

UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE



In re:

Galant Food Company

Respondent

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FMIA Docket No. 14-
PPIA Docket No. 14- 0170

Consent Decision and Order

This proceeding was instituted under the Federal Meat Inspection Act ("FMIA"), as amended (21 U.S.C. §§ 601 et seq.), and the Poultry Products Inspection Act ("PPIA"), as amended (21 U.S.C. §§ 451 et seq.), and the applicable Rules of Practice (7 C.F.R. §§ 1.130 et seq. and 9 C.F.R. § 500.1 et seq.), to withdraw Federal inspection services from Galant Food Company, (hereinafter referred to as Respondent). This proceeding was commenced by a complaint filed by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), on August 13, 2014.

The parties have agreed that this proceeding should be terminated by entry of this Consent Decision and Order (Order) set forth below pursuant to the consent decision provisions of the Rules of Practice (7 C.F.R. § 1.138).

The Respondent admits the findings of jurisdictional fact as set forth herein. The Respondent neither admits nor denies the remaining allegations and waives oral hearing and further procedure. Respondent and its owners, officers, directors, partners, successors, assigns, and affiliates waive any claim against complainant under the Equal Access to Justice Act of 1980

(5 U.S.C. § 504 et seq.) and waive other action against USDA or its employees in connection with this proceeding and the facts and events that give rise to this proceeding. Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to entry of this decision.

Findings of Fact

1. Respondent is now and at all times material herein was, a corporation located at 735 Fremont Avenue, San Leandro, California 94577. Respondent's corporation previously was located at 585 Potrero Street, San Francisco, California 94110, but moved to its current location in June, 2013.

2. Respondent was and has been granted Federal meat and poultry inspection services, pursuant to the FMIA and PPIA, at the above named establishment that was and has been designated as Official Establishment Number 9014M/P.

3. On February 10, 2010, the FSIS District Office in Alameda, California (hereinafter, the Alameda District Office or (ADO), issued respondent a Notice of Suspension (NOS) that suspended the assignment of federal inspectors and withheld marks of federal inspection for respondent's Ready to Eat (RTE) products based on findings of rodent infestation within respondent's establishment, specifically, rodent droppings and one or more dead rodents inside the establishment, which may have rendered the products produced therein adulterated.

4. On May 11, 2010, ADO personnel discovered that respondent's final product labels for two of its RTE products, "Galina's Piroshki, Chicken Provance Puffs" and Galina's Piroshki, Beef & Farm Vegetables Puffs", failed to declare three allergens, soy, eggs and yellow #5, thereby putting the public's health at risk of an adverse reaction. On May 12, 2010, respondent initiated a Class I recall, FSIS RC-032-2010, for these two products.

5. From May 3, 2010, through May 27, 2010, ADO personnel conducted a comprehensive Food Safety Assessment (FSA) of respondent's operation and found that respondent had failed to effectively implement and maintain an Sanitation Standard Operating Procedures (SSOPs) program and a Hazard Analysis and Critical Control Point (HACCP) plan, as required by 9 C.F.R. §§ 416 and 417, respectively.

6. On May 6, 2010, ADO personnel also performed a Routine *Listeria monocytogenes* (RLm) Verification Sampling of respondent's post-lethality product exposed environment, food contact surfaces, and products, and composite analysis of the environmental samples collected from respondent's establishment detected the presence of Lm therein, demonstrating that respondent had failed to maintain sanitation performance standards in its post-lethality processing areas. Based on the foregoing, the ADO issued respondent a Reinstatement of Notice of Suspension (RNOS) on May 27, 2010 in accordance with 9 C.F.R. §§ 417, 416, and 430.

7. On October 13, 2010, the ADO issued respondent another RNOS based on findings of rodent infestation within respondent's establishment, specifically, numerous rodent droppings inside the production area and kitchen, along the base of a wall spanning the entirety of the food processing areas, and on a stairwell leading to a storage area for packing materials, which may have rendered the products produced therein adulterated in violation of 9 C.F.R. § 416.

8. On September 8, 2011, the ADO issued respondent another RNOS based on findings of rodent infestation within respondent's establishment, specifically, multiple findings of rodent droppings inside respondent's processing areas, which may have rendered the products produced therein adulterated in violation 9 C.F.R. § 416.

9. On May 2, 2012, the ADO issued respondent an NOS based on FSIS findings that respondent had produced, packaged, labeled, and applied marks of federal inspection to various RTE meat and poultry products that had not been federally inspected because said products had been produced in a period of time during which respondent had represented to the ADO that it would not be operating, thereby causing the non-federally inspected products to be both adulterated and misbranded.

10. From September 3, 2013, through March 20, 2014, an FSIS Enforcement Investigation and Analysis Officer (EIAO) from the ADO continuously performed an FSA of respondent's establishment during its periods of operation. On September 6, 2013, the EIAO discovered that respondent's final product labels for two of its RTE products, "ENZO'S Italian Combo Calzone" and ENZO'S Chicken Fajita Calzone", failed to declare an allergenic ingredient, eggs, thereby putting the public's health at risk of an adverse reaction and causing the products to be misbranded. That same day respondent initiated a Class I recall, FSIS RC-050-2013, of approximately 1,650 pounds of the fresh or frozen calzone products.

11. On September 12, 2013, the EIAO discovered that respondent's final product label for another one of its RTE products, "Chicken Provance French Puffs" failed to declare an allergenic ingredient, eggs, thereby putting the public's health at risk of an adverse reaction and causing the product to be misbranded. On September 13, 2013, the respondent initiated a Class I recall, FSIS RC-052-2013, of approximately 420 pounds of said product.

12. On September 16, 2013, the ADO issued respondent an NOS based on the two recalls earlier that same month and findings that respondent had failed to effectively implement and maintain allergen controls and other system controls and processes sufficient (1) to ensure that its RTE meat and poultry products were safe, wholesome, and not injurious to health and (2)

to preclude the possible production and shipment of misbranded products in accordance with 9 C.F.R. § 417.

13. On October 21, 2013, the ADO issued respondent an RNOS after respondent failed to abide by the commitments that it made to FSIS in its response to the NOS dated September 16, 2013. Specifically, respondent again failed to effectively implement and maintain required system controls and processes (1) to ensure that its RTE products were safe, wholesome, and not injurious to health, (2) to guard against product mislabeling by ensuring that its labels identified all of the ingredients in its finished RTE products, and (3) to prevent such mislabeled products from entering commerce.

14. On December 12, 2013, an FSIS Front Line Supervisor took a withholding action at respondent's establishment because respondent had falsified its HACCP records.

15. On March 11, 2014, the ADO issued respondent an NOS based on acts of intimidation, interference, and harassment committed by respondent's personnel against FSIS inspectors during the performance of the latter's official duties.

16. On March 20, 2014, the ADO issued a Notice of Intended Enforcement (NOIE) based on the results of an FSA revealing respondent's failure to effectively implement and appropriately maintain the required HACCP plan and SSOPs in accordance with 9 C.F.R. §§ 417 and 416.

17. On April 9, 2014, the ADO issued a NOS based on respondent's failure to respond adequately to the NOIE issued March 20, 2014, and failure to effectively implement and appropriately maintain the required HACCP plan and SSOP and Sanitation Performance Standards (SPS) programs in accordance with 9 C.F.R. §§ 416 and 417.

Conclusion

The parties having admitted the jurisdictional facts and the parties having agreed to entry of this decision, this decision will be entered.

Order

Federal inspection services under the FMIA and the PPIA are withdrawn from Respondent, its owners, officers, directors, partners, successors, affiliates or assigns, directly or indirectly or through any corporate device, for a period of three (3) years, beginning on the effective date of this Order. Provided, however, the withdrawal of Federal meat and poultry inspection services shall be held in abeyance, and inspection services shall be provided to Respondent for so long as the statutory and regulatory requirements for applicable inspection services under the FMIA and PPIA are met, in addition to all terms and conditions of this Order set forth below.

Conditions

1. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall demonstrate compliance with all applicable FSIS statutory and regulatory requirements, including but not limited to 9 C.F.R. Parts 416, 417, 418 and 430, upon a review and examination of (a) Respondent's Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOPs), Hazard Analysis and Critical Control Point (HACCP) system, *Listeria Monocytogenes* ("Lm") sampling and testing program, Recall of Meat and Poultry Products Plan, other written sanitation programs, process controls, corrective actions, and sampling and testing programs, and any other related food safety programs; and (b) the physical and sanitary conditions of respondent's establishment.

Sanitation Performance Standards (SPS)

2. Prior to resumption of inspection services, and subject to verification by FSIS,

Respondent shall:

(a) develop written procedures for monitoring and identifying non-compliance, taking corrective and preventative actions, and recordkeeping that Respondent will implement and conduct to operate and maintain its establishment, including its premises, facilities, equipment, and outside premises in a manner sufficient to: (i) prevent the creation of insanitary conditions and practices, and to preclude harborage and breeding of pests; (ii) comply with the requirements of SPS regulations (9 C.F.R. §§ 416.1 to 416.6); and (iii) ensure that meat and meat food products, and poultry and poultry products that are prepared, packed, and stored at respondent's facility are not adulterated or misbranded; and

(b) address and correct any premises, facility and equipment non-compliance issues previously identified by FSIS, or identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 1(b) of this Order.

3. Upon the resumption of inspection services, and subject to verification by FSIS, respondent shall:

(a) comply with the requirements of the SPS regulations (9 C.F.R. §§ 416.1 to 416.6);

(b) operate and maintain, at all times, its establishment, including its interior premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, and to preclude harborage and breeding of pests;

(c) ensure that meat and meat food products, and poultry and poultry food products, are not adulterated; and

(d) assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrections, and repairs to the establishment buildings, structures, rooms, and compartments to ensure that they are kept in good repair and have sufficient size to allow for processing, handling, and storage of product in a manner to ensure and maintain sanitary conditions, and to preclude harborage and breeding of pests.

(e) implement and maintain the SPS written procedures for the duration of this Order.

Sanitation Standard Operating Procedures (SSOPs)

4. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) develop written sanitation standard operating procedures (SSOPs) to describe the monitoring activities, recordkeeping, and other procedures that Respondent will implement, conduct, and maintain, on a daily and ongoing basis, before, during, and after operations, in accordance with this Order and regulatory requirements (9 C.F.R. §§ 416.11 to 416.16) to ensure sanitary conditions and prevent product adulteration; and

(b) ensure that its SSOPs include specific, written instructions addressing, at a minimum, the following procedures: (i) cleaning and sanitizing of food contact surfaces of facilities, equipment and utensils; (ii) complex equipment use and methods of cleaning; (iii) proper handling, storage, denaturing, and disposal of inedible products; (iv) re-conditioning of contaminated product; and (v) employee hygienic practices. These written instructions shall specify the frequency of each aforementioned procedure.

5. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in this Order and regulatory requirements of 9 C.F.R. §§ 416.11 to 416.16 to ensure sanitary conditions and prevent product adulteration; and

(b) implement and document all corrective and preventive actions, as required by 9 C.F.R. § 416.15; routinely evaluate the effectiveness of its SSOPs; and implement necessary modifications as required by 9 C.F.R. § 416.14 to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, not adulterated, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) Plan

6. Prior to the resumption of inspection services, and subject to verification by FSIS, respondent shall:

(a) reassess its HACCP systems and plans to describe each system of process controls and procedures that Respondent will implement, conduct, and maintain on a daily and on-going basis to control and prevent the introduction of food safety hazards in its meat or poultry food products. These plans shall address specific process controls and procedures within respondent's HACCP system(s) (i.e. *Listeria monocytogenes* (“*Lm*”) in post lethality process steps), including but not limited to, the following: (i) measures to identify the biological, chemical, and physical food safety hazards reasonably likely to occur at each process step, and to eliminate such hazards or reduce them to undetectable levels; (ii) measures to address *Lm* as a hazard in the process; and (iii) measures to eliminate or reduce and control the level of *Lm* to prevent contamination of

respondent's finished Ready-to-Eat (RTE) product, food contact surfaces, and non-contact environmental surfaces; and

(b) retain all decision making documents for its HACCP systems and plan(s), including its hazard analysis or analyses, validation protocols, and all parameters used in said protocols, and data to support the food safety system(s).

7. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) implement, validate and maintain on a daily and on-going basis the HACCP system(s) and plan(s), in accordance with the regulatory requirements of 9 C.F.R. Part 417 and as provided in this Order;

(b) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP system(s) and plan(s) as necessary to ensure that the regulatory requirements for the control and prevention of pathogens and the production and distribution of wholesome, unadulterated, and properly labeled products in commerce are met, as required by and consistent with 9 C.F.R. Part 417; and

(c) conduct ongoing assessments, validation, and testing of the adequacy of the critical control points, critical limits, monitoring, and record-keeping procedures, and corrective actions set forth in the HACCP system(s) and plan(s), to ensure that Respondent's food safety systems remain validated over time, as required by 9 C.F.R. Part 417.

Allergen Prevention and Control Program

8. Prior to the resumption of inspection services, and subject to verification by FSIS, respondent shall:

(a) develop a written allergen program for allergenic ingredients, including monitoring, verification, corrective and preventative actions, and recordkeeping that it will implement, conduct, and maintain, on a daily and ongoing basis, to ensure that all inspected meat and poultry food products do not become adulterated, contaminated, or misbranded. This control program shall include, at a minimum, provisions to:

(i) process, handle, store, and label product with an allergenic ingredient or ingredient of public health concern; and (ii) ensure monitoring, verification, and recordkeeping activities.

(b) ensure written recall procedures are in place to effectively recall potentially adulterated or misbranded products because of the presence of undeclared allergens produced or processed by respondent when found within distribution channels.

9. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall implement, conduct, and maintain, on a daily and on-going basis, its written Allergen prevention and control program, and comply with the requirements of 9 C.F.R. §§ 317.2(f)(1), 318.6, and 381.118(a)(1).

Listeria monocytogenes (Lm) Program Provisions

10. Prior to the resumption of inspection services, and subject to Verification by FSIS, Respondent shall develop a written *Lm* sampling and testing program for their ready-to-eat (RTE) products in accordance with 9 C.F.R. Part 430 and, at a minimum, shall:

(a) Include Alternative 3 for the production of post-lethality exposed RTE product based on its control program for *Lm*;

(b) Include a testing program for food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free from *Lm* or of an indicator organism;

(c) Describe the conditions under which the establishment will implement hold and test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism;

(d) State the frequency for which the testing will be done;

(e) Identify the size and location of the sites that will be sampled; and

(f) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or of an indicator organism is maintained.

11. Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *Lm* program, and corrective actions and preventive measures in accordance with 9 C.F.R. § 417.5.

12. In the event of any positive *Lm* test result for food contact surfaces, non-contact surfaces or RTE products, Respondent shall;

(a) document and implement appropriate corrective and preventative actions;

(b) take appropriate action to identify and eliminate the source of the *Lm* contamination;

(c) reassess its *Lm* program, SSOP, and HACCP or other prerequisite programs; and

(d) monitor and verify the effectiveness of the corrective actions and preventative measures identified and implemented.

13. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall implement, conduct, and maintain, on a daily and on-going basis, its written *Lm* sampling and testing program for the duration of this Order, and comply with 9 C.F.R. § 430.

Establishment Management and Personnel

14. (a) Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall designate, in writing, two full-time employees, one as a principal and the other as an alternate, who shall be responsible for the overall implementation, coordination, documentation, monitoring, recordkeeping, review and maintenance of the facility's SPS, SSOPs, and HACCP plans, *Lm* sampling and testing programs, Allergen Prevention and Control Program, and all other requirements of this Order. The designated principal and alternate shall have completed, prior to the resumption of inspection services, a course of instruction in the seven principles of HACCP, SSOP, and be trained in the *Lm* sampling and testing procedures, and shall be present at all times when operations requiring inspection are conducted.

(b) Respondent shall not conduct any processing operations in the absence of said designated principal or alternate. The designated principal and alternate shall have authority to hold up production, stop production, remove product from production, or take positive control of any products produced, processed, packed, or stored at the establishment that are or are believed to be adulterated or misbranded, or when facility sanitation or production deficiencies are observed. Respondent may name a new designated principal and alternate employee or employees upon written notification to the FSIS.

(c) Prior to the resumption of inspection services, Respondent shall provide a detailed summary of the authority and responsibilities that the designated principal and alternate are granted with respect to actions taken in the establishment.

paragraphs 15 through 18 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Ethics Training and Corporate Code of Conduct

20. Within ninety (90) days of the effective date of this Order, all of respondent's managers, supervisors, and corporate officers shall participate in and successfully complete a training program or educational course encompassing ethical business practices. Prior to participating in this course, Respondent shall submit a detailed description of the proposed training course for concurrence by the Director, Enforcement and Litigation Division (ELD), or designee. Respondent shall maintain for the duration of this Order records documenting the successful completion of such training and shall make those records available upon request by any FSIS program personnel.

21. Within sixty (60) days of the effective date of this Order and subject to verification by FSIS, respondent shall develop and submit for review and concurrence by the Director, ELD, a code or policy statement of business conduct and ethics to ensure food safety and regulatory compliance in business practices (hereinafter "Corporate Code") applicable to all business entities and individuals within or employed by the Respondent. The Corporate Code, at a minimum, shall include:

- (a) a statement of corporate policy addressing business ethics and the public trust;
- (b) a statement of respondent's commitment to comply with all applicable Federal and State food safety and other laws in the conduct of its business;
- (c) guidelines for respondent's employees to follow with respect to food safety and ethics issues; and

- (d) assurances to preclude any acts of intimidation, assault, or interference of FSIS program personnel.

The Corporate Code shall be permanently displayed in a prominent location in the Respondent's federal establishment and shall be discussed with all current and new employees.

Third Party Audits

22. Respondent shall upon resumption of federal inspection services, cause to be made, by a qualified, independent third-party, written audits of:

- (a) Respondent's implementation, monitoring, records and documentation, and maintenance of its sanitation program, SSOPs, HACCP plan, and other process controls, *Lm* sampling and testing, allergen prevention and controls, and other programs;

- (b) the effectiveness of Respondent's sanitation program, SSOPs, HACCP plan, and other process controls, *Lm* sampling and testing, allergen prevention and controls, and other programs to ensure food safety; and

- (c) Respondent's compliance with FSIS statutory and regulatory requirements, the terms of this Order, and any findings and recommendations of the independent, third-party auditor.

23. Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. Respondent's written response shall identify: (i) any modifications to its SSOPs, HACCP plan, *Lm* sampling and testing, allergen prevention and control, or other programs or plans; (ii) any corrective actions implemented or planned in response to the audit; (iii) any other actions implemented or planned in response to the audit; and (iv) information in support of any decision by Respondent not to implement any audit recommendation.

24. Respondent shall submit a copy of each third-party audit, a copy of Respondent's written response, or other documents related to the audit to the Director ELD for review and concurrence within (30) calendar days after each audit is completed.

25. The frequency of the aforementioned audits shall be as follows:

(a) the first audit shall be conducted within ninety (90) calendar days from the effective date of this Order; and

(b) subsequent audits shall be conducted every (180) calendar days thereafter for the duration of this Order.

Record Keeping Provisions

26. Respondent shall maintain full, complete, and accurate copies of (a) all written records required to be maintained by the FMIA, PPIA, and the regulations; (b) all records required to be maintained under applicable Federal, State, and local statutes; and (c) all plans and records of its SPS and SSOP programs, HACCP plan, *Lm* sampling and testing, or other systems, programs, or plans required by the FMIA, PPIA, and the regulations of this Order.

27. Respondent shall immediately notify FSIS program personnel of any changes or modifications to its SSOPs, HACCP plan, *Lm* sampling and testing, or other systems, programs, or plans required by regulation or by this Order, and all associated recordkeeping forms.

28. Respondent shall make all records regarding its federally inspected establishment or other regulated business or business activities at said establishment available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

General Provisions

29. Respondent and any of the respondents, partners, employees, agents or affiliates, shall not:

(a) violate any section of the FMIA, PPIA or regulations promulgated thereunder, any state or local statute involving the preparation, sale, transportation, or attempted distribution of any adulterated, non inspected, misbranded or deceptively packaged meat, or poultry food products;

(b) commit any felony or fraudulent act or other criminal act involving fraud, conspiracy, bribery, or any other act or circumstances indicating a lack of integrity needed for the conduct of operations affecting public health;

(c) willfully make or cause to be made any false entry into any accounts, records, reports, or memoranda kept by respondent in compliance with Federal, State or local statutes or regulations or this Order; neglect or fail to make full, true, and correct entries in such accounts, records, reports or memoranda; and fail to keep such accounts, records, reports, or memoranda that fully and correctly disclose all transactions in respondent's business;

(d) assault, intimidate, impede, threaten or interfere with any program employee in the performance of his or her official duties under the FMIA, PPIA, or regulations promulgated thereunder; and

(e) conduct any operation requiring Federal inspection outside respondent's official hours of operations without first submitting a written request to, and receiving written approval from FSIS.

30. Respondent shall fully and completely cooperate with any FSIS investigation, inquiry, review, or examination of respondent's compliance with the FMIA, PPIA or this Order.

Enforcement Provisions

31. The Administrator, FSIS, may summarily withdraw the grant of federal inspection from Respondent upon a determination by the Director, ELD, that Respondent has committed an

act in violation of, or failed to comply with any requirement of this Order. The withdrawal of Respondent's grant of federal inspection shall become effective immediately upon FSIS's service of a Notice of Summary Withdrawal to Respondent, without further proceeding. Respondent shall retain the right, after any summary withdrawal of Respondent's grant of federal inspection, to request within twenty days an expedited hearing, pursuant to the applicable rules of practice (7 C.F.R. Part 1, subpart H and 9 C.F.R. Part 500). Such request for an expedited hearing must be submitted within twenty (20) calendar days of FSIS' service of a Notice of Summary Withdrawal.

Miscellaneous Provisions


32. Nothing in this Order shall preclude (a) any future criminal, civil, regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to any action under the FSIS Rules of Practice (9 C.F.R. Part 500) or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.


33. If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provision herein.

34. The provisions of this Order shall be applicable for a period of three (3) years from the effective date of this Order.

35. This Consent Decision and Order shall become effective upon issuance by the Administrative Law Judge.

GALANT FOOD COMPANY. (GALANT)
Respondent

BY: 
Len Galant, owner
Galant Food Company


Scott C. Safian, Director
Enforcement and Litigation Division
Food Safety and Inspection Service
U.S. Department of Agriculture

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Mark Bolin
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U.S. Department of Agriculture
Office of the General Counsel

[REDACTED]
Bob Hibbert
Attorney for Respondent

Issued this 15th day of August 2014

at Washington, D.C.

[REDACTED]
/ Administrative Law Judge