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.	CASE NO. 1:15-cv-256 COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, alleges as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain Defendants from violating:

a. 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);

b. 21 U.S.C. § 331(k), by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drugs are held for sale after shipment in interstate commerce; and

c. 21 U.S.C. § 331(u), by failing to comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

JURISDICTION AND VENUE

2. This court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Correia Family Limited Partnership, doing business as Wynsum Holsteins, is a Vermont limited partnership that owns and operates a dairy farm, which has approximately 800 cattle and is located at 1578 Jersey Street South, West Addison, Vermont ("Defendants' farm" or "the farm"), within the jurisdiction of this court.

5. Defendant Anthony Correia, along with his wife Barbara Correia, has co-owned the farm since approximately 1973. He is a general partner of the Correia Family Limited Partnership and is the most responsible person at the farm. He is involved in all aspects of the farm's operation, including making treatment decisions, medicating cows, culling cows for slaughter, record-keeping, and overseeing employees. He performs his duties at the farm, within the jurisdiction of this court.

6. Defendant Barbara Correia, wife of Defendant Anthony Correia, is the other co-owner of the farm and general partner of the Correia Family Limited Partnership. She is responsible for drug procurement, maintaining animal drugs records, bookkeeping, and she regularly represents Defendants in correspondence with FDA. She performs her duties at the farm, within the jurisdiction of this court.

7. Defendant Stephen Correia, son of Defendants Anthony and Barbara Correia, is a limited partner of the Correia Family Limited Partnership. He shares responsibility for the farm,

including medicating cows, culling cows for slaughter, record-keeping, and supervising employees. He performs his duties at the farm, within the jurisdiction of this court.

8. Defendants have been and are engaged in the sale of cows for slaughter for use as food. The cows sold by Defendants for slaughter for human consumption, and the edible tissues of these animals, are food within the meaning of 21 U.S.C. § 321(f).

9. Defendants deliver and cause the introduction of food into interstate commerce. They sell, directly or by auction, dairy cows and bob veal calves to slaughterhouses for use as human food. For instance, on occasions a Vermont-based broker picks up culled cows from the farm for auction where they are then purchased by and delivered to a slaughterhouse located in Whitehall, New York. Other times, representatives from this slaughterhouse pick up culled cows directly from the farm for delivery to Whitehall, New York.

10. Defendants medicate their cows with new animal drugs that have been shipped in interstate commerce, including but not limited to Penicillin G Procaine manufactured in Northern Ireland, Ceftiflex (ceftiofur sodium) manufactured in California, and Meloxicam Tablets manufactured in Taiwan.

11. Defendants cause the adulteration of new animal drugs while such drugs are held for sale after shipment in interstate commerce.

12. Defendants fail to follow the FDA approved labeling and/or veterinary prescription for such drugs when administering them to their cows.

STATUTORY AND REGULATORY PROVISIONS

13. The drugs that Defendants use to treat their cows, including but not limited to Penicillin G Procaine, Ceftiflex (ceftiofur sodium), and Meloxicam Tablets, are new animal drugs within the meaning of 21 U.S.C. § 321(v).

14. FDA approves new animal drugs that are shown to be safe and effective for use under specified conditions. 21 U.S.C. § 360b(d)(1).

15. A new animal drug's conditions for use are set forth in the drug's approved labeling and are published by regulation. 21 C.F.R. Parts 520–29, and 556. The conditions for use include the legal purposes for which the drug may be used (indications), the maximum amount of the drug or its residues that may be contained in the tissues of animals delivered for slaughter for use as food (tolerances), the pre-slaughter withdrawal period required to ensure that treated animals used for food do not have illegal concentrations of the drug remaining in their tissues (withdrawal time), and the amount of the drug that may be administered to an animal (dosage). 21 U.S.C. § 360b(i); 21 C.F.R. Parts 520 – 29, and 556.

16. Levels of new animal drugs in the edible tissues of animals in amounts above the tolerances established in FDA's regulations, 21 C.F.R. Part 556, may pose a significant public health risk. For example, consumers of edible animal tissues that are also sensitive to antibiotics may experience allergic reactions as a result of ingesting food containing antibiotic concentrations above established tolerances. Furthermore, antibiotic residues in animal-derived food products (meat, milk, eggs, etc.) could promote the emergence and selection of antibiotic-resistant strains of bacteria, which is a public health concern in humans who eat or handle animal-derived food products.

17. A new animal drug is unsafe as a matter of law when there is no FDA approval in effect for its use or where the actual use of the drug does not conform to the conditions of the drug's approval. A licensed veterinarian, in the context of a valid veterinarian-client-patient relationship, may prescribe a new animal drug for a use that differs from that specified in the drug's approved labeling (an "extralabel use"), provided that such use does not result in illegal

drug residues in the edible tissues of animals and that such drug is not prohibited from extralabel use under 21 C.F.R. § 530.41. 21 U.S.C. § 360b(a)(4)(A),(B); *see also* 21 C.F.R. §§ 530.3, 530.10-530.11. Even if the extralabel use of a new animal drug is by the lawful order of a veterinarian in the context of a valid veterinarian-client-patient relationship, the drug is still deemed unsafe within the meaning of 21 U.S.C. § 360b(a)(1) if such extralabel use results in an above-tolerance drug residue in the edible tissues of the animal. A new animal drug that is unsafe within the meaning of 21 U.S.C. § 360b(a)(1) is deemed to be adulterated. 21 U.S.C. § 351(a)(5).

18. Food containing an unsafe new animal drug is deemed to be adulterated. 21 U.S.C. § 342(a)(2)(C)(ii).

19. Food that is held under insanitary conditions whereby it may have been rendered injurious to health is deemed to be adulterated. 21 U.S.C. § 342(a)(4).

20. FDA has approved Penicillin G Procaine for use in cattle but only for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*. 21 C.F.R. § 522.1696b(d)(2)(ii). FDA has not approved Penicillin G Procaine for use in cattle for treatment of uterine infections or foot ulcers.

21. FDA has approved Ceftiflex (ceftiofur sodium) for use in cattle but only for treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni,* and for acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. 21 C.F.R. § 522.313c(e)(2)(ii). FDA has not approved Ceftiflex for use in cattle for treatment of mastitis (inflamed mammary glands or udder).

22. FDA has not approved Meloxicam Tablets for use in animals.

DEFENDANTS' VIOLATIONS OF THE ACT

2014 Inspection

23. FDA most recently inspected Defendants' farm between November 12 and December 19, 2014. The inspection was in response to laboratory testing by the United States Department of Agriculture ("USDA") that detected above-tolerance penicillin residues in the kidney tissue of two dairy cows that Defendants sold for slaughter for use as human food.

24. The FDA investigator documented numerous violative conditions including, but not limited to, the following:

a. Defendants caused unsafe drug residues of penicillin in the edible tissues of two dairy cows they offered for slaughter for use as human food through use of the drug contrary to its approved labeling;

b. Defendants use new animal drugs in a manner contrary to label directions without the benefit of a lawful veterinarian order issued pursuant to a valid veterinarian-client-patient relationship. Specifically, without authorization from a licensed veterinarian, Defendants administered in cattle Penicillin G Procaine, Ceftiflex (ceftiofur sodium), and Meloxicam Tablets to treat uterine infections or foot ulcers, mastitis in milking cows, and "sore" milking cows, respectively. All such uses are contrary to the approved indications;

c. Defendants fail to maintain adequate treatment records. Specifically, they do not maintain any treatment records for medicated cows beyond the ten days after freshening (beginning of milk production), and routinely discard such records when their cabinet drawer is full. Moreover, even the records they keep lacked the treatment date, animal identification, withdrawal time for meat and milk, the name of the individual who administered the drug, the name and quantity of the drug administered, and the route of administration;

d. Defendants fail to have an inventory system for determining the quantities of drugs used to treat their cows;

e. Defendants keep expired drugs in their drug storage area;

f. Defendants fail to systematically review treatment records prior to offering cows for slaughter for use as human food, to ensure that drugs are used as directed, and that appropriate withdrawal times have been observed. Defendants generally rely on memory to track which cows have been treated, the treatments administered, and the drug withdrawal times; and

g. Defendants fail to have a system to control administration of drug treatments. Specifically, Defendants store drugs in a refrigerator accessible to all employees on the farm without a system to prevent unauthorized drug administration.

25. At the close of the inspection, the FDA investigator issued an eleven-item List of Inspectional Observations, Form FDA 483 ("Form 483"), to Defendant Anthony Correia, documenting violative conditions observed at the farm, including but not limited to those discussed in Paragraph 24.

2012 Inspection

26. FDA previously inspected Defendants' farm between October 19 and November 19, 2012.

27. The inspection was in response to a violative desfuroylceftiofur residue that USDA found in the kidney tissues of a cow Defendants had offered for slaughter for human consumption.

28. During the 2012 inspection, the FDA investigator documented the same or similar violations as those FDA later documented during the 2014 inspection, including but not limited to the following:

a. causing an unsafe residue of a drug, desfuroylceftiofur, in the edible tissues of a cow that Defendants offered for slaughter for human consumption through use of the drug contrary to its approved labeling;

b. administering animal drugs (Penicillin G Procaine, Excede, and FlunixiJect) contrary to the drugs' approved labeling without a lawful order in the context of a valid veterinarian-client-patient relationship;

c. failing to maintain adequate treatment records for cows that Defendants offered for sale for use as food;

d. failing to have an inventory system for determining the quantities of drugs used to treat cows; and

e. keeping expired drugs in the drug storage area. These were the same expired drugs that the FDA investigator later observed during the 2014 inspection.

29. At the close of this inspection, the FDA investigator issued a six-item Form 483 to Defendant Anthony Correia, documenting violative conditions observed at the farm, including but not limited to those discussed in Paragraph 28 above.

Laboratory Testing

30. USDA collected tissue samples from dairy cows and veal calves that Defendants sold for slaughter for use as human food and analyzed those samples for drug residues.

31. USDA's testing on multiple occasions since 2000 revealed above-tolerance new animal drugs residues, including penicillin, desfuroylceftiofur, and neomycin, in Defendants'

dairy cows or veal calves. Specifically, the drug residues found in cows sold by Defendants for slaughter for use as human food include but are not limited to the following:

Sample Date	USDA Analytical Form Number	Animal	Drug Residue	Tissue	Residue (ppm)	Tolerance (ppm)
1/20/2015	101004271	Dairy cow	Penicillin	Kidney	0.056	0.05
7/2/2014	100842401	Dairy cow	Penicillin	Kidney	0.105	0.05
4/28/2014	100784675	Dairy cow	Penicillin	Kidney	0.320	0.05
5/7/2012	100146404	Dairy cow	Desfuroylceftiofur	Kidney	12.96	0.4
1/5/2010	513963	Bob veal calf	Neomycin	Kidney	7.63	7.2
3/28/2006	461341	Dairy cow	Penicillin	Kidney	0.18	0.05
11/28/2000	285272	Dairy cow	Penicillin	Kidney	0.13	0.05

32. Generally, such residues suggest that Defendants failed to administer these drugs in accordance with the dosage, withdrawal time, and/or other use limitations set forth in the drugs' approved labeling.

History

33. Defendants have a long history of violating the Act. Many of the violations documented during FDA's most recent inspection of Defendants' farm, described in Paragraph 24, are the same as, or similar to, violations documented by FDA during its 2012 inspection, described in Paragraph 28. At the close of each of these inspections, FDA provided Defendant Anthony Correia with a Form 483 documenting the observed violations.

34. Following the 2012 inspection, FDA issued Defendants a Warning Letter on March 4, 2013, detailing violations observed during that inspection. The Warning Letter emphasized the serious nature of the violations, stated that it was not exhaustive, and warned Defendants that failure to correct these violations could result in regulatory action, including an injunction.

35. Following the issuance of each Form 483 and the Warning Letter, Defendants promised corrective actions. However, Defendants' responses were inadequate and/or they failed to follow through with their promised corrections.

36. Between November 2000 and February 2015, USDA has issued at least seven residue violation letters to Defendants. The letters warned Defendants that violative drug residues in the edible tissues of their food-producing animals cause the food to be adulterated, that USDA has identified them as a repeat violator, and that continued violation could lead to criminal or injunctive action by USDA or FDA.

37. Additionally, on May 6, 2013, the state of Vermont assessed, under state law, a penalty against the Defendants for selling livestock for slaughter for use as human food with a residue level exceeding an FDA-established tolerance. This penalty was based on the violative desfuroylceftiofur residue that USDA collected from the kidney tissue of Defendants' cow on May 7, 2012.

DEFENDANTS' CONDUCT AND VIOLATIONS

Defendants Violate 21 U.S.C. § 331(a)

38. Because of their poor record-keeping practices and improper administration of drugs, (1) Defendants have sold for slaughter dairy cows and bob veal calves that were treated with drugs in a manner contrary to the approved conditions for use set forth in the drugs' approved labeling; and (2) the edible tissues of cows Defendants sold for slaughter for use as food contained drug residues in amounts above the levels permitted by law.

39. Defendants, without an order from a licensed veterinarian in the context of a valid veterinarian-client-patient relationship, administered drugs, including, but not limited to, Penicillin G Procaine, Ceftiflex (ceftifor sodium), and Meloxicam Tablets to their cows without

complying with the drugs' approved indications, withdrawal time, and/or dosage. A new animal drug used in a manner that fails to conform to the drug's approved conditions of use, without a lawful veterinarian order in the context of a veterinarian-client-patient relationship, as permitted pursuant to 21 U.S.C. § 360b(a)(4)(A), is deemed to be unsafe under 21 U.S.C. § 360b(a)(1). Accordingly, Defendants caused these new animal drugs to be unsafe within the meaning of 21 U.S.C. § 360b(a)(1).

40. Additionally, Defendants caused new animal drugs to be unsafe within the meaning of 21 U.S.C. § 360b(a)(1) because their extralabel use of animal drugs, such as Penicillin G Procaine, in their cows resulted in violative tissue residues.

41. Because the edible tissues of cows Defendants offered for slaughter for use as food contained new animal drugs, and those drugs are unsafe within the meaning of 21 U.S.C. § 360b(a)(1), Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii).

42. Defendants' poor record-keeping and improper drug administration practices constitute insanitary conditions whereby Defendants' food (edible tissues of their animals) may have been rendered injurious to health, and thus cause the food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4).

43. Accordingly, Defendants violate 21 U.S.C. § 331(a) by delivering and causing to be delivered into interstate commerce food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii), and 342(a)(4).

Defendants Violate 21 U.S.C. § 331(k)

44. Defendants purchase, receive, and use new animal drugs, within the meaning of 21 U.S.C. § 321(v), to treat their animals, including, but not limited to, Penicillin G Procaine, Ceftiflex (ceftiofur sodium), and Meloxicam Tablets.

45. Defendants hold the drugs that they use to treat their cows for sale within the meaning of 21 U.S.C. § 331(k) after these drugs have been shipped in interstate commerce.

46. Defendants, without a lawful order from a licensed veterinarian in the context of a valid veterinarian-client-patient relationship, administer new animal drugs after shipment in interstate commerce without complying with approved indications for use, withdrawal time, and/or dosage requirements. These unapproved uses render the new animal drugs unsafe pursuant to 21 U.S.C. § 360b(a)(1) and, consequently, adulterated within the meaning of 21 U.S.C. § 351(a)(5).

47. Moreover, Defendants' extralabel use of new animal drugs, such as Penicillin G Procaine, resulted in residues above an established safe level, safe concentration, or tolerance. Such drugs, therefore, are also unsafe within the meaning of 21 U.S.C. § 360b(a)(1) and, consequently, adulterated within the meaning of 21 U.S.C. § 351(a)(5). *See* 21 C.F.R. § 530.11(d).

48. Accordingly, Defendants violate 21 U.S.C. § 331(k) by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5) while such drugs are held for sale after shipment in interstate commerce.

Defendants Violate 21 U.S.C. § 331(u)

49. Because Defendants do not use new animal drugs in accordance with the drugs' approved conditions for use and/or by or on the lawful order of a licensed veterinarian in the context of a veterinarian-client-patient relationship, they do not comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

50. Accordingly, Defendants violate 21 U.S.C. § 331(u) by failing to comply with the requirements under 21 U.S.C. § 360b(a)(4)(A) regarding the extralabel use of new animal drugs.

51. Despite numerous warnings from two federal agencies and a penalty assessment by the state of Vermont, Defendants continue to violate the Act. Based on Defendants' repeated violations, especially in the face of these warnings and after multiple promises to take corrective actions that Defendants have failed to implement, the United States is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate the Act.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently restrain and enjoin, under the provisions of 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order from, directly or indirectly:

A. violating 21 U.S.C. § 331(a) by introducing, delivering, and causing the introduction and delivery for introduction into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. violating 21 U.S.C. § 331(k) by doing and causing to be done any act that causes an article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drug is held for sale after its shipment in interstate commerce; and

C. violating 21 U.S.C. § 331(u) by failing to comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A);

II. Order Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any

of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order, unless and until Defendants bring their operations into compliance with the law to the satisfaction of FDA, to do the following:

A. cease introducing, delivering, and causing to be introduced and delivered into interstate commerce any article of food within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues; and

B. except for administering medication to any of Defendants' ill food-producing animals after the animal has been examined by a licensed veterinarian who diagnoses the animal and prescribes the particular drug for that animal, cease administering to animals any new animal drug, within the meaning of 21 U.S.C. § 321(v), while such drug is held for sale after shipment in interstate commerce;

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed; and

IV. Award the United States its costs herein, including costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 4th day of December, 2015.

Respectfully submitted,

ERIC S. MILLER
United States Attorney

By: _____

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