IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 13 C 2606
	)	
GOURMET EXPRESS MARKETING, INC., a corporation, and PATRICK A. BRUNO, an individual,	)	Judge Gottschall
	)	
Defendants.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against defendants Gourmet Express Marketing, Inc., a corporation, and Patrick A. Bruno, an individual (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this consent decree of permanent injunction ("Decree") without contest, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This court has jurisdiction over the subject matter of this action, and personal jurisdiction over all parties, pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332.

2. The complaint for permanent injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing, and delivering for introduction, into interstate commerce, food that is adulterated within the meaning of 21 U.S.C. §§ 342(b)(2) and (b)(4).

4. Defendants violated the Act, 21 U.S.C. § 331(k), by causing food to be adulterated within the meaning of 21 U.S.C. §§ 342(b)(2) and (b)(4), while the food is held for sale after shipment in interstate commerce.

5. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing, and delivering for introduction, into interstate commerce, food that is misbranded within the meaning of 21 U.S.C. §§ 343(b), (e)(2), and (t).

6. Defendants violated the Act, 21 U.S.C. § 331(k), by causing food to be misbranded within the meaning of 21 U.S.C. §§ 343(b), (e)(2), and (t), while the food is held for sale after shipment in interstate commerce.

7. Defendants and each and all of their officers, agents, representatives, employees, contractors, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing and causing to be done any of the following acts:

A. introducing and delivering for introduction into interstate commerce any seafood that is adulterated within the meaning of 21 U.S.C. §§ 342(b)(2) or (b)(4);

B. causing any seafood to be adulterated within the meaning of 21 U.S.C. §§ 342(b)(2) or (b)(4), while the food is held for sale after shipment in interstate commerce;

C. introducing and delivering for introduction into interstate commerce any seafood that is misbranded within the meaning of 21 U.S.C. §§ 343(b) or (e)(2) or (t);

D. causing any seafood to be misbranded within the meaning of 21 U.S.C. §§ 343(b) or (e)(2) or (t), while the food is held for sale after shipment in interstate commerce; and

E. failing to implement and continuously maintain the requirements of this Decree.

8. Defendants and each and all of their officers, agents, representatives, employees, contractors, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received notice of this Decree, are subject to the following requirements at Defendants' facility located at 230 South Lombard Road, Addison, Illinois, (and any other or new location at which Defendants receive, process, prepare, pack, label, or distribute seafood):

A. Within fifteen (15) business days after entry of this Decree, Defendants shall retain, at Defendants' expense, an independent person or persons (the "Expert") who is without any personal or financial ties (other than the consulting agreement) to Defendants or their families, and who, by reason of background, education, or experience, is qualified to develop and implement a written plan for receiving, processing, preparing, packing, labeling, and distributing Defendants' seafood to ensure that all representations on product labeling are accurate and that products are what they purport to be. The Expert shall also be qualified to develop and implement an employee training program that instructs personnel on the procedures included in the written plan for ensuring the accuracy and reliability of product labeling. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert as soon as they retain such Expert;

B. Within thirty (30) business days after entry of this Decree, the Expert selected by Defendants shall:

(1) Develop and implement a written plan for Defendants' operations, namely the receipt, processing, preparing, packing, labeling, and distribution of seafood, to ensure that all representations on product labeling are accurate and that products are what they purport to be. The plan shall include, at a minimum, written procedures for:

(a) weighing and labeling seafood that has been, or will be, ice-glazed to ensure the accuracy of all representations of the seafood's net weight on product labeling, and documenting that these procedures have been followed for each unit of seafood distributed;

(b) maintaining continuous labeling of all seafood, from receipt of each bulk unit of seafood through distribution of each unit of finished product to customers, so that the species of every unit of seafood in Defendants' facility is readily identifiable, verifiable, accurate, and consistent;

(c) maintaining records of all of Defendants' seafood purchases, including the species and amount of seafood ordered and the species and amount of seafood received, plus the supplier's lot number and a copy of the supplier's label, for each unit of seafood that Defendants purchase and receive;

(d) maintaining records of all customer orders, including the species and amount of each seafood product requested; and

(e) maintaining records of each unit of seafood shipped to fill each customer order so that the records clearly identify which incoming product is used to fill each customer order. For each unit of seafood shipped, the records must include, at a minimum, the species, net weight, a lot number assigned by Defendants, the original lot number assigned by Defendants' supplier on the incoming product, and copies of the label on the outgoing product and the original label used by Defendants' supplier on the incoming product;

(2) Develop an employee training program that includes, at a minimum, instruction on the procedures described in paragraph 8(B)(1), and provide training in accordance with the training program to Defendants' employees and contractors. The Expert shall document that each employee or contractor has received and understands the training; and

(3) Evaluate whether Defendants are effectively implementing the written plan developed pursuant to paragraph 8(B)(1); write a report of the evaluation; certify to FDA that Defendants adequately implement the plan to ensure the accuracy and reliability of their product labeling; and submit the certification and copies of the report and plan to FDA.

9. Within thirty (30) business days after entry of this Decree, and every four (4) months thereafter, Defendant Bruno shall provide an affidavit to FDA certifying Defendants' compliance with the written plan developed pursuant to paragraph 8(B)(1), to ensure that all representations on product labeling are accurate and that products are what they purport to be. The affidavit signed by Defendant Bruno shall also describe in detail the steps Defendants have taken to ensure continuing compliance.

10. While this Decree is in effect, Defendants shall maintain all records that are required by paragraph 8 and all records that relate to the receipt and distribution of all seafood, and shall make all of the records immediately available to FDA, upon request.

11. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility located at 230 South Lombard Road, Addison, Illinois, (and any other or new location at which Defendants receive, process, prepare, pack, label, or distribute seafood) and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and applicable regulations. During the inspections, FDA shall be permitted: to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, labeling, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process and finished articles of food, containers, labeling, and packaging material; and to examine and copy all records related to receiving, processing, preparing, packing, labeling,

holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

12. Defendants shall pay all costs of FDA's inspections, supervision, review, analyses, and other work that FDA deems necessary to evaluate the Defendants' compliance with any part of this Decree at the standard rates prevailing at the time that the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour and fraction thereof per representative for analytical work; $0.565 per mile for travel by automobile; the government rate or 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 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. Defendants shall pay these costs within twenty (20) business days after receiving an invoice from FDA assessing such costs.

13. If, based on any inspection, analysis or other information, FDA finds that Defendants are not in compliance with the requirements of this Decree, the Act, or applicable regulations, FDA may, as and when it deems necessary, issue a directive notifying Defendants in writing of the noncompliance and ordering Defendants to take immediate action, including but not limited to one or more of the following actions:

A. cease receiving, processing, preparing, packing, labeling, holding, or distributing seafood;

B. submit additional samples of seafood for analytical testing;

C. recall seafood; and

D. take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and applicable regulations, including, but not limited to, requiring that Defendants re-institute or expand any of the requirements in paragraph 8 of this Decree.

14. The following process and procedures shall apply when FDA issues a directive under paragraph 13:

A. Unless a different time frame is specified by FDA in its directive, within five (5) business days after receiving such directive, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's directive, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's directive, immediately implement the directive (as modified, if applicable) and may, if they so

choose, bring the matter before this court on an expedited basis for judicial review. While seeking that review, Defendants shall continue to diligently implement and comply with FDA's directive, unless and until the court stays, reverses, or modifies FDA's directive. Judicial review of FDA's directive shall be made pursuant to paragraph 19.

D. Any cessation of operations ordered pursuant to paragraphs 13 and 14 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree and may resume operations.

15. Defendants shall provide notice of this Decree in the following manner:

A. Within fifteen (15) business days after the entry of this Decree, Defendants shall: (1) provide a copy of the Decree, by personal service or by certified mail, return-receipt requested, to each and all of Defendants' officers, agents, representatives, employees, attorneys, contractors, successors, assigns, and any and all persons in active concert or participation with any of them; and (2) explain the terms of the Decree to each employee.

B. Within twenty (20) business days after the entry of this Decree, Defendants shall provide to FDA an affidavit from a person with personal knowledge of the facts therein, stating the fact and manner of Defendants' compliance with paragraph 15(A) and identifying the names and positions of all persons who were notified pursuant to paragraph 15(A).

C. After entry of the Decree, Defendants shall, within five (5) business days after employment of any new employee: (1) provide a copy of the Decree, by personal service or by certified mail, return-receipt requested, to all such employees; and (2) explain the terms of the Decree to all such employees.

16. Defendants shall notify FDA at least twenty (20) business days before any change in ownership, name, or character of the Defendants' business that occurs after the entry of this Decree,

such as reorganization, relocation, assignment, or sale of the business that may affect compliance obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assignee at least twenty (20) business days prior to such sale or change of business and shall furnish to FDA an affidavit of compliance with this paragraph within ten (10) business days before such sale or change of business.

17. If any Defendant fails to comply with this Decree, then Defendants shall pay to the United States liquidated damages in the sum of five thousand dollars ($5,000.00) for each day that the Defendant fails to comply with this Decree and an additional ten thousand dollars ($10,000.00) for each shipment of each food that fails to comply with this Decree. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States to seek, and the court to impose, additional criminal or civil contempt penalties based on conduct that may also be the basis for the payment of liquidated damages.

18. If any Defendant violates this Decree and is found in civil or criminal 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, investigational and analytical expenses, and any other costs or fees relating to the contempt proceedings.

19. All decisions specified in this Decree 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 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.

20. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

21. All notifications, correspondence, and communications to FDA required by this Decree shall be submitted to the Director, Chicago District Office, U.S. Food and Drug Administration, 550 West Jackson Boulevard, Suite 1500 South, Chicago, Illinois 60661, with a copy to the United States Attorney's Office for the Northern District of Illinois, attention Donald Lorenzen, 219 South Dearborn Street, Chicago, Illinois 60604, and shall reference this civil action by case name and civil action number.

22. This Decree resolves only those claims set forth in the complaint in this action, and does not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against Defendants herein.

23. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with applicable laws and regulations and this Decree for at least sixty (60) months after satisfying all of their obligations under paragraph 8 of this Decree, Defendants may petition this court for relief from this Decree, and the United States will not oppose such petition.

24. This court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

We hereby consent to the entry of this Decree.

For Plaintiff:

GARY S. SHAPIRO
Acting United States Attorney

By:_____
DONALD R. LORENZEN
Assistant U.S. Attorney
219 South Dearborn Street
Chicago, Illinois 60604
(312) 353-5330
donald.lorenzen@usdoj.gov

Dated: April ___, 2013

Of Counsel:
WILLIAM B. SCHULTZ
Acting General Counsel
Food and Drug Division
Office of General Counsel
U.S. Department of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
White Oak 31, Room 4550
Silver Spring, MD 20993-0002

For Defendants:

_____ Dated: April ___, 2013
PATRICK A. BRUNO, on behalf of
GOURMET EXPRESS MARKETING, INC.

_____ Dated: April ___, 2013
PATRICK A. BRUNO, in his individual capacity

_____ Dated: April ___, 2013

FREDERICK H. BRANDING
Olsson Frank Weeda Terman Matz PC
The Watergate, Suite 500
600 New Hampshire Avenue, NW
Washington, D.C. 20037
(202) 286-0067
and
79 West Monroe
Suite 1000
Chicago, Illinois 60603
(847) 687-8415
fbranding@ofwlaw.com
Attorney for Defendants

_____ Dated: April ___, 2013

DANIEL C. MURRAY
Johnson & Bell
33 West Monroe Street
Suite 2700
Chicago, Illinois 60603
(312) 372-0770
murrayd@jbltd.com
Attorney for Defendants

SO ORDERED this _____ day of _____, 2013.

_____
UNITED STATES DISTRICT JUDGE