

**CHAD C. SPRAKER**  
Assistant United States Attorney  
**PETER J. LEININGER**  
Special Assistant United States Attorney  
U.S. Attorney's Office  
901 Front Street, Suite 1100  
Helena, MT 59626  
Phone: (406) 457-5120  
FAX (406) 457-5130  
Email: chad.spraker@usdoj.gov

**ATTORNEY FOR PLAINTIFF**  
**UNITED STATES OF AMERICA**

**UNITED STATES DISTRICT COURT**  
**DISTRICT OF MONTANA**  
**BUTTE DIVISION**

UNITED STATES OF AMERICA

v.

MEIKO AMERICA, INC.,

Defendant.

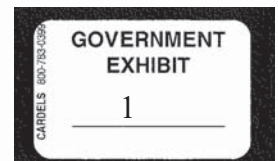
Criminal No.:

**DEFERRED PROSECUTION AGREEMENT**

The United States Attorney's Office for the District of Montana and Meiko America, Inc. ("Meiko" or "the Company"), pursuant to the authority granted by Meiko's Board of Directors, enter into this Deferred Prosecution Agreement.

**Criminal Information and Deferred Prosecution**

1. Meiko consents to the filing, in the United States District Court for the District of Montana, of a one count misdemeanor criminal information charging Meiko with the



introduction and causing the introduction into interstate commerce of a misbranded drug, in violation of Title 21, United States Code, Sections 331(c), 333(a)(1), and 352, and agrees to venue of the case in the District of Montana.

2. This Agreement shall be in effect for a period of three years from the date of its execution (the "Term of the Agreement"). Meiko may petition the Government to shorten the term of the Agreement after one year. The Government has sole discretion to determine whether a shorter term is warranted.

3. In consideration of the Company's entering into this Agreement and its commitment to: (a) accept corporate responsibility for the conduct described in Attachment A; (b) pay \$76,063.37 to the United States; (c) enforce the Compliance Program set forth in Attachment B; and (d) otherwise comply with the terms of this Agreement, the Government agrees to defer for the Term of the Agreement its prosecution of Meiko on the Information described in paragraph 1 (1) for the conduct described in Attachment A; and/or (2) any importation, storage, or shipping of pharmaceuticals, including but not limited to, counterfeit, adulterated, or misbranded pharmaceuticals from January 1, 2008 through the date of this Agreement that was either the subject matter of the investigation that led to this Agreement or known to the Government as of the date of this Agreement, including but not limited to, conspiracy, 18 U.S.C. § 371, smuggling, 18 U.S.C. § 545, false statements, 18 U.S.C. § 1001, and distribution of misbranded or adulterated pharmaceuticals, 21 U.S.C. §§ 331, et seq. This Paragraph does not provide any protection against prosecution for illegal activities, if any, committed in the future by Meiko, or its parent companies or subsidiaries, nor does it apply to any illegal conduct that may have occurred in the past which is not described in this Paragraph.

4. During the Term of the Agreement, Meiko waives its right to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code section 3161, and Federal Rule of Criminal Procedure 48(b), and the parties agree that, pursuant to 18 U.S.C. § 3161(h)(2), the period of delay during which prosecution is deferred is excluded from the time within which trial of the offense charged must commence.

5. The Government further agrees that if the Company fully complies with all of its obligations under this Agreement, at the conclusion of the Term of the Agreement, the Government will seek dismissal with prejudice of the criminal prosecution against the Company described in Paragraph 1.

Breach of Agreement

6. It is understood that if, within the Term of the Agreement, the Government determines in the reasonable exercise of its sole discretion, that the Company or any of its employees, officers or directors: (a) has deliberately given false, incomplete, or misleading testimony or information in the investigation that led to this Agreement, (b) has committed any knowing and intentional criminal conduct relating to the importation or distribution of pharmaceuticals manufactured in foreign countries after the date of this Agreement, or (c) has otherwise deliberately violated any provision of this Agreement, including that set forth in Attachment B, the Company shall, in the sole discretion of the Government, be subject to prosecution for any federal criminal violation of which the Government has knowledge, including a prosecution based upon the conduct specified in Attachment A. Conduct by a Meiko employee who is not an officer or director will not constitute breach of this Agreement unless



that employee acted in the course and scope of his or her employment and intended to benefit the Company.

7. The Company agrees that it is within the sole discretion of the Government to determine whether there has been a deliberate violation of this Agreement. The Company understands and agrees that the exercise of discretion by the Government under this Agreement is not reviewable by any court. In the event that the Government preliminarily determines that the Company has deliberately violated this Agreement, the Government shall provide written notice to the Company of that preliminary determination sufficient to notify the Company of the conduct that constitutes the breach and shall provide the Company with thirty calendar days from the date of that written notice in which to make a presentation to the Government to demonstrate that no deliberate breach has occurred, or to the extent applicable, that the breach has been cured, or that the Government should, in any event, neither revoke the Agreement nor prosecute the Company. The Government shall thereafter provide written notice to the Company of its final determination regarding whether a deliberate breach has occurred and has not been cured and whether the Government will revoke the Agreement.

8. Meiko further understands and agrees that any prosecution following such determination may be premised on any information provided by Meiko and its employees, officers and directors to the Government and any leads derived therefrom. Meiko agrees that, in any such proceeding, it will not seek to suppress the use of any such information, or any leads derived therefrom, under the United States Constitution, Federal Rule of Evidence 410, Federal Rule of Criminal Procedure 11(f), or any other rule; that it will not contradict in any such proceeding the Agreed Statement of Facts in Attachment A; and that it will stipulate to the

admissibility of the Agreed Statement of Facts in Attachment A. Meiko further agrees that it shall not contest the authenticity of documents and materials provided to the Government by Meiko and/or Meiko's parent companies or subsidiaries in the course of the Government's investigation, but Meiko otherwise may challenge the admissibility of any such materials in any prosecution of Meiko. By signing this Agreement, Meiko waives all rights in the foregoing respects.

Tolling of the Statute of Limitations

9. Meiko agrees to toll and to exclude from any calculation of time the running of the statute of limitations for any criminal charges brought by the U.S. Attorney's Office for the District of Montana relating to the importation or distribution of pharmaceuticals manufactured in foreign countries for three years from the date of execution of this Agreement. By this Agreement, the Company expressly intends to and hereby does waive its rights to make a claim premised upon the statute of limitations, as well as any constitutional, statutory, or other claim concerning pre-indictment delay, in connection with any action brought by the U.S. Attorney's Office for the District of Montana. Such waivers are knowing, voluntary, and in express reliance upon the advice of the Company's counsel. Nothing in this Agreement shall prevent or preclude Meiko from raising any defense or making any claim or argument based upon the statute of limitations or pre-indictment delay relating to the passage of time prior to the signing of this agreement. Nor shall this Agreement be construed to revive any offense for which the statute of limitations had expired prior to the date of this Agreement.

Acceptance of Responsibility

10. Meiko accepts and acknowledges responsibility for the acts of its present and former employees, as set forth in the Agreed Statement of Facts in Attachment A. Meiko further agrees that the factual statements set forth in the Agreed Statement of Facts in Attachment A are accurate. Meiko condemns and does not condone the conduct set forth in the Agreed Statement of Facts in Attachment A, and has taken steps to prevent such conduct from occurring in the future, including the creation and implementation of the Corporate Compliance Agreement set forth in Attachment B.

Cooperation

11. During the term of this Agreement, Meiko agrees to cooperate fully with the Government in any ongoing investigation of individuals or entities who may have been involved in the importation and distribution of non-FDA approved, misbranded, or counterfeit pharmaceuticals, including the conduct described in Attachment A. Meiko also agrees to cooperate fully with the Government in *United States v. Canadadrugs.com Limited Partnership, et al.*, Case No. 2:14-cr-00027 (D. Montana), until any such case is resolved, even if such case extends beyond the term of this Agreement. Meiko agrees that its cooperation shall include, but is not limited to, the following:

- a. timely provision to the Government of all non-privileged documents and other materials, including documents and materials located outside the United States (and not otherwise prohibited from disclosure to the Government by foreign law), that the Government may request; and
- b. its best efforts upon sufficient notice to make available in a timely and voluntary manner to the Government all present officers and former, directors and employees for sworn testimony before a federal grand jury or in a federal trial and interviews with federal law enforcement authorities. Cooperation under this paragraph will include identification of witnesses not previously identified who,



to the knowledge of Meiko may have material information regarding the matters under investigation.

12. Meiko's obligation to cooperate pursuant to the preceding paragraph is not intended to apply if a prosecution by the Government is commenced against Meiko as a result of a breach of this Agreement.

13. Nothing in this Agreement is intended to request or require Meiko to waive its attorney-client privilege or work production protections and no such waiver shall be deemed effected by any provision herein.

14. With respect to any information, testimony, document, record, or tangible evidence provided to the Government pursuant to this Agreement, Meiko consents to any and all disclosures to other government agencies, whether agencies of the United States or a foreign government, of such materials as the Government, in its sole discretion, shall deem appropriate.

#### Notice of Cooperation

15. The Government agrees to bring to the attention of governmental authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of Meiko's cooperation and remediation, upon request. By agreeing to provide this information to any such authorities, the Government is not agreeing to advocate on Meiko's behalf, but rather is providing facts to be evaluated independently by those authorities.

#### Monetary Payment

16. Meiko agrees to make the above-described \$76,063.37 payment to the federal government as a settlement for all of the conduct described in Attachment A (the "Settlement Funds"). Within ten (10) business days of the date of execution of this Agreement by the parties,

Meiko shall pay the Settlement Funds by certified check or bank cashier's check made payable to the <sup>Clerk of Court</sup> ~~United States of America~~.

<sup>cc 5</sup>  
<sup>10-24-16</sup>  
17. Meiko releases any and all claims it may have to the Settlement Funds. The total amount paid is a final payment and shall not be refunded should the Government later determine that Meiko has breached this Agreement and commence a prosecution against Meiko. Further, in the event of a breach of this Agreement, nothing shall preclude the Government from arguing in such a prosecution that the Court should impose fine or forfeiture in addition to the Settlement Funds. The Government agrees, however, that in the event of a subsequent breach and prosecution, it will recommend to the Court that the Settlement Funds paid pursuant to this Agreement be offset against whatever fine or forfeiture the Court shall impose as part of its judgment. Meiko understands that such a recommendation will not be binding on the Court. Meiko acknowledges that no tax deduction or insurance claim may be sought in the event a court imposes fines or forfeiture.

#### Corporate Compliance Agreement

18. Meiko agrees to implement the Corporate Compliance Agreement set forth in Attachment B. Meiko will begin to implement the measures set forth in Attachment B within thirty (30) days of the date of execution of this Agreement by the parties. Meiko agrees that it will maintain these measures at least through the term of this Agreement.

#### Basis for Agreement

19. The Government enters into this Agreement based upon the following facts and circumstances: (a) Meiko's ongoing cooperation with the Government and the FDA since April 2012; (b) Meiko's willingness to accept responsibility for the conduct of its present and former



officers and employees; (c) Meiko has undertaken, and has agreed to undertake, remedial measures to ensure that such conduct will not recur; and (d) Meiko's demonstration of compliance with federal Food and Drug and Customs laws.

Statements to the Media and Public

20. Meiko agrees that it will not make any public statement contradicting Attachment A. If the Government notifies the Company that it has preliminarily determined, in its sole discretion, that the Company has made any such contradictory statement, the Company may avoid a finding of breach of this Agreement by repudiating such statement, in a manner satisfactory to the Government, both to the recipients of such statement and to the Government within 48 hours after receipt of notice from the Government. The Company consents to the public release by the Government of any such repudiation. Consistent with the above, the Company may avail itself of any legal or factual arguments available to it in any litigation, investigation or proceeding (not involving the Government), as long as doing so does not otherwise violate any term of this Agreement. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory or administrative proceeding or civil case initiated by any governmental or private party against such individual.

Corporate Authority

21. Meiko hereby warrants and represents that it is authorized to enter into this Agreement and that the person signing on behalf of Meiko has been granted authority by the Meiko Board of Directors to bind Meiko.

Binding Nature of the Agreement

22. It is understood that this Agreement is binding on Meiko and the United States Attorney's Office for the District of Montana but that this Agreement does not bind any other federal agencies, or any state or local enforcement or regulatory agencies.

Successor Liability

23. Meiko agrees that in the event it sells, merges or transfers all or substantially all of its business operations as they exist during the term of this Agreement, whether such sale is structured as a stock or asset sale, merger, or transfer, it shall include in any contract for sale, merger or transfer provisions binding the purchaser or any successor-in-interest thereto to the obligations described in this Agreement. Meiko expressly understands that the protections provided under this Agreement shall not apply to any acquirer or successor entities unless and until such acquirer or successor formally adopts and accepts this Agreement.

Notice

24. Any notice to Meiko under this Agreement shall be given by personal delivery, overnight delivery by a recognized courier service, or registered or certified mail, addressed to Meiko America, Inc., 19600 Magellan Drive, Torrance, CA 90502, with a copy to Kenneth B. Julian, Manatt, Phelps & Phillips LLP, Park Tower, 695 Town Center Drive, 14th Floor, Costa Mesa, CA 92626.

Required Signatures, Authorization

25. By signing this Agreement, Meiko's duly authorized representative and Meiko's counsel acknowledge that the terms set forth above accurately reflect the parties' understanding of the Deferred Prosecution Agreement between Meiko and the Government.

26. This agreement may be signed in counterparts, and electronic or facsimile signatures shall be deemed originals.

Complete Agreement

27. This Agreement sets forth the terms of the Deferred Prosecution Agreement between Meiko and the Government. No promises, agreements, or conditions have been entered into other than those set forth in this Agreement. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral.

28. No amendments or modifications to this Agreement shall be valid unless they are in writing and signed by the Government, the attorneys for Meiko and a duly authorized representative of Meiko.

**FOR THE UNITED STATES OF AMERICA**

DATED:

10-24-16

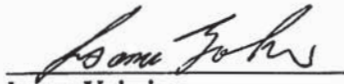
MICHAEL W. COTTER  
United States Attorney



Chad C. Spraker  
Assistant United States Attorney

**FOR MEIKO AMERICA INC.**

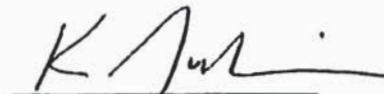
DATED: 10/17/2016



Isamu Yokoi  
President and CFO, Meiko America, Inc.

DATED:

10/17/2016



Kenneth B. Julian  
Manatt, Phelps & Phillips LLP



**Attachment A**

**AGREED STATEMENT OF FACTS**

1. Meiko America, Inc. ("Meiko") is a corporation organized under the laws of California and headquartered in Torrance, California.

2. From approximately August 2008 through February 2012, Meiko was engaged by a third party client to receive, store, and ship drugs. After Meiko ceased doing business with the third-party, it was informed by law enforcement that these drugs were not approved by the United States Food and Drug Administration, and were misbranded under the Food, Drug, and Cosmetic Act.

3. The misbranded drugs included oncology drugs such as Avastin and a Turkish version of the drug, Altuzan. On various occasions in this time frame, per the instructions of Meiko's third party client, Meiko received, stored, and shipped these drugs to healthcare providers in the United States.

4. At various times in 2011, based upon facts it observed, Meiko questioned its third party client about, among other things, (i) whether the drugs Meiko was receiving, storing, and shipping had been approved for sale in the United States by the U.S. Food and Drug Administration; (ii) whether these drugs had been cleared by U.S. Customs and Border Protection before being delivered to Meiko; and (iii) whether the relevant customs forms on the shipments received by Meiko understated the value of the products therein.

5. Meiko's third party client stated to Meiko that it was "following all the requirements...to stay compliant." However, the third party client did not specifically address whether the relevant customs forms understated the value of the drugs. Despite being aware of these facts, Meiko did not immediately terminate the business relationship.

6. In December 2011, Meiko's third party client instructed Meiko to ship five units of the drug Avastin, lot #B6011B02. Meiko complied with the instruction and shipped the Avastin at issue. Meiko was not informed by its third party client that the Avastin was potentially counterfeit. Subsequent lab testing conducted by the United States Food and Drug Administration confirmed that Avastin distributed by Meiko's third party client labeled as lot #B6011B02 was counterfeit and did not contain the active ingredient bevacizumab.

**Attachment B**

**MEIKO COMPLIANCE PROGRAM**

The following Meiko America, Inc. ("Meiko") Compliance Program (the "Compliance Program") has been prepared pursuant to a Deferred Prosecution Agreement dated this same date between Meiko (the "Company") and the United States Attorney's Office for the District of Montana ("United States" or "the Government"). Compliance with all the terms and standards of the Compliance Program is a condition of the Deferred Prosecution Agreement.

**I. Applicability and Purpose**

**A.** The Compliance Program is not intended to replace any other United States statute or regulation.

**B.** This Compliance Program shall be incorporated into the Deferred Prosecution Agreement by reference, and compliance with the terms of the Compliance Program will be a condition of the Deferred Prosecution Agreement. Deliberate, intentional or knowing failure to comply with any part of this Compliance Program may be a basis on which the Government may seek to revoke or modify the Deferred Prosecution Agreement.

**C.** Any documents required by this Compliance Program shall be provided to the designated signatory for the Government upon request.

**D.** Any proposed modifications to this Compliance Program must be made in writing and signed by the Company and the designated signatory for the Government.

**II. The Compliance Program**

Pursuant to the Compliance Program, the Company shall implement the following requirements:

- 1.** Meiko shall institute a training program to ensure that pertinent employees are familiar with the requirements of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* that could potentially apply to Meiko's conduct.
- 2.** Meiko shall evaluate its current business to ensure that it is not currently receiving, distributing, or handling misbranded or unapproved prescription drugs.
- 3.** If Meiko becomes aware that it is receiving, distributing, or handling misbranded or unapproved prescription drugs, Meiko shall report all information concerning such activity to the United States Food and Drug Administration within 30 days of discovery.



4. Meiko shall annually certify to the United States that it is in compliance with the terms of this Compliance Program.

### **III. Non-compliance**

The Compliance Program is part of the Deferred Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of this Compliance Program may be a violation of the Deferred Prosecution Agreement and may be grounds for the revocation or modification of the Deferred Prosecution Agreement.

This Compliance Program does not in any way release the Company from complying with any applicable state or federal statutes and/or regulations, and does not limit imposition of any sanctions, penalties, or any other actions, available under those state or federal statutes and regulations.

### **IV. Term**

This Compliance Program shall be in effect for thirty-six (36) months, the term of the Deferred Prosecution Agreement.

### **V. Self-enforcement**

The Company further agrees that it will undertake and implement the necessary procedures to ensure that this Compliance Program is diligently complied with by all employees, managers, and other employees during the term of the Deferred Prosecution Agreement.

### **VI. Revisions/modifications**

The requirements of this Compliance Program, including the dates and time periods mentioned herein, shall be strictly complied with. Should the Company be unable to comply with any of the deadlines, the Company shall immediately notify the designated representative of the Government in writing of the reasons for non-compliance.

### **VII. Reports**

All reports, documents and correspondence required under this Compliance Program to be sent to the Government shall be sent to the following offices:

1. U.S. Attorney's Office  
District of Montana  
ATTN: Chad Spraker  
2601 2nd Ave N.  
Box 3200  
Billings, MT 59101



2. U.S. Food and Drug Administration  
ATTN: Peter Leininger  
10903 New Hampshire Ave.  
WO32-4377  
Silver Spring, MD 20903

All reports, documents, notices and correspondence from the Government to the Company concerning this Compliance Program shall be sent to the following office:

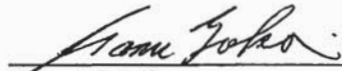
Kenneth B. Julian  
Manatt, Phelps & Phillips, LLP  
Park Tower  
695 Town Center Drive, 14th Floor  
Costa Mesa, CA 92626

#### **VIII. Certifications**

The Company has read this Compliance Program carefully and understands it thoroughly. The Company enters into this Compliance Program knowingly and voluntarily, and therefore agree to abide by its terms. By his signature below, the corporate representative agrees that he is duly authorized by the Company's Board of Directors to enter into and comply with all of the provisions of this Deferred Prosecution Agreement.

DATED:

*10/17/2016*



Isamu Yokoi  
President and CFO, Meiko America, Inc.

As counsel to Meiko America, Inc., I have discussed with my corporate client and its duly authorized representative the terms of the Compliance Program and have fully explained its requirements. I have no reason to doubt that my client is knowingly and voluntarily entering into this Compliance Program.

DATED:

*10/17/2016*



Kenneth B. Julian  
Manatt Phelps & Phillips LLP

On behalf of the United States, the following agree to the terms of the Compliance Program.

DATED: 10-24-16

MICHAEL W. COTTER

United States Attorney

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

Chad Spraker

Assistant United States Attorney