

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

5	UNITED STATES OF AMERICA,)	
6	Plaintiff,)	C 15-00325 KAW
7	v.)	
8	FONG KEE TOFU CO., INC.,)	CONSENT DECREE OF
9	a corporation, and)	PERMANENT INJUNCTION
10	JEN YING FONG, SUNY FONG, and)	
11	YAN HUI FANG, individuals,)	
12	Defendants.)	

13 Plaintiff, the United States of America, by its undersigned attorneys, having filed a
14 Complaint For Permanent Injunction against Fong Kee Tofu Co., Inc., a corporation, and Jen
15 Ying Fong, Suny Fong, and Yan Hui Fang, individuals (collectively “Defendants”), and
16 Defendants having appeared and consented to entry of this Consent Decree of Permanent
17 Injunction (“Decree”) without contest and before any testimony has been taken, and the United
18 States of America, having consented to this Decree;

19 IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

- 20 1. This Court has jurisdiction over the subject matter and all parties to this action.
- 21 2. The Complaint states a cause of action against Defendants under the Federal
22 Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the “Act”).
- 23 3. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food, within
24 the meaning of 21 U.S.C. § 321(f), to become adulterated, within the meaning of 21 U.S.C.
25 § 342(a)(4), while such articles are held for sale after shipment of one or more components in
26 interstate commerce. The articles of food are adulterated within the meaning of 21 U.S.C.

1 § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby
2 they may have become contaminated with filth.

3 4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing certain articles of
4 food, within the meaning of 21 U.S.C. § 321(f), to become misbranded within the meaning of 21
5 U.S.C. §§ 343(e), (f), (i)(1), (i)(2),(q), and/or (w), while such articles are held for sale after
6 shipment of one or more of their components in interstate commerce.

7 5. Defendants and each and all of their directors, officers, agents, representatives,
8 employees, attorneys, successors, assigns, and any and all persons or entities in active concert or
9 participation with any of them (including individuals, partnerships, corporations, subsidiaries,
10 and affiliates), who receive actual notice of this Decree (collectively, “Associated Persons”), are
11 hereby permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the equitable
12 authority of this Court, from directly or indirectly receiving, preparing, processing,
13 manufacturing, labeling, packing, holding, and distributing any food at 1135 Revere Avenue,
14 San Francisco, California 94124, or at or from any other locations at which Defendants now, or
15 in the future, directly or indirectly receive, prepare, process, manufacture, label, pack, hold,
16 and/or distribute food (“the facility”), unless and until:

17 A. Defendants retain, at their expense, an independent person or persons (the
18 “Sanitation Expert”) who is without any personal or financial ties (other than the retention
19 agreement) to Defendants or their families, and who, by reason of background, education,
20 training, or experience, is qualified to develop and implement a written sanitation control
21 program that will protect food, food-contact surfaces, and food-packaging materials from
22 contamination from any source, including, but not limited to, chemicals, toxins, microorganisms,
23 and filth, and determine whether Defendants comply with the Act and its implementing
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1 regulations, including, but not limited to, the current good manufacturing practice (“cGMP”)
2 requirements for food, see 21 C.F.R. Part 110, and:

3 i. Defendants notify the United States Food and Drug Administration
4 (“FDA”) in writing of the name(s) and qualifications of the Sanitation Expert as soon as they
5 retain such expert;

6 ii. The Sanitation Expert develops a written sanitation control
7 program (the “Program”), including a written employee training program, for receiving,
8 preparing, processing, manufacturing, packing, holding, and distributing Defendants’ articles of
9 food, and such plan is submitted to FDA prior to implementation. The plan should, among other
10 things, require that the adequacy of cleaning and sanitizing be verified through generalized
11 microbial testing, such as aerobic plate count or adenosine triphosphate (“ATP”) testing;

12 iii. Defendants receive written notification from FDA approving the
13 Program;

14 iv. Defendants make the FDA-approved Program available and
15 accessible (in English, Spanish, and Chinese) to all their employees;

16 v. Defendants assign responsibility and authority for implementing
17 and monitoring the FDA-approved Program on a continuous basis to an employee who is trained
18 in sanitation control requirements and qualified to implement and monitor the FDA-approved
19 Program;

20 vi. The Sanitation Expert conducts a comprehensive inspection of the
21 facility and Defendants’ methods and controls used to receive, prepare, process, manufacture,
22 pack, hold, and distribute foods to determine whether Defendants have adequately established
23 and implemented the FDA-approved Program, whether Defendants have adequately addressed
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1 the FDA investigators' inspectional observations listed on each Form FDA-483 issued to
2 Defendants since 2010, and whether Defendants comply with the Act, and its implementing
3 regulations, including the cGMP requirements for food;

4 vii. Within twenty (20) business days after the inspection described in
5 paragraph 5(A)(vi) is completed, the Sanitation Expert prepares and submits contemporaneously
6 to FDA and Defendants, by courier service or overnight delivery service, a written report of the
7 inspection, which shall include a list of any observed deviations from the FDA-approved
8 Program, the Act, and its implementing regulations, including, but not limited to, the cGMP
9 requirements for food;

10 viii. Defendants notify FDA and the Sanitation Expert in writing of the
11 actions they have taken to correct each and all deviations listed in the Sanitation Expert's report,
12 if any;

13 ix. The Sanitation Expert certifies to FDA in writing that, based upon
14 the Sanitation Expert's inspection and Defendants' response, if any, as described in paragraphs
15 5(A)(vi) and 5(A)(viii), the facility and Defendants' methods and controls used to receive,
16 prepare, process, manufacture, pack, hold, and distribute food appear to be in compliance with
17 the FDA-approved Program, the Act, and its implementing regulations, including, but not limited
18 to, the cGMP requirements for food;

19 x. FDA, as and when it deems necessary, inspects the facility,
20 including the buildings, equipment, utensils, food, and all relevant records contained therein, to
21 evaluate Defendants' compliance with this Decree, the Act, and its implementing regulations. If
22 FDA decides to inspect Defendants' facility pursuant to this paragraph, FDA will initiate the
23 inspection within forty (40) business days after receiving the Sanitation Expert's certification
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1 pursuant to paragraph 5(A)(ix), or as soon as practicable in the event that FDA representatives
2 are attending to FDA matters that cannot be rescheduled; and

3 xi. Defendants receive written notification from FDA that the facility
4 and Defendants' methods and controls used to receive, prepare, process, manufacture, pack,
5 hold, and distribute food appear to be in compliance with the Act and its implementing
6 regulations;

7 B. Defendants retain, at their expense, an independent person or persons (the
8 "Labeling Expert") who is without any personal or financial ties (other than the retention
9 agreement) to Defendants or their families, except that the Labeling Expert may be the same
10 person(s) as the Sanitation Expert, and who, by reason of background, education, training, or
11 experience, is qualified to determine whether Defendants' products are labeled in compliance
12 with the Act and its implementing regulations, including, but not limited to, the food labeling
13 requirements, see, e.g., 21 C.F.R. Part 101, and:

14 i. Defendants notify FDA in writing of the name(s) and
15 qualifications of the Labeling Expert as soon as they retain such expert;

16 ii. The Labeling Expert performs a review of each and all of
17 Defendants' products' labeling to determine whether each product's labeling complies with the
18 Act and its implementing regulations, including, but not limited to, the food labeling
19 requirements;

20 iii. Within twenty (20) business days after the review described in
21 paragraph 5(B)(ii) is completed, the Labeling Expert prepares and submits contemporaneously to
22 FDA and Defendants, by courier service or overnight delivery service, a written report of the
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1 review, which shall include a list of observed deviations, if any, from compliance with the Act
2 and its implementing regulations, including, but not limited to, the food labeling requirements;

3 iv. Defendants notify FDA and the Labeling Expert in writing of the
4 actions they have taken to correct all deviations listed in the Labeling Expert's report, if any;

5 v. The Labeling Expert certifies to FDA in writing that all of
6 Defendants' products' labeling complies with the Act, and its implementing regulations,
7 including, but not limited to, the food labeling requirements;

8 vi. Defendants submits to FDA true and complete copies of any and
9 all product labeling and FDA reviews such labeling to evaluate Defendants' compliance with the
10 Act and its implementing regulations; and

11 vii. Defendants receive written notification from FDA that their
12 products' labeling appears to be in compliance with the Act and its implementing regulations;

13 C. Defendants recall and destroy, at their expense, under FDA's supervision,
14 and in accordance with the procedures provided in paragraph 6, all articles of food (including,
15 but not limited to, in-process and finished articles of food), excluding fresh tofu, that were
16 received, prepared, processed, manufactured, labeled, packed, held, and/or distributed between
17 March 19, 2014 and the date of entry of this Decree. Defendants shall also recall and destroy, at
18 their expense, under FDA's supervision, and in accordance with the procedures provided in
19 paragraph 6, all fresh tofu that was received, prepared, processed, manufactured, labeled, packed,
20 held, and/or distributed within thirty (30) business days before entry of this Decree;

21 D. Defendants pay all costs of FDA's supervision, inspections, investigations,
22 analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence
23 expenses incurred under paragraph 5, at the rates set forth in paragraph 10 of this Decree; and

1 E. Defendants receive written authorization from FDA to resume receiving,
2 preparing, processing, manufacturing, labeling, packing, holding, and distributing articles of food
3 at and from the facility. In no circumstance shall FDA’s silence be construed as a substitute for
4 written authorization.

5 6. Within ten (10) business days after entry of this Decree and also within ten (10)
6 business days after receiving any recalled food, Defendants shall, under FDA’s supervision and
7 pursuant to a method approved in advance in writing by FDA, destroy all food in Defendants’
8 possession, custody, and/or control. Defendants shall reimburse FDA for supervising the
9 destruction at the rates set forth in paragraph 10 of this Decree.

10 7. Within thirty (30) business days after receiving the written authorization
11 described in paragraph 5(E), Defendants shall retain at their expense, an independent person or
12 persons (the “Auditor”) who is without any personal or financial ties (other than the retention
13 agreement) to Defendants or their families, except that the Auditor may be the same person(s) as
14 the Sanitation Expert and/or the Labeling Expert, and who, by reason of background, education,
15 training, or experience, is qualified to determine whether the facility and Defendants’ methods
16 and controls used to receive, prepare, process, manufacture, label, pack, hold, and distribute food
17 comply with the Act and its implementing regulations, including, but not limited to, the cGMP
18 and food labeling requirements. See, e.g., 21 C.F.R. Parts 101 (food labeling), 110 (cGMP).

19 Thereafter:

20 A. Defendants shall notify FDA in writing of the name(s) and qualifications
21 of the Auditor as soon as they retain such auditor;

1 required. If, after receiving the Audit Report, Defendants believe that a correction of the
2 deviations will take longer than fifteen (15) business days, Defendants shall, within five (5)
3 business days after receiving the Audit Report, submit to FDA in writing a proposed schedule for
4 completing corrections (“Correction Schedule”). The Correction Schedule must be reviewed and
5 approved by FDA in writing prior to implementation by Defendants. In no circumstance shall
6 FDA’s silence be construed as a substitute for written approval; and

7 G. Within twenty (20) business days after Defendants receive the Audit
8 Report or within the time frame provided in the Correction Schedule approved by FDA, the
9 Auditor shall review each and all corrective action(s) taken by Defendants. Within five (5)
10 business days after beginning that review, the Auditor shall report in writing to FDA whether
11 each of the Audit Report Observations has been corrected, and, if not, which Audit Report
12 Observations remain uncorrected.

13 8. Defendants and each and all of the Associated Persons who receive actual notice
14 of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C.
15 § 332(a) from, directly or indirectly, doing or causing any act that:

16 A. Violates 21 U.S.C. § 331(k), by causing articles of food within the
17 meaning of 21 U.S.C. § 321(f) to become misbranded within the meaning of 21 U.S.C. § 343
18 while such articles are held for sale after shipment of one or more of their components in
19 interstate commerce;

20 B. Violates 21 U.S.C. § 331(k), by causing articles of food within the
21 meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 21 U.S.C.
22 § 342(a)(4) while such articles are held for sale after shipment of one or more of their
23 components in interstate commerce; and/or

1 C. Results in the failure to implement and continuously maintain the
2 requirements of this Decree.

3 9. Representatives of FDA shall be permitted, without prior notice and as and when
4 FDA deems necessary, to make inspections of the Defendants' operations and facility and any
5 other locations at or from which Defendants receive, prepare, process, manufacture, label, pack,
6 hold, and/or distribute articles of food and, without prior notice, to take any other measures
7 necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act,
8 and its implementing regulations. During the inspections, FDA shall be permitted to have
9 immediate access to buildings, equipment, raw ingredients, finished and unfinished materials and
10 products, containers, labeling, and packaging material therein; to take photographs and make
11 video recordings; to take samples of Defendants' raw ingredients, finished and unfinished
12 materials and products, containers, labeling, packaging material, and other material; and to
13 examine and copy all records related to receiving, preparing, processing, manufacturing,
14 labeling, packing, holding, and distributing of any and all of Defendants' products. The
15 inspections shall be permitted upon presentation of a copy of this Decree and appropriate
16 credentials. The inspection authority granted by this Decree is separate from, and in addition to,
17 the authority to make inspections under the Act, 21 U.S.C. § 374.

18 10. Defendants shall pay all costs of FDA's supervision, inspections, investigations,
19 analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence
20 expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this
21 Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make
22 payment in full to FDA within twenty (20) business days of receiving written notification from
23 FDA of the costs. As of the date that this Decree is signed by the parties, these rates are: \$89.35
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1 per hour and fraction thereof per representative for inspection or investigative work; \$107.09 per
2 hour or fraction thereof per representative for analytical or review work; \$0.575 per mile for
3 travel by automobile; government rate or the equivalent for travel by air or other means; and the
4 published government per diem rate or the equivalent for the areas in which the inspections are
5 performed per representative and per day for subsistence expenses. In the event that the standard
6 rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall
7 be increased or decreased without further order of the Court.

8 11. Within ten (10) business days after entry of this Decree, Defendants shall post a
9 copy of this Decree (in English, Spanish, and Chinese) prominently in an employee common
10 area at Defendants' facility and shall ensure that this Decree remains posted for as long as this
11 Decree remains in effect. Within fifteen (15) business days after entry of this Decree,
12 Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the
13 facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph.

14 12. Within ten (10) business days after entry of this Decree, Defendants shall hold a
15 general meeting or series of smaller meetings for all employees, at which they shall describe the
16 terms and obligations of this Decree. Within fifteen (15) business days after entry of this Decree,
17 Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the
18 facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph,
19 and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held
20 pursuant to this paragraph.

21 13. Within ten (10) business days after entry of this Decree, Defendants shall provide
22 a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt
23 requested), to each and all of the Associated Persons. Defendants shall provide to FDA within
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1 twenty (20) business days after the date of the entry of this Decree an affidavit, from a person
2 with personal knowledge of the facts state therein, stating the fact and manner of compliance and
3 identifying the names, addresses, and positions of all persons so notified, and attaching a copy of
4 the executed certified mail return receipts.

5 14. In the event that any Defendant becomes associated with any additional
6 Associated Person(s) at any time after entry of this Decree, Defendants shall immediately
7 provide a copy of this Decree, by personal service or certified mail (restricted delivery, return
8 receipt requested), to such Associated Person(s). Within ten (10) business days of each instance
9 that any Defendant becomes associated with any additional Associated Person, Defendants shall
10 provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein,
11 stating the fact and manner of Defendants' compliance with this paragraph, identifying the
12 names, addresses, and positions of all persons who received a copy of this Decree pursuant to
13 this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten
14 (10) business days of receiving a request from FDA for any information or documentation that
15 FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall
16 provide such information or documentation to FDA.

17 15. Defendants shall notify FDA in writing at least fifteen (15) business days before
18 any change in ownership, name or character of their business, including reorganization,
19 relocation, dissolution, bankruptcy, assignment, sale resulting in the emergence of a successor
20 business or corporation, the creation or dissolution of subsidiaries, or any other change in the
21 corporate structure or identity of Fong Kee Tofu Co., Inc., or any of their parents or subsidiaries,
22 or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that
23 may affect compliance with the obligations arising from this Decree. Defendants shall provide
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1 any prospective successor or assign with a copy of this Decree at least ten (10) business days
2 prior to any assignment or change in business, and shall provide FDA with an affidavit, from a
3 person with personal knowledge of the facts stated therein, stating the fact and manner of
4 Defendants' compliance with this paragraph, no later than ten (10) business days after providing
5 a copy of this Decree to a prospective successor or assign.

6 16. If, at any time after entry of this Decree, FDA determines, based on the results of
7 an inspection, sample, analyses, or other information, that Defendants have failed to comply with
8 any provision of this Decree, have violated the Act or its implementing regulations, or that
9 additional corrective actions are necessary to achieve compliance with this Decree, the Act or its
10 implementing regulations, FDA may, as and when it deems necessary, notify Defendants in
11 writing and order Defendants to take appropriate action, including, but not limited to, ordering
12 Defendants to immediately take one or more of the following actions:

13 A. Cease receiving, preparing, processing, manufacturing, labeling, packing,
14 holding, and/or distributing any articles of food;

15 B. Recall all articles of food that have been distributed and/or are under the
16 custody and control of Defendants' agents, distributors, customers, or consumers;

17 C. Submit samples of raw ingredients, in-process, or finished articles of food
18 to a qualified laboratory to determine whether they are contaminated with chemicals, toxins,
19 microorganisms, or filth; and/or

20 D. Take any other corrective actions as FDA deems necessary to bring
21 Defendants into compliance with this Decree, the Act, and its implementing regulations.

22 The provisions of this paragraph shall be separate and apart from, and in addition to, all
23 other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective
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1 actions, including the costs of FDA’s supervision, inspections, investigations, analyses,
2 examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses
3 to implement and monitor recalls and other actions, at the rates specified in paragraph 10 of this
4 Decree.

5 17. Upon receipt of any order issued by FDA pursuant to paragraph 16, Defendants
6 shall immediately and fully comply with the terms of the order. Any cessation of operations or
7 other action as described in paragraph 16 shall be implemented immediately upon notice from
8 FDA and shall continue until Defendants receive written notification from FDA that Defendants
9 appear to be in compliance with this Decree, the Act, and its implementing regulations and
10 written authorization from FDA to resume operations. After a cessation of operations, and while
11 determining whether Defendants are in compliance with this Decree, the Act, and its
12 implementing regulations, FDA may require Defendants to re-institute or re-implement any of
13 the requirements of this Decree.

14 18. If any Defendant fails to comply with the provisions this Decree, the Act, and/or
15 its implementing regulations, then Defendants shall pay to the United States of America
16 liquidated damages in the sum of three thousand dollars (\$3,000) for each day that Defendants
17 fail to comply with this Decree, an additional sum of three thousand dollars (\$3,000) in
18 liquidated damages per day for each violation of this Decree, the Act, and/or its implementing
19 regulations, and an additional sum equal to twice the retail value of each shipment of adulterated
20 or misbranded food. Defendants understand and agree that the liquidated damages specified in
21 this paragraph are not punitive in nature and their imposition does not in any way limit the ability
22 of the United States to seek, and the Court to impose, additional civil or criminal penalties based
23 on the conduct that may also be the basis for payment of the liquidated damages.

1 Entry consented to:

2 For Defendants

For Plaintiff

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5 JEN YING FONG
6 Individually and on behalf of
7 Fong Kee Tofu Co., Inc. as its Owner

MIKE BLUME
Director
Consumer Protection Branch

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10 SUNY FONG, in his individual
11 capacity

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13 YAN HUI FANG, in his individual
14 capacity

OF COUNSEL:

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17 Attorney for Defendants Fong Kee Tofu
18 Co., Inc. and Suny Fong

WILLIAM B. SCHULTZ
General Counsel

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ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

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Entry consented to:

For Defendants

X Jen Ying Fong
JEN YING FONG
Individually and on behalf of
Fong Kee Tofu Co., Inc. as its Owner

Suny Fong
SUNY FONG, in his individual
capacity

X Yan Hui Fang
YAN HUI FANG, in his individual
capacity

Kasie Lee
KASIE LEE
Attorney for Defendants Fong Kee Tofu
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Silver Spring, MD 20993

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA

Plaintiff,

v.

FONG KEE TOFU CO. INC.,
a corporation, and
JEN YING FONG, SUNY FONG, and
YAN HUI FANG, individuals,

Defendants.

Civil Action No.

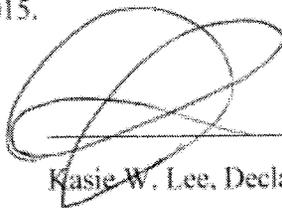
DECLARATION OF COUNSEL

DECLARATION OF COUNSEL

1. I am the attorney representing Fong Kee Tofu Co. in the above-named action.
2. On January 15, 2015 at 4:30 p.m., all three of the named defendants, Jen Ying Fong, Suny Fong, and Yan Hui Fang, met at my office located at One Sansome Street, 35th Floor, San Francisco, CA 94104.
3. I reviewed the 16-page Consent Decree of Permanent Injunction with all three defendants and provided interpretation of said consent decree in Cantonese, a Chinese dialect.
4. I am fluent in Cantonese and English.
5. All three defendants signed the consent decree after I interpreted it to them in Cantonese.

I declare under penalty of perjury that the foregoing is true and correct.

Dated this 15th day of January, 2015.

A handwritten signature in black ink, consisting of several overlapping loops and a horizontal line extending to the right, positioned above a solid horizontal line.

Kasie W. Lee, Declarant