendor selection and qualification are conducted appropriately;

c. Appropriate assessment is conducted regarding vendor notifications with regard to drug product quality and approved specifications;

d. All required post-approval filings are timely made with FDA and that all post-approval commitments made to FDA are fulfilled; and

e. Appropriate controls over computer or related systems are exercised to assure changes in master production and control records or other records are instituted only by authorized

personnel.

Periodic Risk-Based Review

4. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company. The Company shall review its compliance policies and procedures regarding the FDCA and its associated regulations no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company, its customers, and its products. The Company is not required to include as part of this annual review standard operating procedures or work instructions meant to be used during the manufacture of FDA-regulated products.

Proper Oversight and Independence

5. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

6. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the FDCA and its associated regulations are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust or in positions that require such training (*e.g.*, regulatory,

quality assurance, manufacturing, research, legal, compliance), and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

7.e The Company will maintain, or where necessary establish, an effective system fore providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations, including when they need advice on an urgent basis.

Internal Reporting and Investigation

8.e The Company will maintain, or where necessary establish, an effective system fore internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations.

9.e The Company will maintain, or where necessary establish, an effective and reliablee process with sufficient resources for responding to, investigating, and documenting allegations of violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

Enforcement and Discipline

10. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations.

11. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations by the Company's directors, officers, and employees. Such procedures should be applied consistently, fairly, and in a manner commensurate with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program regarding the FDCA and its associated regulations is effective.

Third-Party Relationships

12. The Company will institute appropriate risk-based due diligence and compliance requirements pertaining to the retention and oversight of all agents and business partners, including:

a. properly documented due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;

b. informing agents and business partners of the Company's commitment to abiding by the FDCA and its associated regulations and of the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations; and

c. seeking a reciprocal commitment from agents and business partners.

13. The Company will identify and record the business rationale for using a third party in a transaction and will conduct adequate due diligence with respect to the risks posed by a third-party partner such as a third-party partner's reputations and relationships, if any, with regulatory authorities and agencies. The Company will ensure that contract terms with third parties specifically describe the services to be performed, that the third party is actually performing the described work, and that its compensation is commensurate with the work being provided in that industry and geographical region. The Company will engage in ongoing monitoring of third-party relationships through updated due diligence, training, audits, and/or annual compliance certifications by the third party.

14. Where necessary and appropriate, the Company will include standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the FDCA and its associated regulations, which may, depending upon the circumstances, include:

a. undertakings relating to compliance with the FDCA and its associated regulations;

b. rights to conduct audits of the facilities, documents, and records of the agent or business partner to ensure compliance with the foregoing; and

c. rights to terminate an agent or business partner as a result of any breach of the FDCA and its associated regulations, the Company's compliance code, policies, or procedures, or the representations and undertakings related to such matters.

Mergers and Acquisitions

15. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential

new business entities, including appropriate due diligence regarding the FDCA and its associated regulations by legal and compliance personnel. The Company will ensure that its compliance code, policies, and procedures regarding the FDCA and its associated regulations apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:

a. train the directors, officers, employees, agents, and business partners consistent with Paragraph 6 above on the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations; and

b. where warranted, conduct an audit of all newly acquired or merged businesses as quickly as practicable concerning compliance with the FDCA and its associated regulations.

Monitoring, Testing, and Remediation

16. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance codes, policies, and procedures regarding the FDCA and its associated regulations designed to evaluate and improve their effectiveness in preventing and detecting violations of the FDCA and its associated regulations and the Company's compliance codes, policies, and procedures regarding the FDCA and its associated regulations, as applicable, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company, its customers, and its products. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

ATTACHMENT D

COMPLIANCE REPORTING REQUIREMENTS

The duties and authority of the Independent Compliance Monitor (the "Monitor"), and the obligations of KVK Tech, Inc. (the "Company"), on behalf of itself and its subsidiaries and affiliates, with respect to the Monitor and the United States Department of Justice, Consumer Protection Branch, and the United States Attorney's Office for the Eastern District of Pennsylvania (collectively, the "Offices") are as described below. In addition, the Company agrees that it will report to the Offices periodically. The Monitor and Company shall transmit copies of all work plans, reports, certifications, and other notices to the Offices as required herein in accordance with the requirements for all notices as described in Paragraph 30 of the Deferred Prosecution Agreement (the "Agreement").

INDEPENDENT COMPLIANCE MONITOR

1.e The Company will retain the Monitor for a period of thirty-six (36) months (the "Terme of the Monitorship") unless the early termination provision of Paragraph 4 of the Agreement is triggered. The cost of the Monitor will be borne by the Company.

Monitor's Mandate

2.e The Monitor's primary responsibility is to assess and monitor the Company'se compliance with the terms of the Agreement, including the Corporate Compliance Program in Attachment C, to specifically address and reduce the risk of any recurrence of the Company's misconduct. During the Term of the Monitorship, the Monitor will evaluate, in the manner set forth below, the effectiveness of the policies and procedures, internal controls, training, and record- keeping as they relate to the Company's current and ongoing compliance with regulations promulgated under the Federal Food, Drug, and Cosmetic Act under:

a. 21 C.F.R. part 314 relating to applications for approval to market a new drug ("Application Regulations"); and

b. 21 C.F.R. parts 210 and 211 relating to current good manufacturing practice ("cGMP Regulations"); and take such reasonable steps as, in his or her view, may be necessary to fulfill the foregoing mandate (the "Mandate"). This Mandate shall include an assessment of the Board of Directors' and senior management's commitment to, and effective implementation of, the Corporate Compliance Program described in Attachment C.

Company's Obligations

3. The Company shall cooperate fully with the Monitor, and the Monitor shall have the authority to take such reasonable steps as, in his or her view, may be necessary to be fully informed about the Company's compliance program in accordance with the principles set forth herein and subject to applicable law, including any applicable data protection and labor laws and regulations. To that end, the Company shall: facilitate the Monitor's access to the Company's documents and resources; not limit such access, except as provided in Paragraphs 5–6; and, where necessary, provide guidance on applicable local law (such as relevant data protection and labor laws). The Company shall provide the Monitor with access to all information, documents, records, facilities, and employees, as reasonably requested by the Monitor, that fall within the scope of the Mandate of the Monitor under the Agreement. The Company shall use its best efforts to provide the Monitor with access to the Company's former employees and its third-party vendors, agents, and consultants. If the Company challenges a request made by the Monitor under this paragraph, the determination of the reasonableness of the request will be made by the Offices in their sole discretion.

4. Any disclosure by the Company to the Monitor concerning violations of the cGMP or Application Regulations shall not relieve the Company of any otherwise applicable obligation to

truthfully disclose such matters to the Offices as described below in the Additional Reporting Requirements.

Withholding Access

5. The parties agree that no attorney-client relationship shall be formed between the Company and the Monitor. In the event that the Company seeks to withhold from the Monitor access to information, documents, records, facilities, or current or former employees of the Company that may be subject to a claim of attorney-client privilege or to the attorney work-product doctrine, or where the Company reasonably believes production would otherwise be inconsistent with applicable law, the Company shall work cooperatively with the Monitor to resolve the matter to the satisfaction of the Monitor. If the matter cannot be resolved, at the request of the Monitor, the Company shall promptly provide written notice to the Monitor and the Offices. Such notice shall include a general description of the nature of the information, documents, records, facilities, or current or former employees that are being withheld, as well as the legal basis for withholding access. The Offices may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

Monitor's Coordination with the Company and Review Methodology

6. In carrying out the Mandate, to the extent appropriate under the circumstances, the Monitor should coordinate with Company personnel, including in-house counsel, compliance personnel, regulatory and quality personnel, manufacturing personnel, and internal auditors, on an ongoing basis. The Monitor and the Offices may confer on an ongoing basis to the extent appropriate. The Monitor may rely on the product of the Company's processes, such as the results of studies, reviews, sampling and testing methodologies, audits, and analyses conducted by or on behalf of the Company, as well as the Company's internal resources (e.g., legal, compliance, regulatory, quality, and internal audit), which can assist the Monitor in carrying out the Mandate through increased efficiency

and Company-specific expertise, provided that the Monitor has confidence in the quality of those resources. The Monitor may take steps he or she deems appropriate to investigate and test the quality of those resources. The Monitor's reviews should use a risk-based approach, and thus, the Monitor is not expected to conduct a comprehensive review of all business activities. In carrying out the Mandate, the Monitor should consider, for instance, risks presented by: (a) the industries in which the Company operates; (b) the Company's products; (c) the Company's customers; (d) the Company's current and future business opportunities and transactions; (e) current and potential business partners, including third parties and joint ventures; and (f) the Company's history of statutory and regulatory violations.

7.e In undertaking the reviews to carry out the Mandate, the Monitor shall formulatee conclusions based on, among other things: (a) inspection of relevant documents, including the Company's current compliance policies and procedures regarding cGMP or Application Regulations; (b)on-site observation of selected systems and procedures of the Company, including those related toe internal controls, record-keeping, quality, regulatory, manufacturing, and internal audits; (c) meetings with, and interviews of, relevant current and, where appropriate, former directors, officers, employees, business partners, agents, and other persons at mutually convenient times and places; and (d) analyses, studies, and testing of the Company's compliance program.

Monitor's Written Work Plans

8.e To carry out the Mandate, during the Term of the Monitorship, the Monitor shalle conduct an initial ("first") review and submit a first report, followed by at least two follow-up reviews and reports, as described in Paragraphs 10–17, below. With respect to the first report, after consultation with the Company and the Offices, the Monitor shall prepare and submit the first written work plan within sixty (60) calendar days of being retained, and the Company and the Offices shall provide comments within thirty (30) calendar days after receipt of the written work plan. With respect to each follow-up report, after consultation with the Company and the Offices, the Monitor shall prepare and

submit a written work plan at least thirty (30) calendar days prior to commencing a review, and the Company and the Offices shall provide comments within twenty (20) calendar days after receipt of the written work plan. Any disputes between the Company and the Monitor with respect to any written work plan shall be decided by the Offices in their sole discretion. All written work plans shall identify with reasonable specificity the activities the Monitor plans to undertake in execution of the Mandate, including a written request for documents. The Monitor's work plan for the first review shall include such steps as are reasonably necessary to conduct an effective first review in accordance with the Mandate, including by developing an understanding, to the extent the Monitor deems appropriate, of the facts and circumstances surrounding any violations that may have occurred before the date of the Agreement. In developing such understanding, the Monitor is to rely, to the extent possible, on available information and documents provided by the Company. It is not intended that the Monitor will conduct his or her own inquiry into the historical events that gave rise to the Agreement.

First Review

9.e The first review shall commence no later than one hundred twenty (120) calendar dayse from the date of the retention of the Monitor (unless otherwise agreed by the Company, the Monitor, and the Offices). The Monitor shall prepare and submit to the Board of Directors of the Company and the Offices a written report within one hundred fifty (150) calendar days of commencing the first review, setting forth the Monitor's assessment and, if necessary, making recommendations reasonably designed to improve the effectiveness of the Company's program for ensuring compliance with the cGMP or Application Regulations. The Monitor should consult with the Company concerning his or her findings and recommendations on an ongoing basis and should consider the Company's comments and input to the extent the Monitor deems appropriate. The Monitor may also choose to share a draft of his or her report with the Company prior to finalizing it. The Monitor's report need not recite or

describe comprehensively the Company's history or compliance policies, procedures and practices. Rather, the report should focus on areas the Monitor has identified as requiring recommendations for improvement or which the Monitor otherwise concludes merit particular attention. After consultation with the Company and with prior written approval of the Offices, the Monitor may extend the time period for submission of the first report for a brief period of time.

10. Within one hundred fifty (150) calendar days after receiving the Monitor's first report, the Company shall adopt and implement all recommendations in the report unless, within sixty (60) calendar days after receiving the report, the Company notifies the Monitor and the Offices in writing concerning any recommendations that the Company considers inconsistent with applicable law or regulation or impractical, and the reasons why. With respect to any such recommendation, the Company shall include in its written notice a proposal for an alternative policy, procedure, or system designed to achieve the same objective or purpose, and the Company need not adopt that recommendation within the one hundred fifty (150) calendar days of receiving the report. As to any recommendation on which the Company and the Monitor do not agree, such parties shall attempt in good faith to reach an agreement within forty-five (45) calendar days after the Company serves the written notice.

11. In the event the Company and the Monitor are unable to agree on an acceptable alternative proposal, the Monitor shall notify the Offices and the Company shall promptly consult with the Offices. The Offices may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement. Pending such determination, the Company shall not be required to implement any contested recommendation(s). The determination shall be decided by the Offices in their sole discretion.

12. With respect to any recommendation that the Monitor determines cannot reasonably be implemented within one hundred fifty (150) calendar days after receiving the report, with prior written approval of the Offices, the Monitor may extend the time period for implementation.

Follow-Up Reviews

13. A follow-up review shall commence no later than one hundred and eighty (180) calendar days after the submission of the first report (unless otherwise agreed by the Company, the Monitor, and the Offices). The Monitor shall prepare and submit to the Board of Directors of the Company and the Offices a written follow-up ("second") report within one hundred twenty (120) calendar days of commencing the second review, setting forth the Monitor's assessment and, if necessary, making recommendations in the same fashion as set forth in Paragraph 10 with respect to the first review. After consultation with the Company and with prior written approval of the Offices, the Monitor may extend the time period for submission of the second report for a brief period of time.

14. Within one hundred twenty (120) calendar days after receiving the Monitor's second report, the Company shall adopt and implement all recommendations in the report, unless, within thirty (30) calendar days after receiving the report, the Company notifies the Monitor and the Offices in writing concerning any recommendations that the Company considers inconsistent with applicable law or regulation or impractical, and the reasons why. With respect to any such recommendation, the Company shall include in its written notice a proposal for an alternative policy, procedure, or system designed to achieve the same objective or purpose, and the Company need not adopt that recommendation within the one hundred twenty (120) calendar days of receiving the report. As to any recommendation on which the Company and the Monitor do not agree, such parties shall attempt in good faith to reach an agreement within thirty (30) calendar days after the Company serves the written notice.

15.e In the event the Company and the Monitor are unable to agree on an acceptablee alternative proposal, the Monitor shall notify the Offices and the Company shall promptly consult with the Offices. The Offices may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement. Pending such determination, the Company shall not be required to implement any contested recommendation(s). The determination shall be decided by the Offices in their sole discretion. With respect to any recommendation that the Monitor determines cannot reasonably be implemented within one hundred twenty (120) calendar days after receiving the report, with prior written approval of the Offices, the Monitor may extend the time period for implementation.

16.e The Monitor shall undertake a second follow-up ("third") review not later than onee hundred fifty (150) calendar days after the submission of the second report. The Monitor shall prepare and submit to the Board of Directors of the Company and the Offices a third report within one hundred and twenty (120) calendar days of commencing the review, and recommendations shall follow the same procedures described in Paragraphs 14–16. No later than thirty (30) calendar days before the end of the Term of the Monitorship, the Monitor also shall submit to the Offices a certification as to whether the Company's compliance program, including its policies, procedures, and internal controls, is reasonably designed and implemented to prevent and detect violations of the cGMP or Application Regulations.

Monitor's Discovery of Reportable Events

17.e Except as set forth below in Paragraph 19, should the Monitor discover during thee course of his or her engagement a matter that, after a reasonable opportunity to conduct an appropriate review or investigation of the allegations, a reasonable person would consider a material violation of the cGMP or Application Regulations (a "Reportable Event"), the Monitor shall immediately report the Reportable Event to the Company's General Counsel and/or Chief Compliance Officer for further action, unless the Reportable Event was already so disclosed. The Monitor also may report the

Reportable Event to the Offices at any time, and shall report the Reportable Event to the Offices when they request the information. A minor cGMP issue will not be considered a Reportable Event unless it constitutes a significant compliance program failure.

18. If the Monitor believes that a Reportable Event poses a substantial risk of harm to the public, the Monitor shall immediately report that information to the General Counsel and/or Chief Compliance Officer of the Company and to the Offices. If the Monitor believes that a Reportable Event may constitute a felony under the laws of the United States, the Monitor shall immediately report such information solely to the Offices, and in such cases, disclosure of the same to the General Counsel or Chief Compliance Officer of the Company should only occur as the Offices deem appropriate under the circumstances.

19. The Monitor shall address in his or her reports the appropriateness of the Company's response to disclosed Reportable Events whether previously disclosed to the Offices or not. Further, if the Company or any entity or person working directly or indirectly on behalf of the Company withholds information necessary for the performance of the Monitor's responsibilities and the Monitor believes that such withholding is without just cause, the Monitor shall also immediately disclose that fact to the Offices and address the Company's failure to disclose the necessary information in his or her reports.

20. Neither the Company nor anyone acting on its behalf shall take any action to retaliate against the Monitor for any such disclosures or for any other reason.

Additional Reporting Requirements

21. The Company shall submit written reports to the Offices concerning Reportable Events on a quarterly basis, whether previously disclosed to the Offices by the Monitor or not. A Reportable Event may be the result of an isolated event or a series of occurrences. The written report shall include:

(a)ewhether any Reportable Events have been determined to have occurred during the precedinge calendar quarter, and providing updated information about Reportable Events that the Company determined to have occurred during any prior calendar quarter, as may be necessary in the reasonable determination of the Company or at the Offices' request; (b) a description of the Reportable Event, including the relevant facts, the positions of the persons involved, and the legal authorities implicated; (c)ea description of the Company's actions taken to investigate and correct the Reportable Event; ande (d) a description of any further steps the Company plans to take to address the Reportable Event ande prevent it from recurring. The written reports shall be submitted to the Offices no later than fifteen (15) calendar days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending September 30), excepting any calendar quarter that ends within thirty (30) calendar days of the expiration of the Agreement.

22.e No later than twelve (12) months from the Effective Date of this Agreement, the Companye shall submit to the Offices a certification from the Chief Executive Officer of the Company, in the form of executing the document attached as Attachment E to this Agreement. The certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed. The Company shall deliver a second certification no later than twelve (12) months after the first certification, and a final certification no later than thirty (30) calendar days before the expiration of the Agreement.

Additional Information and Meetings During the Agreement

23.e Upon request of the Offices in their sole discretion, the Company shall provide to thee Offices additional information or documents regarding its compliance-related improvements, processes, and controls. The Company's cooperation pursuant to this Paragraph is subject to applicable

law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Offices a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion.

24. When the Offices deem it appropriate in their sole discretion, representatives from the Company, the Monitor, and the Offices will meet to discuss the status of the review and reporting obligations, and any suggestions, comments, or improvements the Company or Monitor may wish to discuss with or propose to the Offices.

. ***Confidentiality of Submissions***

25. Submissions by the Monitor and the Company, including the work plans and reports, may include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the submissions could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the monitorship and reporting requirements. For these reasons, among others, the submissions and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.

ATTACHMENT E

CERTIFICATION

To: United States Department of Justice
Consumer Protection Branch
Attn: Corporate Compliance & Policy Unit

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certifies, pursuant to Attachment D of the Deferred Prosecution Agreement ("DPA") filed on in the U.S. District Court for the Eastern District of Pennsylvania by and between the United States Department of Justice, Consumer Protection Branch, and the United States Attorney's Office for the Eastern District of Pennsylvania (collectively, the "Offices") and KVK Tech, Inc. (the "Company"), that the undersigned is aware of the Company's obligations under Attachment D of the DPA and has reviewed the Monitor's [first/second/third] written work plan and compliance report. The undersigned further certifies that to date, the Company has disclosed to the Offices all Reportable Events as required by Attachment D of the DPA.

The undersigned further acknowledges and agrees that the reporting requirements contained in Attachment D of the DPA and the representations contained in this certification constitute a significant and important component of the DPA and the Offices' determination of whether the Company has satisfied its obligations under the DPA.

The undersigned hereby certifies that he is the Chief Executive Officer ("CEO") of the Company and has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States

for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the Eastern District of Pennsylvania. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the Eastern District of Pennsylvania.

By: _____ Dated: _____

ANTHONY TABASSO
Chief Executive Officer
KVK Tech, Inc.

ATTACHMENT D

CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, KVK Research, Inc., (the "Company") has been engaged in discussions with the United States Department of Justice, Consumer Protection Branch, and the Office of the United States Attorney for the Eastern District of Pennsylvania (collectivcly, the "Offices") regarding issues arising in relation to violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"); and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Offices; and

WHEREAS, the Company's President and Chief Executive Officer, Anthony Tabasso, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Offices;

Therefore, the Board of Directors has RESOLVED that:

1.e The Company: (a) acknowledges the filing of the two-count Information charging thee Company with misdemeanor violations of the FDCA, namely the introduction of adulterated drugs into interstate commerce, in violation of sections 331(a) and 333(a)(1) of Title 21, United States Code; and (b)ewaives any right it might have had to indictment on such charges and enters into a Deferrede Prosecution Agreement (the "Agreement") with the Offices.

2.e The Company accepts terms and conditions of this Agreement, including, but note limited to: (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, section 3161 of Title 18, United States Code, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Eastern District of Pennsylvania; and (c) a knowing waiver of any applicable statute of limitations defenses in any prosecution by the Offices relating to the conduct described in the Information, the Statement of Facts, or conduct known to the Offices prior to the

Effective Date of this Agreement;

3. The President and Chief Executive Officer of Company, Anthony Tabasso, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Guilty Plea Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the President and Chief Executive Officer of Company Anthony Tabasso may approve;

4. The President and Chief Executive Officer of Company, Anthony Tabasso, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the President and Chief Executive Officer of Company, Anthony Tabasso, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 02/07/2024

By: _____
ANTHONY TABASSO, ESQ.
Chairman of the Board of Directors
KVK Research, Inc.

ACKNOWLEDGMENT

COMMONWEALTH OF PENNSYLVANIA)
) SS
COUNTY OF BUCKS)

On this, the 7th day of February, 2024, before me, the undersigned Notary Public, personally appeared Anthony P. Tabasso who acknowledged himself to be the Chairman of the Board for KVK Research, Inc., and he being ~~authorized~~ to do so, executed the within instrument, and acknowledged that he executed the same for the purposes therein contained.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

Notary Public
My commission expires:

Commonwealth of Pennsylvania - Notary Seal
SUSAN DICROCE - Notary Public
Bucks County
My Commission Expires Jul 25, 2024
Commission Number 1270745