

1 JOYCE R. BRANDA
Acting Assistant Attorney General
2 JONATHAN F. OLIN
Deputy Assistant Attorney General
Civil Division
3 U.S. Department of Justice
MICHAEL S. BLUME, Director
4 Consumer Protection Branch
MELANIE SINGH
5 Counsel, Consumer Protection Branch
U.S. Department of Justice
PO Box 386
6 Washington, DC 20044-0386
(202) 616-9928 (phone)
7 (202) 514-8742 (fax)
Melanie.Singh@usdoj.gov
8 Attorneys for Plaintiff United States of America

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10 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

11
12 UNITED STATES OF AMERICA,)
Plaintiff,) CIVIL ACTION NO. _____
13 v.)
14 FONG KEE TOFU CO., INC.,)
a corporation, and) COMPLAINT FOR
15 JEN YING FONG, SUNY FONG, and) PERMANENT INJUNCTION
YAN HUI FANG, individuals,)
16 Defendants.)
17

18 Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the
19 United States Food and Drug Administration ("FDA"), respectfully represents to this Court as
20 follows:
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COMPLAINT FOR PERMANENT INJUNCTION

1. This action is brought by the United States of America, pursuant to the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 332(a), and the equitable authority of this Court, to permanently enjoin and restrain Fong Kee Tofu Co., Inc., a corporation, and Jen Ying Fong, Suny Fong, and Yan Hui Fang, individuals (collectively, “Defendants”), from violating 21 U.S.C. §331(k), by causing articles of food that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) and misbranded within the meaning of 21 U.S.C. § 343.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this District is proper pursuant to 28 U.S.C. §§1391(b) and (c).

INTRADISTRICT ASSIGNMENT

4. The conduct alleged in this Complaint occurred within San Francisco County.

DEFENDANTS

5. Defendant Fong Kee Tofu Co., Inc. (“Fong Kee Tofu” or “the firm”) is a California corporation with its principal place of business at 1135 Revere Avenue, San Francisco, California 94124 (“the facility”). Fong Kee Tofu prepares, processes, manufactures, labels, packs, holds, and distributes soy products.

6. Defendant Jen Ying Fong is a co-owner and corporate officer of Fong Kee Tofu. He has responsibility over the firm's operations, including, but not limited to, manufacturing, finances, sanitation, and employee training. He performs his duties at the facility, within the jurisdiction of this Court.

1 7. Defendant Suny Fong is a co-owner and corporate officer of Fong Kee Tofu.
2 He has responsibility over the firm's operations, including, but not limited to, manufacturing,
3 label design, sanitation, and food distribution. He performs his duties at the facility, within the
4 jurisdiction of this Court.

5 8. Defendant Yan Hui Fang is a co-owner and the Chief Executive Officer of Fong
6 Kee Tofu. Yan Hui Fang has ultimate responsibility for the firm's operations and practices.

7 9. Defendants have been and are now engaged in receiving, preparing, processing,
8 manufacturing, labeling, packing, holding, and distributing articles of food, within the meaning
9 of 21 U.S.C. § 321(f). Such products include, but are not limited to, soy drinks, firm tofu, soft
10 tofu, fried tofu balls (oil bean cake), and soybean cake.

11 10. Defendants' soy products (including tofu) are made from ingredients that have
12 been shipped in interstate commerce, specifically soybeans from Missouri.

13 **DEFENDANTS' VIOLATIONS OF THE ACT**

14 11. Defendants violate 21 U.S.C. § 331(k) by causing food to become adulterated,
15 within the meaning of 21 U.S.C. § 342(a)(4), while it is held for sale after shipment in interstate
16 commerce.

17 12. Food processors must adhere to the current good manufacturing practice
18 ("cGMP") requirements for manufacturing, packing, and holding human food. 21 C.F.R. pt.
19 110. Failure to follow the cGMP requirements renders food adulterated in violation of 21 U.S.C.
20 § 342(a)(4). 21 C.F.R. § 110.5(a).

21 13. As detailed in paragraph 17 below, recent FDA inspections establish that
Defendants' soy products are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that
they have been prepared, packed, or held under insanitary conditions whereby they may have

1 become contaminated with filth. The insanitary conditions include Defendants' failure to take
2 effective measures to exclude pests from the facility and to protect against the contamination of
3 food with filth, as evidenced by, among other things, the persistent presence of flies during
4 production.

5 14. Defendants violate 21 U.S.C. § 331(k) by causing food to become misbranded,
6 within the meaning of 21 U.S.C. § 343, while it is held for sale after shipment in interstate
7 commerce.

8 15. As detailed in paragraph 18 below, certain of Defendants' soy products are
9 misbranded within the meaning of 21 U.S.C. §§ 343(e), (f), (i)(1), (i)(2), (q), and/or (w) because
10 the products' labeling, respectively: (1) does not bear the manufacturer's, packer's, or
11 distributor's name and place of business and does not contain an accurate statement of the
12 quantity of the contents in terms of weight, measure, or numerical count; (2) does not
13 prominently display a word, statement, or other information required by or under authority of the
14 Act; (3) does not bear the common or usual name of the food; (4) does not bear the common or
15 usual name of each ingredient; and/or (5) does not bear required nutrition information.

16 **RECENT FDA INSPECTIONS**

17 16. Defendants have an extensive history of operating their food manufacturing
18 facility under insanitary conditions, failing to follow the food cGMP requirements, and
19 misbranding their food products. FDA has documented Defendants' pattern of continuing
20 violative conduct in FDA inspections in 2014, 2013, 2011, and 2010.

21 April 2014 Inspection

1 17. FDA's most recent inspection of Fong Kee Tofu was conducted between March
2 19 and April 8, 2014 (the "April 2014 Inspection"), in follow-up to a previous violative
3 inspection in January 2013.

4 18. The April 2014 Inspection uncovered significant evidence of filth in the facility
5 and Defendants' failure to correct violations found during previous inspections. Specifically,
6 FDA investigators observed the following violations, among others:

7 (a) Defendants failed to take effective measures to exclude pests from the
8 processing areas and protect the food on the premises from being contaminated by pests, as
9 required by 21 C.F.R. § 110.35(c). For example, a fly landed on the outer edge of an unsealed,
10 plastic package that contained pieces of ready-to-eat firm tofu. There were also approximately
11 20 insects flying around the firm's tofu processing area, approximately 25 insects flying outside
12 the cooler door, and pigeons sitting outside on top of plastic-wrapped raw soybean pallets.
13 Additionally, the loading dock door was kept open several times during the day thereby
14 providing an access route for pests. This is a repeat observation from the January 2013,
15 December 2011, and November 2010 Inspections. This observation was also noted in the
16 Warning and Untitled Letters sent to the Defendants in 2012 and 2011.

17 (b) Defendants failed to maintain equipment and utensils in an acceptable
18 condition through appropriate cleaning and sanitizing, as required by 21 C.F.R. § 110.80(b)(1).
19 For example, investigators observed dark yellow residue on the handles and sides of stainless
20 steel trays used to hold ready-to-eat bulk firm tofu. This residue remained visible even after the
21 FDA investigator observed Defendants' employees cleaning the trays. There were also long
white residue strips on the conveyor belt used to produce firm tofu. Additionally, the FDA
investigator observed employees retrieving spatulas that had been stored under empty cardboard

1 boxes and other dust and debris, and using the spatulas, without cleaning them, to transfer ready-
2 to-eat bulk firm tofu into cardboard boxes. This is a repeat observation from the January 2013,
3 December 2011, and November 2010 Inspections.

4 (c) Defendants failed to take all reasonable measures and precautions to
5 ensure that all persons working in direct contact with food, food-contact surfaces, and food-
6 packaging materials conform to hygienic practices while on duty, as required by 21 C.F.R. §
7 110.10(b)(3). For example, during food processing, employees touched insanitary non-food
8 contact surfaces or exited from and returned to the processing area without washing their hands
9 and/or changing their gloves. Specifically, employees touched forklifts, handled a black hose
10 that was on the wet production floor, and touched plastic drapes that had black residue on them,
11 and then packed ready-to-eat bulk firm tofu without washing or sanitizing their hands. This is a
12 repeat observation from the January 2013, December 2011, and November 2010 Inspections.
13 This observation was also noted in the 2012 Warning and 2011 Untitled Letters.

14 (d) Defendants failed to ensure that the plant and facilities are constructed in
15 such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean, and that
16 drip or condensate does not contaminate food, food-contact surfaces, and food-packaging
17 materials, as required by 21 C.F.R. § 110.20(b)(4). For example, the inspection revealed broken
18 or missing tiles throughout the entire production area and tofu debris in broken tile cracks.
19 Additionally, condensation from the ceiling dripped onto the ready-to-eat bulk tofu and the
20 stainless steel packing table, and there was apparent mold near this condensation. Condensation
21 from a metal panel on the firm tofu processing line also dripped on the in-process firm tofu
product. This is a repeat observation from the January 2013, December 2011, and November

1 2010 Inspections. This observation was also noted in the 2012 Warning and 2011 Untitled
2 Letters.

3 (e) Defendants failed to take effective measures to handle work-in-process in
4 manner that protects against contamination, as required by 21 C.F.R. § 110.80 (b)(5). For
5 example, employees repeatedly pushed and pulled metal roller racks with trays of uncovered
6 ready-to-eat bulk firm tofu into a walk-in-cooler through plastic drapes that were covered with
brown and black residue. This observation was also noted in the 2012 Warning Letter.

7 At the close of the inspection, the FDA investigator issued a Form FDA-483, List of
8 Inspectional Observations ("Form FDA-483"), to Defendants Jen Ying Fong and Suny Fong.
9 The FDA investigator also discussed with these Defendants some of the labeling violations
discussed in paragraph 18.

10 19. During the April 2014 Inspection, the FDA investigator collected samples of
11 Defendants' product labeling. Defendants' products are misbranded within the meaning of the
12 Act, 21 U.S.C. § 343, as follows:

13 (a) Certain foods received, prepared, processed, manufactured, labeled,
14 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C. §
15 343(e), in that their labeling fails to declare "the name and place of business of the manufacturer,
16 packer, or distributor," and "an accurate statement of the quantity of the contents in terms of
17 weight, measure, or numerical count" Defendants' bulk fried tofu balls are misbranded
18 within the meaning of 21 U.S.C. § 343(e) because they are packaged in unlabeled plastic bags
19 with no label that declares the place of business of the manufacturer, packer, or distributor, or an
accurate statement of quantity.

20 (b) Certain foods received, prepared, processed, manufactured, labeled,
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1 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C. §
2 343(f) in that “any word, statement, or other information required by or under authority of this
3 Act to appear on the label or labeling is not prominently placed thereon” If a food product
4 label contains any representation in a foreign language, all words, statements, and other
5 information required by or under authority of the Act to appear on the label must appear in such
6 foreign language. 21 C.F.R. § 101.15(c)(2). Defendants’ soft tofu and bulk firm tofu products
7 are misbranded within the meaning of 21 U.S.C. § 343(f) because their labels contain
8 information in two languages, but do not contain all of the required information in both
9 languages. Specifically, the soft tofu product’s label states “Fong Kee” and “water tofu” in
10 Chinese, but does not contain any of the other required information in Chinese. The bulk firm
11 tofu product’s label states “Fong Kee Tofu” in Chinese, but does not contain any of the other
12 required information in Chinese.

11 (c) Certain foods received, prepared, processed, manufactured, labeled,
12 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C. §
13 343(i)(1), in that their labeling fails to bear “the common or usual name of the food.” The label
14 shall include, among other things, a statement of identity. 21 C.F.R. § 101.3. Defendants’ bulk
15 fried and firm tofu products are misbranded within the meaning of 21 U.S.C. § 343(i)(1),
16 because the bulk fried tofu balls are packaged in unlabeled plastic bags and the bulk firm tofu
17 products are packaged in cardboard boxes that do not have any statement of identity.

17 (d) Certain foods received, prepared, processed, manufactured, labeled,
18 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C. §
19 343(i)(2), in that these products are fabricated from two or more ingredients but their labeling
20 does not bear the common or usual name of each such ingredient. Defendants’ bulk fried and
21

1 soft tofu products are misbranded within the meaning of 21 U.S.C. § 343(i)(2). Specifically,
2 Defendants' bulk fried tofu balls, which are packaged in unlabeled plastic bags, fail to declare
3 any ingredients. Additionally, Defendants' soft tofu products declare "natural calcium sulfate"
4 on the label; however, "natural" is not part of the common or usual name of this ingredient. See
21 C.F.R. §101.4.

5 (e) Certain foods received, prepared, processed, manufactured, labeled,
6 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C.
7 § 343(q) because their labels fail to bear nutrition information that provides specific information.
8 Unless certain exemptions apply, a label must bear nutrition information. 21 C.F.R. § 101.9.
9 Defendants' soft tofu products are misbranded within the meaning of 21 U.S.C. § 343(q). Their
10 labels fail to, among other things, declare a % Daily Value for Saturated Fat, as required by 21
C.F.R. § 101.9(d)(7)(ii).

11 (f) Certain foods received, prepared, processed, manufactured, labeled,
12 packed, held, and distributed by Defendants are misbranded within the meaning of 21 U.S.C. §
13 343(w) in that the food products contain a major food allergen, but do not declare the food
14 allergen. A major food allergen includes soybeans. 21 U.S.C. § 321(qq)(1). Defendants' bulk
15 fried tofu balls are misbranded within the meaning of 21 U.S.C. § 343(w) because they are
16 packaged in unlabeled plastic bags that fail to declare the presence of soybeans.

17 20. Following the April 2014 Inspection, Defendants left a telephone message with
18 FDA's San Francisco District Office, stating that Fong Kee Tofu had found a cleaning service
19 for its machines. By e-mail dated April 29, 2014, Defendant Suny Fong promised additional
20 corrections, such as instructing employees to wash their hands and observing employees for a
month. The April 29, 2014 e-mail also stated, among other things, that the broken or missing

1 tiles had been repaired. Defendants' telephone message and e-mail do not adequately address
2 the firm's violations because they only partially address some of Defendants' cGMP deviations
3 and do not address Defendants' labeling deficiencies. Moreover, Defendants promised similar
4 corrections following previous inspections, such as training employees to wash their hands and
5 monitoring employees for a set period, and repairing the floors, but subsequent inspections
6 revealed that corrections were not adequate to prevent violations.

7 Previous FDA Inspections and Attempts to Obtain Defendants' Compliance with the Law

8 21. Prior to the April 2014 Inspection, FDA most recently inspected Fong Kee Tofu
9 on three occasions: between January 15 and 28, 2013; December 13 and 21, 2011; and October
10 26 and November 2, 2010.

11 22. During each of the inspections referenced in paragraph 21, FDA documented
12 cGMP deviations and labeling violations that were the same as, or similar to, those described in
13 paragraphs 17 and 18, respectively, and FDA investigators discussed the violations with at least
14 one of the Defendants at the close of each inspection.

15 23. FDA issued a Warning Letter to Defendants on March 7, 2012, stating that
16 Defendants' failure to take effective measures to exclude pests from the facility's processing
17 area, among other sanitation issues, caused their products to be adulterated within the meaning of
18 21 U.S.C. § 342(a)(4). The Warning Letter also stated that Defendants caused certain products
19 to be misbranded within the meaning of 21 U.S.C. § 343, because of violative product labels.
20 The cGMP and labeling violations cited in the Warning Letter were similar to those recently
21 found in the April 2014 Inspection.

22 24. Prior to that, FDA also issued an Untitled Letter to Defendants on March 22,
23 2011. The Untitled Letter described Defendants' cGMP and labeling violations. The cGMP and

1 labeling violations cited in the Untitled Letter were similar to those recently found in the April
2 2014 Inspection.

3 25. Following the January 15 to 28, 2013 inspection, FDA held a meeting with
4 Defendant Suny Fong on April 10, 2013. During this meeting, FDA discussed with Defendant
5 Sung Fong the cGMP and labeling deviations documented during the January 2013 inspection.
6 FDA also informed Defendant Suny Fong of the possible consequences for failing to take
7 corrective actions, including permanent injunction.

8 26. Despite FDA's efforts, and warnings and Defendants' promises to correct the
9 violations, Defendants have consistently failed to manufacture and label their products in
10 compliance with the Act and its implementing regulations.

11 27. The findings from the April 2014 Inspection establish that Defendants continue to
12 violate 21 U.S.C. § 331(k) by causing the adulteration and misbranding of food while held for
13 sale after shipment of one or more components in interstate commerce.

14 28. The United States is informed and believes that, unless restrained by order of the
15 Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

16 WHEREFORE, Plaintiff respectfully requests that the Court:

17 I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each
18 and all of their directors, officers, agents, representatives, employees, attorneys, successors,
19 assigns, and any and all persons or entities in active concert or participation with any of them
20 (including individuals, partnerships, corporations, subsidiaries, and affiliates), from directly or
21 indirectly doing or causing to be done any of the following acts:

1 (a) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for
 2 sale after shipment of one or more of its components in interstate commerce to become
 3 adulterated within the meaning of 21 U.S.C. § 342(a)(4);

4 (b) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for
 5 sale after shipment of one or more of its components in interstate commerce to become
 6 misbranded within the meaning of 21 U.S.C. §§ 343(e), (f), (i)(1), (i)(2), (q), and/or (w);

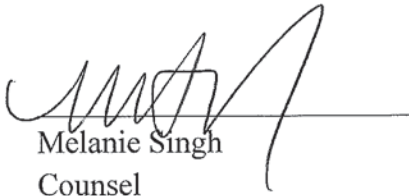
7 II. Order Defendants and each and all of their directors, officers, agents,
 8 representatives, employees, attorneys, successors, assigns, and any and all persons or entities in
 9 active concert or participation with any of them (including individuals, partnerships,
 10 corporations, subsidiaries, and affiliates) who receive notice of the Court's Order, to cease,
 11 directly or indirectly, receiving, preparing, processing, manufacturing, labeling, packing, and
 12 distributing all food at or from Defendants' facility, or any other or new location(s) at or from
 13 which Defendants receive, prepare, process, manufacture, label, pack, or distribute food, unless
 14 and until Defendants bring their receiving, preparing, processing, manufacturing, labeling,
 15 packing, and distributing operations into compliance with the Act and its implementing
 16 regulations to the satisfaction of FDA; and

17 III. Award the United States its costs herein, including costs of investigation to date,
 18 and such other relief as the Court deems just and proper.

19 DATED this 23rd day of January, 2015.

20 Respectfully submitted,

21 MICHAEL S. BLUME
 Director



Melanie Singh
Counsel
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
Tel.:(202) 616-9928
Fax: (202) 514-8742

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

DEEONA R. GASKIN
Assistant Chief Counsel
U.S. Department of Health and
Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993