UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF VERMONT

UNITED STATES OF AMERICA, Plaintiff, v. CORREIA FAMILY LIMITED PARTNERSHIP, dba WYNSUM HOLSTEINS, and ANTHONY CORREIA, BARBARA CORREIA, and STEPHEN CORREIA, individuals, Defendants.	)	CIVIL ACTION NO. 1:15-cv-00256-jgm CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against the Correia Family Limited Partnership, doing business as Wynsum Holsteins, Anthony Correia, Barbara Correia, and Stephen Correia (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Consent Decree for Permanent Injunction ("Decree"), without contest and without admitting or denying the allegations in the Complaint, 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 of this action and personal jurisdiction over all parties to this action 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 (the "Act"), 21 U.S.C. §§ 301 *et seq.*

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by delivering and causing to be introduced into interstate commerce food that is adulterated within

the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4). The Complaint alleges that Defendants also violate the Act, 21 U.S.C. § 331(k), by adulterating and causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(5), of new animal drugs while such drugs are held for sale after shipment in interstate commerce. The Complaint alleges that Defendants also violate the Act, 21 U.S.C. § 331(u), by failing to comply with the requirements in 21 U.S.C. § 360b(a)(4)(A) regarding the extralabel use of new animal drugs.

4. Upon entry of this Decree, 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 who have received notice of this Decree, are hereby permanently restrained and enjoined, under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly introducing or causing to be introduced into interstate commerce, and/or delivering or causing to be delivered for introduction into interstate commerce, any article of food, excluding milk, within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues, and/or administering to animals any drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), while such drugs are held for sale after shipment in interstate commerce, unless and until:

A. Defendants establish and implement a system that ensures that each of the animals that they acquire, purchase, hold, transport, sell, consign, or lease is individually and permanently identified by tag number;

B. Defendants establish and implement a written record-keeping system that prevents them from selling, consigning, leasing, and/or distributing any animals whose edible tissues contain new animal drugs in amounts above the levels permitted by law. This system shall include, but not necessarily be limited to, keeping written records on every animal to which

Defendants administer drugs. These records shall include, at a minimum: (1) the identity of each animal Defendants medicate; (2) the date each drug is administered to each animal; (3) the identity of each drug administered; (4) the dosage of each drug used; (5) the route of administration of each drug used; (6) the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship for each drug used, if applicable; (7) the name of the person who administers each drug; (8) the proper withdrawal period for each drug administered; (9) the date such withdrawal period will terminate for each drug administered; (10) the date each medicated animal is shipped for slaughter or leaves Defendants' control; and (11) the name and address of the purchaser, broker, receiver, lessee, or consignee of each medicated animal that is shipped for slaughter or leaves Defendants' control;

C. Defendants establish and implement a system that ensures that their use of new animal drugs conforms to the uses approved by the United States Food and Drug Administration ("FDA") and set forth in each drug's approved labeling or, for new animal drugs used in an extralabel manner, to the lawful written order of a licensed veterinarian in accordance with 21 U.S.C. § 360b(a)(4)(A), provided that order does not result in illegal residues. This system shall include, but not necessarily be limited to, measures to ensure that the following shall not occur:

i. administering drugs in Defendants' animals that are not approved for use in that species or for the disease or other condition for which the animal is being treated, unless such extralabel use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530;

ii. selling, delivering, or offering to deliver medicated animals for slaughter before the expiration of the relevant withdrawal period for any drug with which the animals have been treated;

iii. administering drugs contrary to the approved dosage, unless such extralabel use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530; and

iv. administering drugs contrary to the approved duration or frequency, unless such extralabel use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530;

D. Defendants establish and implement a quarantine or segregation system that ensures ready distinction between medicated and unmedicated animals and that prevents Defendants from selling, consigning, leasing, and/or delivering for slaughter for use as food any animals with illegal new animal drug residues in their edible tissues;

E. Defendants establish and implement a drug inventory and accountability system that prevents them from selling, consigning, leasing, and/or delivering any animals with illegal new animal drug residues in their edible tissues. This system shall include a written record for each drug that Defendants purchase or receive for use in medicating any of their animals. These records shall include, but not necessarily be limited to: (1) the name of the drug; (2) the date of purchase or receipt of the drug; (3) the quantity, strength, and form of the drug purchased or received; (4) the expiration date of the drug purchased or received; (5) the name and address of the supplier or seller of the drug; (6) the date each drug is administered; and

(7) the amount and method of each administration of each drug. In addition, the inventory and accountability system shall include periodic checks of inventory and records, no less frequently than once every fourteen (14) calendar days, to ensure that the records accurately document the drugs currently on hand and the disposition of all drugs purchased or received, including whether the drugs have been administered;

F. Defendants establish and implement a system that ensures that each animal that has been medicated is not directly or indirectly sold, consigned, leased, or delivered for immediate or ultimate slaughter until the withdrawal period (specified in the drug's approved labeling or, for new animal drugs used in an extralabel manner, in the lawful written order of a licensed veterinarian made in accordance with 21 U.S.C. § 360b(a)(4)(A) for each drug used on such animal) has expired.

This system shall also ensure that Defendants provide each purchaser, broker, receiver, lessee, or consignee, before that purchaser, broker, receiver, lessee, or consignee accepts any animal from Defendants, a written statement certifying that: (a) any animal that has been medicated has also been withdrawn from drugs for the appropriate time period; (b) the animal has been medicated, each drug with which the animal was treated, the date the animal was treated with each drug, the dosage of each drug, the required withdrawal period for each drug, and the date(s) on which the withdrawal period(s) will expire; or (c) the animal has not been medicated. Defendants shall, prior to selling, leasing, or otherwise transferring any animal, obtain the signature of the purchaser, broker, receiver, lessee, or consignee documenting date of receipt of the statement from Defendants. Defendants shall keep, as part of their records, a copy of the signed written statement described in this Paragraph;

G. Defendants shall establish and implement a system that identifies the source of each animal that they purchase or otherwise receive. Defendants shall request from each seller or owner the following information as to each animal: whether such animal has been medicated; the date of such medication; the drug used; the dosage of the drug; and the withdrawal period for such drug. Defendants shall document and maintain, as part of their records, the information described in this Paragraph and any refusals from a seller or owner to provide such information;

H. Defendants have reported to FDA in writing the steps they have taken to comply with Paragraphs 4.A – G;

I. FDA has inspected Defendants' operations, including the records relating to the drug purchase and administration, and the sale, consignment, and distribution of food-producing animals. Provided that FDA finds that Defendants' report under paragraph 4.H appears to be satisfactory and notifies Defendants, in writing, of such finding, FDA will initiate the inspection within thirty (30) business days of such written notification, or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled;

J. Defendants have paid for the costs of the inspections at the rates specified in Paragraph 13; and

K. FDA has notified Defendants in writing that they appear to be in compliance with the requirements of Paragraphs 4.A – G and J of this Decree.

5. Prior to obtaining written notification from FDA as specified in Paragraph 4.K, Defendants may administer drugs as prescribed to an ill, food-producing animal that they own and that is located on their farm, but only after the animal has been examined by a licensed veterinarian and that veterinarian has diagnosed and prescribed the particular drug for that

animal. Defendants shall maintain copies of the veterinarian's diagnosis, prescription, and receipts for treatment or the equivalent, and provide those to FDA upon request.

6. Defendants shall maintain all records described in Paragraph 4 for at least two (2) years after the date that Defendants sell, consign, deliver, or lease the animal. These records shall be made available immediately to FDA upon request for purposes of inspection and copying.

7. Within ten (10) business days after the entry of this Decree, Defendants shall: (a) provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, including any veterinarians from whom Defendants receive new animal drugs, and all persons to whom Defendants have sold, consigned, or delivered any cattle or calves for slaughter within one year preceding the date of entry of the Decree; and (b) explain the terms of the Decree to each employee and member of the Correia Family Limited Partnership in English or another language that such employees would understand.

8. Within fifteen (15) business days after the entry of this Decree, Defendants shall provide FDA's New England District Office District Director (at the address set forth in Paragraph 18) with an affidavit from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with Paragraph 7 and identifying the names and positions of all persons who were notified pursuant to Paragraph 7.

9. After entry of the Decree, Defendants shall, within three (3) calendar days of hiring of any new employee at Defendants' operations: (a) provide a copy of the Decree, by personal service or by certified mail return receipt requested, to all such employees; and

(b) explain the terms of the Decree to all such employees in English or another language that such employees would understand.

10. After Defendants receive FDA's written notification as described in Paragraph 4.K, 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, are permanently restrained and enjoined from directly or indirectly doing and/or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342 (a)(2)(C)(ii) or 342(a)(4);

B. Administering to any food-producing animal any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), unless such administration conforms to such drug's labeled indications and conditions for use or, for new animal drugs used in an extralabel manner, such administration (1) is by or on the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, (2) does not result in an illegal drug residue, and (3) is otherwise in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530;

C. Doing any act with respect to any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), if such act is done while such drug is held for sale after shipment in interstate commerce and results in such drug being adulterated within the meaning of 21 U.S.C. § 351(a)(5); and

D. Failing to implement and continuously maintain the requirements of this Decree.

11. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations, including any new locations, and any facility or location at which Defendants hold or store animals and/or drugs used to treat animals, including food-producing animals and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include taking photographs and samples and examining and copying all records that relate to drug administration and the holding, delivery, sale, consignment, or distribution of food-producing animals at any facility or location Defendants operate, manage, or control. Such 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. Upon request, Defendants shall promptly provide any information and records to FDA regarding the sale, consignment, delivery, or medication of any animals.

13. Defendants shall reimburse FDA for the costs of conducting and evaluating all inspection, laboratory, analytical, and other work that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $89.35 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $107.09 per hour and fraction thereof per representative for laboratory and analytical work; $0.575 per mile for travel by automobile; the government rate or equivalent for travel by air; 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 generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. If Defendants violate this Decree and are 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, investigational and analytical expenses, and court costs relating to such contempt proceedings.

15. If, based on the results of any inspection or analysis conducted after the inspection described in Paragraph 4.I, or any other information, FDA finds that Defendants are not in compliance with this Decree, the Act, and all applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the non-compliance and may require that Defendants immediately take one or more of the following actions:

A. Cease selling and delivering, and causing to be sold and delivered, any article of food within the meaning of 21 U.S.C. § 321(f);

B. Cease administering to animals any drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v); and/or

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

Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. Any cessation of operations or other action ordered by FDA as described above shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree, the Act, and all applicable regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

16. Defendants shall notify FDA at least twenty (20) business days before any change in ownership, name, or character of the 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 provide a copy of this Decree to 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 at least ten (10) business days prior to such sale or change of business.

17. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of the Court.

18. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the District Director, FDA New England District Office, One Montvale Avenue, Stoneham, Massachusetts 02180.

19. All decisions specified in this Decree shall be vested in the discretion of 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.

20. If any Defendant fails to comply with the provisions of this Decree, then on written notice by FDA, that Defendant shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that Defendant fails to comply with this Decree and an additional one thousand dollars ($1,000.00) for each animal that Defendant sells or delivers for sale in violation of 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 Plaintiff 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.

21. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with the laws and regulations, the Act, and this Decree for the preceding sixty (60) months, Plaintiff will not oppose such petition.

22. 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.

SO ORDERED this 14th day of December, 2015.

U.S. DISTRICT COURT JUDGE

Entry consented to:

For Defendants

ANTHONY CORREIA
Individually and on behalf of the
Correia Family Limited Partnership, dba
Wynsum Holsteins, as its general and
limited partner

For Plaintiff

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United States Attorney

BENJAMIN WEATHERS-LOWIN
Assistant United States Attorney

JUDGMENT ENTERED ON DOCKET
DATE: 12/14/15

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Individually and on behalf of the
Correia Family Limited Partnership, dba
Wynsum Holsteins, as its general and limited
partner

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