

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
v.)	CIVIL ACTION NO. 16-1072
NATIVE AMERICAN ENTERPRISES,)	
LLC, a limited liability company, and)	
WILLIAM N. MCGREEVY, and)	
ROBERT C. CONNER,)	<u>CONSENT DECREE OF</u>
individuals,)	<u>PERMANENT INJUNCTION</u>
)	
Defendants.)	
)	
)	
)	

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Native American Enterprises, LLC (“NAE”), and William N. McGreevy and Robert C. Conner (the “Individuals”) (hereinafter NAE and the Individuals are collectively, “Defendants”), and Defendants, without admitting or denying the allegations in the Complaint and disclaiming any liability in connection therewith, having appeared and consented to the entry of this Consent Decree of Permanent Injunction (“Decree”) without contest and before any testimony has been taken, 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 and over all parties to this action.
2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. §§ 301 et seq. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing,

or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4). The Complaint also alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration of articles of food 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. The Complaint alleges that articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, and/or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

3. For the purpose of this Decree, “meat products” includes “meat food products” as defined by the Federal Meat Inspection Act, 21 U.S.C. § 601(j) and “poultry products” as defined by the Poultry Products Inspection Act, 21 U.S.C. §453(f).

4. For purposes of this Decree, “packaged products” means food products other than meat products that are received by Defendants in packaged form, and that remain packaged and are not opened, manufactured, prepared, processed, and/or packed by Defendants, and/or each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) (hereinafter, “Associated Persons”).

5. Upon entry of this Decree, Defendants shall destroy, under FDA’s supervision, all in-process and finished articles of food, other than meat products and packaged products, in Defendants’ custody, control, or possession.

6. Defendants represent to the Court that as of the date this Decree is signed by Defendants, they are not, at 230 N. West Street, Wichita, Kansas or any other location, directly

or indirectly engaged in the manufacturing, preparing, processing, packing, and/or labeling of any article of food (including refried beans and sauces, as described in the Complaint for Permanent Injunction filed in this action) other than meat products as defined in Paragraph 3. Defendants store and distribute packaged products at 230 N. West Street, Wichita, Kansas.

7. Upon entry of the Decree, Defendants shall provide to the U.S. Food and Drug Administration (“FDA”) in writing at the address specified in Paragraph 27 a list of all food products, including ingredient lists and formulations for such products, that they intend to process, manufacture, prepare, pack and/or label. FDA will notify Defendants within five (5) business days whether any products on this list are food other than meat products as defined in Paragraph 3. If FDA notifies Defendants that any food products they intend to manufacture, prepare, process, pack and/or label are food other than meat products, Defendants shall immediately cease such manufacturing, preparing, processing, packing, and/or labeling unless and until they comply with Paragraph 9 and receive written notification from FDA as specified in Paragraph 9(M). Should Defendants change the food products or the formulations for any food they intend to process, manufacture, prepare, pack, and/or label after providing FDA with this initial list, they shall notify FDA in writing at the address specified in Paragraph 27 at least ninety (90) calendar days in advance of such changes.

8. If Defendants intend to resume, directly or indirectly, manufacturing, preparing, processing, packing, and/or labeling any article of food other than meat products at 230 N. West Street, Wichita, Kansas or any other location, Defendants must first notify FDA in writing at the address specified in Paragraph 27 at least ninety (90) calendar days in advance of resuming such operations. This notice shall include a description of the type(s) of operations Defendants intend to resume, including a list of any new or reformulated food products, and the ingredient lists and

formulations for such products, and the locations at which Defendants intend to resume such operations. Defendants shall not resume such operations unless and until they comply with Paragraphs 9(A)-(L) of this Decree and have received written notification from FDA as specified in Paragraph 9(M).

9. Upon entry of this Decree, Defendants and their Associated Persons who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing and/or labeling, at or from their facility located at 230 N. West Street, Wichita, Kansas, and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, package hold, and/or distribute food (“Defendants’ facility”), any article of food other than meat products unless and until:

A. Defendants select and retain, at Defendants’ expense, an independent laboratory (the “laboratory”) having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within Defendants’ facility and analyze those samples for the presence of *Listeria monocytogenes* (“*L. mono*”) using a method that is acceptable to FDA. Within three (3) calendar days of retaining the laboratory, Defendants shall provide FDA with a copy of the laboratory service contract, which shall contain provisions acceptable to FDA for regular environmental and finished product sample collection and analyses, including how and where to sample, the number and frequency of samples to be collected, and the methods of analyses, in accordance with the Sanitation Control and Food Safety Plan discussed in Paragraph 9(C) below;

B. Defendants select and retain, at Defendants' expense, an independent expert(s) (the "Sanitation and Food Safety Expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to: (1) develop and ensure adequate implementation of a Sanitation Control and Food Safety Plan, covering Defendants' manufacturing processes for any article of food other than meat products, cleaning and sanitizing operations, pest control, employee health and hygiene precautions and facility construction and maintenance (including the facility's buildings and sanitation-related systems (i.e., plumbing and sewage disposal), equipment, and utensils contained therein) at Defendants' facility; and (2) inspect Defendants' facility and determine whether the methods, facilities, and controls operated and administered are in conformity with this Decree, the Act, and its implementing regulations. Within three (3) calendar days of retaining the Sanitation and Food Safety Expert, Defendants shall notify FDA in writing of the name and qualifications of the Sanitation and Food Safety Expert;

C. Defendants' Sanitation and Food Safety Expert, in consultation with the laboratory, after review of all FDA observations since July 2013 to present, develops an effective written Sanitation Control and Food Safety Plan for any food other than meat products which shall, at a minimum:

- (i) Establish adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and/or distributing articles of food other than meat products to minimize the risk of introducing *L. mono*, other pathogenic organisms, and filth into food, food-contact surfaces, and food-packaging materials, and to ensure that

foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facility and all equipment therein suitable for use in receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") as well as monitoring and record-keeping procedures to ensure that Defendants' facility and equipment therein are continuously maintained in a sanitary condition and in compliance with current good manufacturing practice ("GMP") requirements. *See* 21 C.F.R. Part 110;

(ii) Establish an effective Environmental Monitoring and Testing Program to ensure that pathogenic organisms such as *L. mono* are not present within the facility. The Environmental Monitoring and Testing Program shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout Defendants' facility. The Environmental Monitoring and Testing Program must include sufficient environmental sampling of at least ten swabs per lot, and intensified sampling if routine testing reveals *Listeria species* ("*L. spp.*"); follow-up on any *L. spp.* isolate from any food-contact surface to determine if it is *L. mono*; regular finished-product testing; and a plan to place on hold all food products other than meat products that have come in contact with a site that tests positive for *L. spp.* pending laboratory results

of those food products and the *L. spp.* environmental isolate. Food products can be released only if the laboratory test results for food products are negative for *L. mono* and the *L. spp.* environmental isolate is not *L. mono*. The Environmental Monitoring and Testing Program shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing for approval by FDA in writing before testing begins; and

D. Establish a written employee training program that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing for food other than meat products, and documentation that each employee has received such training. Defendants' Sanitation and Food Safety Expert shall test to confirm that each employee fully understands the substance of the employee training program.

E. Defendants assign continuing responsibility for implementing and monitoring the Sanitation Control and Food Safety Plan to a person(s), who, by reason of background, education, training or experience, is competent to maintain Defendants' facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

F. FDA approves, in writing, the Sanitation Control and Food Safety Plan, including the Environmental Monitoring and Testing Program;

G. Defendants make written copies of the Sanitation Control and Food Safety Plan available and accessible to all their employees;

H. The Sanitation and Food Safety Expert conducts a comprehensive inspection of Defendants' facility, including the buildings, sanitation-related systems,

equipment, utensils, articles of food, and relevant records contained therein, to determine whether Defendants have adequately established and implemented the Sanitation Control and Food Safety Plan; have adequately addressed FDA investigators' inspectional observations listed on each Form FDA-483 issued to Defendants since July 2013 and any other violations noted by any state authority; and are operating in compliance with this Decree, the Act, and its implementing regulations. The Sanitation and Food Safety Expert shall submit all findings to Defendants and FDA concurrently within ten (10) calendar days of completion of the inspection.

I. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including:

(i) Documentation that Defendants have cleaned and sanitized Defendants' facility and equipment therein, and made improvements, thereby rendering the facility and equipment suitable for receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any articles of food other than meat products, and documentation that Defendants have conducted environmental testing in a manner acceptable to FDA;

(ii) Specific measures that Defendants have taken to address each of the violations documented by FDA since July 2013; and

(iii) A copy of the Sanitation Control and Food Safety Plan, including the Environmental Monitoring and Testing Program;

J. Defendants develop and implement a system to facilitate traceback and recalls in the event of a violation or the potential for food-borne illness, and Defendants test their system to ensure that it will be adequate;

K. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

L. Defendants have paid all costs of inspection, analysis, review, investigations, examination and supervision for FDA's oversight with respect to Paragraph 9(A)-(K), at the rates set forth in Paragraph 15 below; and

M. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 9(A) through (L) of this Decree, the Act, and its implementing regulations.

N. Nothing in this Decree shall prohibit Defendants from distributing packaged products as defined in Paragraph 4.

10. Upon resuming manufacturing, preparing, processing, packing, and/or labeling food other than meat products after completing the requirements of Paragraph 9; Defendants shall, in consultation with the laboratory and the Sanitation and Food Safety Expert, continuously implement the following steps to prevent future contamination from L. mono, other pathogenic organisms, and/or filth in their food products and facility by effectively implementing, on an ongoing basis, the Sanitation Control and Food Safety Plan developed pursuant to Paragraph 9(C), including the Environmental Monitoring and Testing Program developed pursuant to Paragraph 9(C)(ii). If any laboratory test completed pursuant to the Environmental Monitoring and Testing Program shows the presence of L. mono in any article of food other than meat products, Defendants must immediately cease production and notify FDA that production has ceased. All food other than meat products manufactured on the same day as

the positive L. mono sample must be destroyed at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation in writing by FDA. Defendants may resume production of food other than meat products only after they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations.

11. If, after receiving FDA's Paragraph 9(M) notification, Defendants terminate or in any way alter their service contract with the laboratory retained to conduct sample collection and analyses identified in Paragraph 9(A) and described in their Sanitation Control and Food Safety Plan and/or Environmental Monitoring and Testing Program, Defendants shall notify FDA within five (5) calendar days. If Defendants terminate their service contract, Defendants shall retain a new independent laboratory in accordance with paragraph 9(A) as soon as practicable and provide FDA a copy of the service contract with the new laboratory within five (5) calendar days of execution.

12. Nothing in this Decree shall prohibit Defendants from contracting with a third-party to prepare, process, manufacture, pack, and/or label food (the "Supplier"), so long as:

A. The Supplier is not directly or indirectly owned, controlled, or operated by Defendants, and is without personal or financial ties (other than the contract between the Supplier and Defendants) to Defendants or their immediate families;

B. The Supplier is in compliance with the Act and its implementing regulations;

C. FDA has not issued a warning letter or untitled letter or initiated enforcement action against the supplier within five (5) years prior to entry of this Consent Decree; and

D. The Supplier does not use Defendants' employees, facility, equipment, food ingredients, packaging material, or any other commodities from Defendants' facility.

13. Should Defendants seek to contract with a Supplier, Defendants shall notify FDA in writing at the address specified in Paragraph 27 at least ten (10) business days before any such contract commences. This notice shall include, but not be limited to: (1) a copy of the solicitation that Defendants seek to fulfill using the Supplier; (2) the Supplier's name; (3) the address where the Supplier shall prepare, process, manufacture, pack, and/or label the food; (4) the address where the Supplier will ship the finished food; (5) a brief description of the type(s) of food the Supplier will prepare, process, manufacture, pack, and/or label for Defendants; (6) a brief description of any other food products that the Supplier prepares, processes, manufactures, packs, and/or labels; (7) sample labels for the food products; (8) a copy of any quality agreements between Defendants and the Supplier; and (9) an affidavit from Defendants as required by Paragraph 24; and (10) written confirmation from the Supplier that Defendants have provided the Supplier with a copy of this Decree. If any of the information provided in this Paragraph changes, Defendants shall provide an updated notice to FDA in writing at the address specified in Paragraph 27 as soon as practicable.

14. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and any Supplier, and to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing 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, and packaging material; to take photographs and make video recordings; to take samples of Defendants' in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, processing, manufacturing, preparing, packing, holding, and/or 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.

15. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: \$90.65 per hour and fraction thereof per representative for inspection work; \$108.63 per hour or fraction thereof per representative for analytical or review work; 54 cents per mile for travel 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 representative and per day 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.

16. Defendants and each and all of their Associated Persons who have received notice of this Decree, 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, 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; and/or

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

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

A. Cease receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any articles of food other than meat products;

B. Revise, modify, or expand any report(s) prepared under this Decree;

C. Recall, at Defendants' sole expense, adulterated articles of food other than meat products that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

D. Submit additional materials or information to FDA, including, but not limited to, samples of ingredients, in-process or finished articles of food other than meat

products, containers, and packaging materials to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, and/or filth;

E. Issue a safety alert, public health advisory, and/or press release; and/or

F. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

18. The provisions of Paragraph 17 shall be 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, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 15 of this Decree.

19. The following process and procedures shall apply in the event that FDA issues an order under Paragraph 17:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that (1) 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 taking the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the complete basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objections.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its

order, as FDA deems appropriate. If FDA affirms or modifies its order, 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 order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this Paragraph shall be made pursuant to Paragraph 22.

D. The process and procedures set forth in Paragraphs 19(A)-(C) shall not apply to any order issued pursuant to Paragraph 17 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such a case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this Paragraph shall be made pursuant to Paragraph 22.

20. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of five thousand dollars (\$5,000.00) for each day that the Defendant fails to comply with this Decree; an additional sum of one thousand dollars (\$1000.00) in liquidated damages per day for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. 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.

21. 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, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to contempt proceedings.

22. All decisions specified in this Decree shall be vested in the discretion of the FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review 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.

23. Within ten (10) calendar days after entry of this Decree, Defendants shall: (a) provide a copy of this Decree by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their Associated Persons; (b) prominently post a copy of this Decree in an employee common area at Defendants' facility, and ensure that this Decree remains posted so long as it remains in effect; and (c) hold a meeting for their employees, at which Defendants shall describe the terms and obligations of this Decree. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with 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.

24. In the event that any Defendant becomes associated with any additional Associated Persons or any Supplier at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days after each instance that Defendant becomes associated with any such additional Associated Persons or Suppliers, 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 Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of 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.

25. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this Paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

26. Defendants shall not involve Scott J. McGreevy, directly or indirectly, in the food processing operations of Defendant Native American Enterprises, LLC, nor sell or transfer additional shares of Defendant Native American Enterprises, LLC or any of its assets to Scott J.

McGreevy or any business association or enterprise with which Scott J. McGreevy is associated, unless and until Scott J. McGreevy agrees in writing to be bound by this Consent Decree and is so ordered by the Court.

27. Defendants shall address all communications required under this Decree to the Director, Kansas City District Office, United States Food and Drug Administration, 8050 Marshall Dr., Suite 205, Lenexa, Kansas, 66219, and shall reference this civil action by case name and civil action number.

28. If, and for so long as, an Individual Defendant ceases to be employed by or act on behalf of NAE, then that Defendant shall not be subject to the terms of this Decree except as to such Individual's act(s) or failure(s) to act under this Decree prior to the time such Individual ceased to be employed by or act on behalf of NAE or Associated Persons.

29. Nothing in this Decree shall exempt Defendants from complying with federal law, including, but not limited to, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and applicable regulations. Defendants shall fully and completely cooperate with any investigation inquiry, review, or examination of Defendant's compliance with the Federal Meat Inspection Act, Poultry Products Inspection Act or this Decree.

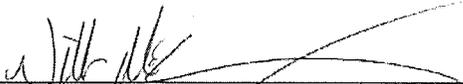
30. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

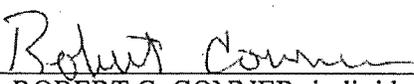
SO ORDERED this 31st day of May, 2016.

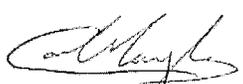
s/ J. Thomas Marten
United States District Judge

We hereby consent to the entry of the forgoing Decree:

FOR DEFENDANTS FOR PLAINTIFF

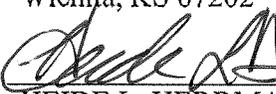

WILLIAM N. MCGREEVY, individually,
and on behalf of NATIVE AMERICAN
ENTERPRISES, LLC


ROBERT C. CONNER, individually


CARL F.A. MAUGHAN
4425 W. Zoo Blvd., Ste. 5
Wichita, KS 67212

Attorney for Defendants NATIVE
AMERICAN ENTERPRISES, LLC,
WILLIAM N. MCGREEVY, AND
ROBERT C. CONNER

BARRY R. GRISSOM
United States Attorney
District of Kansas
EMILY METZGER
Assistant United States Attorney
District of Kansas
1200 Epic Center
301 N. Main
Wichita, KS 67202


HEIDE L. HERRMANN
Consumer Protection Branch, Civil Division
United States Department of Justice
P.O. Box 386
Washington, DC 20044

Of Counsel:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation

SONIA W. NATH
Associate Chief Counsel for Enforcement
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
White Oak 31, Room 4568 10903
New Hampshire Avenue
Silver Spring, MD 20993-0002