UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA,

Plaintiff,

v.

SCOTTY'S INCORPORATED,
a corporation, d/b/a
BRUCE ENTERPRISES and
BRUCE'S FRESH PRODUCTS,

and

SANDRA J. JACKSON
an individual,

Defendants

Case 2:14-cv-14450-RHC-RSW

ORDER OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunctive Relief and Motion for Summary Judgment against Scotty's Incorporated ("Scotty's Inc." or "the firm") and Sandra J. Jackson (collectively, "Defendants"), and Defendants having appeared and it having been shown that Defendants are violating, and unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301–399f;

IT IS HEREBY ORDERED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Act.

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food, namely, ready-to-eat ("RTE") sandwiches, that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. Defendants violate the Act, 21 U.S.C. § 331(k), by doing an act that causes the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food, namely, RTE sandwiches, while such articles are held for sale after shipment of one or more components in interstate commerce.

5. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing RTE sandwiches, at or from their facility located at 3426 Junction Street, Detroit, Michigan, and any other locations at or from which Defendants now or in the future, receive, prepare, process, pack, hold, or distribute any RTE sandwiches, unless and until:

A. Defendants retain a person (or persons) (the "expert") who is without any personal or financial ties (other than the retention agreement) to Defendants, and who, by reason of background, education, training, and experience, is qualified to:

1. Ensure that Defendants comply with the Act and current good manufacturing practice requirements for food ("CGMP"), 21 C.F.R. Part 110;

2. Develop, and ensure proper implementation of, a written sanitation control program encompassing all of Defendants' operations to ensure that Defendants comply with the Act and CGMP requirements, 21 C.F.R. Part 110;

3. Ensure that Defendants comply with the seafood hazard analysis and critical control point regulations ("HACCP"), 21 C.F.R. Part 123, when processing seafood products, including conducting hazard analyses, developing a written HACCP plan(s) and recordkeeping system(s), validating processes, and verifying the proper implementation of the HACCP control program;

4. Develop and conduct employee training programs on sanitation controls, CGMP, and seafood HACCP regulations; and

5. Inspect Defendants' facility and establish procedures to ensure that the methods, facilities, and controls are continuously administrated in conformity with this Order, the Act, and all applicable regulations. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the expert within five (5) business days after retaining such expert;

B. Defendants have submitted to FDA the following, created by or with the expert identified in paragraph 5.A:

1. A written sanitation control program encompassing all of Defendants' operations, to ensure that Defendants comply with the Act and 21 C.F.R. Part 110;

2. Written HACCP plans for each and every type of seafood received, prepared, processed, packed, held, and/or distributed by Defendants for which food safety

hazards are identified, including critical control points and critical limits, as required by 21 C.F.R. § 123.6;

3. Written corrective action plans, as part of the HACCP plan(s), to be taken whenever there is a deviation from a critical limit, as described in 21 C.F.R. § 123.7(b);

4. Employee training programs, translated into each employee's native language, on all foodborne hazards, including the sanitation control program, the CGMP requirements, and seafood HACCP regulations; and

5. A plan to destroy all finished and in-process RTE sandwiches, including RTE sandwich ingredients, in Defendants' custody, control, or possession at the time this Order is entered;

C. FDA has approved, in writing, the written sanitation control program, HACCP plan(s), employee training programs, and destruction plan developed by the expert, as specified in paragraph 5.B;

D. Defendants' employees successfully complete the employee training program developed by the expert and approved in writing by FDA pursuant to paragraph 5.C, and Defendants submit documentation to FDA that each employee has received such training;

E. Defendants destroy, at their expense, and under FDA supervision, all finished and in-process RTE sandwiches, including RTE sandwich ingredients, that are in Defendants' custody, possession, or control at the time this Order is entered. Such destruction shall occur within twenty (20) business days after entry of this Order and shall be in accordance with the destruction plan developed by the expert and approved by FDA in writing pursuant to paragraph 5.C;

F. Defendants, at their expense, after destroying all finished and in-process RTE sandwiches, including RTE sandwich ingredients, that are in Defendants' custody, possession, or control at the time this Order is entered pursuant to paragraph 5.E, clean and sanitize their facility and equipment therein and make improvements, rendering the facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing RTE sandwiches, and Defendants ensure that the facility and equipment therein will be continuously maintained in a sanitary condition;

G. Defendants report to FDA, in writing, the actions they have taken to bring their operations into compliance with this Order, the Act, and all applicable regulations, including specific measures they have taken to address each of the deficiencies documented by FDA since 2006;

H. The expert conducts a comprehensive inspection of Defendants' facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute RTE sandwiches to determine whether Defendants' processing facility is sanitary and Defendants are fully prepared to operate in compliance with this Order, the Act, and all applicable regulations. The expert shall verify that Defendants have corrected all of the deficiencies documented by FDA. The expert shall submit all findings, in writing, concurrently to Defendants and FDA, within ten (10) business days after completion of the inspection;

I. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Order, the Act, and all applicable regulations, conducts inspections of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, all RTE sandwiches, and relevant records contained therein;

J. Defendants pay all costs of supervision, inspections, investigations, analyses, examinations, and reviews for FDA's oversight with respect to paragraphs 5.A through 5.I, at the rates set forth in paragraph 9 below; and

K. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 5.A through 5.J of this Order, the Act, and all applicable regulations.

6. Immediately upon resuming operations after completing the requirements set forth in paragraph 5, Defendants shall, in consultation with the expert, continuously implement the sanitation program, HACCP plan(s), and training program developed by the expert and approved in writing by FDA pursuant to paragraph 5.C. Within twenty (20) business days after Defendants' resumption of operations, the expert shall conduct a comprehensive inspection of Defendants' facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute RTE sandwiches to determine whether Defendants are operating in compliance with this Order, the Act, and all applicable regulations. The expert shall submit a report documenting all findings concurrently to Defendants and FDA within ten (10) business days after completion of this inspection. Thereafter, the expert shall conduct inspections every three (3) months for three (3) years, and then annually for the next two (2) years. The expert shall submit a report documenting all findings concurrently to Defendants and FDA within ten (10) business days after completion of each inspection.

7. Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who

receive actual notice of this Order, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more components in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this Order.

8. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and any other locations at which Defendants receive, prepare, process, pack, hold, or distribute RTE sandwiches, and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and all applicable regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished RTE sandwiches, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished RTE sandwiches, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all RTE sandwiches. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Order. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed by the parties, these rates are: $89.35 per hour or fraction thereof per representative for inspection or investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

10. Defendants shall promptly provide any information or records to FDA regarding the receiving, preparing, processing, packing, holding, and distribution of RTE sandwiches upon request. Defendants shall maintain copies of their HACCP plan(s), and all records required by their HACCP plan(s) and 21 C.F.R. Part 123, at their facility in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan(s), by regulation, and/or this Order, shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

11. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, or that

additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, holding, and distributing RTE sandwiches;

B. Recall all RTE sandwiches that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Institute or re-implement any of the requirements set forth in this Order; and/or

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Order, the Act, and all applicable regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 9 of this Order.

12. Any cessation of operations as described in paragraph 11(A) shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Order, the Act, and all applicable regulations.

13. Within ten (10) business days after entry of this Order, Defendants shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt

requested), to each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within twenty (20) business days after the date of entry of this Order, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

14. Defendants shall prominently post a copy of this Order in an employee common area at Defendants' facility within ten (10) business days after entry of this Order and shall ensure that the Order remains posted for a period of at least six (6) months.

15. Defendants shall, within ten (10) business days after entry of this Order, hold a general meeting or series of smaller meetings for employees of Defendants' facility, at which they shall describe the terms and obligations of this Order.

16. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Order, Defendants shall immediately provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) business days after each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Order pursuant to this paragraph. Within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate

Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant Scotty's Incorporated, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) business days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Order, then Defendants shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that Defendants fail to comply with this Order; an additional sum of five hundred dollars ($500.00) in liquidated damages per day for each violation of this Order, the Act, and/or all applicable regulations; and an additional sum equal to twice the retail value of each shipment of adulterated RTE sandwiches. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

19. If any Defendant violates this Order and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

20. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

21. Defendants shall address all communications with FDA required under this Order to Director, Detroit District Office, Food and Drug Administration, 300 River Place Drive, Suite 5900, Detroit, Michigan 48207, and shall reference this civil action by case name and civil action number in such communications.

22. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

S/Robert H. Cleland
ROBERT H. CLELAND
UNITED STATES DISTRICT JUDGE

Dated: May 12, 2016

I hereby certify that a copy of the foregoing document was mailed to counsel of record and/or pro se parties on this date, May 12, 2016, by electronic and/or ordinary mail.

S/Lisa Wagner
Case Manager and Deputy Clerk
(313) 234-5522