

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA,)
)
Plaintiff,)
 v.)
)
OLD CAROLINA FARM, and)
FRANCIS H. RODERICK, an individual,)
10802 Cook Brothers Road)
Ijamsville, Maryland 21754)
)
Defendants.)

Civil Action No. _____

COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, and for its Complaint against Defendants, alleges and represents 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), to enjoin and restrain Old Carolina Farm and Francis H. Roderick (collectively, "Defendants") from violating: (a) 21 U.S.C. § 331(a), by introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction 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. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b).

DEFENDANTS

3. Defendant Old Carolina Farm (“OCF”), is a dairy operation with its principal place of business at 10802 Cook Brothers Road, Ijamsville, Maryland. OCF maintains over 300 acres of land on which it raises approximately 250 cattle and calves, operates a dairy, and grows crops. OCF sells its cattle and calves to auction houses in Westminster and Hagerstown, Maryland to be slaughtered for human consumption.

4. Defendant Francis H. Roderick is the owner of OCF. He has overall responsibility for, and authority over, all of OCF’s operations. Specifically, his responsibilities include: administering drugs to the animals, milking dairy cows, maintaining equipment/machinery, hiring employees, and contacting the Taylorsville Veterinary Clinic for veterinary services. Defendant Roderick performs his duties at OCF, within the jurisdiction of this Court.

5. Levels of antibiotics in the edible tissues of animals in amounts above FDA-established tolerances pose a significant public health risk. Consumers of edible animal tissues that are sensitive to antibiotics may experience severe allergic reactions as a result of ingesting food containing out-of-tolerance antibiotic levels. Furthermore, meat containing above-tolerance antibiotic levels could lead to the development of antibiotic-resistant strains of bacteria in humans who eat or handle meat containing antibiotic residues.

STATUTORY AND REGULATORY PROVISIONS

6. Cattle and calves 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).

7. Defendants deliver and cause the delivery of food for introduction into interstate commerce. Defendants sell cattle and calves to Four States Livestock Sales (“FSLs”) in Hagerstown, Maryland, which, in turn, sells Defendants’ animals to slaughterhouses in Pennsylvania.

8. Defendants receive and treat their cattle and calves with antibiotics that have been shipped in interstate commerce. The antibiotics are drugs within the meaning of 21 U.S.C. § 321(g) and new animal drugs within the meaning of 21 U.S.C. § 321(v).

9. Defendants purchase new animal drugs from outside Maryland, which they administer to their animals. Defendants hold these drugs for sale within the meaning of 21 U.S.C. § 331(k) after they have been shipped in interstate commerce.

10. The United States Food and Drug Administration (“FDA”) approves new animal drugs that have been shown to be safe and effective for use under specified conditions set forth in the drug’s approved labeling. 21 U.S.C. § 360b(d)(1).

11. A new animal drug’s conditions for use are published by regulation. 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 (“tolerance”), and the pre-slaughter withdrawal period required to ensure that treated animals used for food do not have concentrations of the drug remaining in their tissues in excess of the specified tolerance for the drug. The conditions for use also include the types of animals to which the drug may be

administered (“species limitations”) and the amount of drug that may be administered to a specific animal (“dosage”). 21 U.S.C. § 360b(i).

12. A new animal drug is unsafe as a matter of law when there is no approval by FDA in effect for its use or where the actual use of the drug does not conform to the conditions of the drug’s approval, unless the drug is used in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and is in compliance with 21 C.F.R. Part 530. 21 U.S.C. §§ 360b(a)(1) and 360b(a)(4).

13. A new animal drug that is unsafe within the meaning of 21 U.S.C. § 360b is deemed to be adulterated. 21 U.S.C. § 351(a)(5).

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

15. Penicillin, sulfadimethoxine, oxytetracycline, gentamicin, sulfamethazine, flunixin, and excenel (ceftiofur hydrochloride) are new animal drugs within the meaning of 21 U.S.C. § 321(v).

These drugs have been approved for use under specified conditions set forth in the labeling of the drugs.

a. The tolerance for penicillin in the edible tissues of cattle is 0.05 parts per million (“ppm”). 21 C.F.R. § 556.510.

b. The tolerance for sulfadimethoxine in the edible tissues of cattle is 0.1 ppm. 21 C.F.R. § 556.640.

c. In 1997, the tolerance levels for oxytetracycline in the muscle, liver, and kidney tissues of non-lactating dairy cattle were 2 ppm, 6 ppm, and 12 ppm, respectively. 21 C.F.R. § 556.500.

d. No tissue residue of gentamicin sulfate is permitted in the edible tissues of cattle or

calves. See 21 C.F.R. § 556.300.

e. No tissue residue of sulfamethazine is permitted in the edible tissues of calves. See 21 C.F.R. § 556.670.

f. The tolerance for flunixin in the liver of cattle is 0.125 ppm. 21 C.F.R. § 556.286.

FDA INSPECTIONS

16. FDA most recently inspected OCF between May 20, and May 26, 2009. FDA observed and documented the following violative conditions:

a. Defendants caused an illegal residue in a food-producing animal of an approved animal drug by using the drug contrary to its labeling and failing to take appropriate measures to assure that assigned time frames for withdrawal were met and that no illegal residue occurred. Defendant Roderick admitted in a signed affidavit that Defendants treated cow 1436 with flunixin, that he was unaware that flunixin has a withdrawal time prior to slaughter, and that Defendants sold the cow for slaughter for human food while they were treating the cow with flunixin.

b. Defendants failed to systematically review treatment records prior to offering an animal for slaughter as human food, assure that drugs had been used only as directed, and assure that appropriate withdrawal times had been observed. Defendants do not have any treatment records for cow 1436.

c. Defendants failed to maintain complete treatment records. Defendant Roderick stated in a signed affidavit that he does not maintain any animal medical treatment records for flunixin.

d. Defendants lacked an adequate inventory system for determining the quantities of drugs

used to medicate cows. Defendant Roderick admitted in a signed affidavit that he does not maintain any drug inventory records.

17. During the May 2009 inspection, Defendant Roderick informed the FDA investigator that he did not intend to begin keeping treatment or drug inventory records.

18. On May 26, 2009, FDA issued Defendant Roderick a Form FDA 483, List of Inspectional Observations ("Form FDA 483"), documenting the observations listed in paragraph 16.

19. FDA previously inspected Defendants' operations between October 16 and 23, 2007. During that inspection, FDA observed and documented the following violative conditions:

a. Defendants caused an illegal tissue residue in a food-producing animal. The United States Department of Agriculture, ("USDA") determined that a bob veal calf (number W 509) sold by Defendants for slaughter for human consumption had an illegal sulfamethazine residue. Defendant Roderick admitted releasing this calf to a hauler on July 25, 2007, for ultimate sale to a slaughter house in Pennsylvania, while the animal was undergoing treatment.

b. Defendants failed to systematically review treatment records prior to offering an animal for slaughter for human food, assure that drugs had been used only as directed, and assure that appropriate withdrawal times had been observed. Defendants did not have treatment records available for bob veal calf W 509 to document its withdrawal times.

c. Defendants failed to maintain treatment records.

d. Defendants failed to maintain an adequate inventory system for determining quantities of drugs used to medicate calves.

20. On October 23, 2007, FDA issued Defendant Roderick a Form FDA 483 documenting

the observations listed in paragraph 19.

21. On January 16, 2008, FDA issued Defendant Roderick a Warning Letter, documenting FDA's observations from the October 2007 inspection and warning that failure to correct the violations could result in enforcement action without further notice, including seizure and/or injunction.

22. FDA also previously inspected Defendants' operations between September 17 and 21, 1999. During this inspection, FDA observed and documented the following violative conditions:

a. Defendants failed to maintain medication/treatment records that identify the animal, the date of medication, the drug, the dosage administered, and the pre-slaughter withdrawal time.

b. Defendants failed to follow label directions for medication administered to animals. Defendants administered excenel to treat mastitis when the drug label indicated its use to treat foot rot only. Defendants also failed to follow the labeled pre-slaughter withdrawal time for this drug.

c. Defendants failed to have a system to control who administers drug treatments to animals. Defendants' records do not always identify who administered drugs or when drugs are administered.

d. Defendants failed to maintain a system to review treatment records prior to offering an animal for slaughter for human food, assure that drugs had been used as directed, and assure that appropriate withdrawal times had been observed. USDA reported a violative gentamicin residue in one of the Defendants' dairy cows.

23. At the conclusion of the September 1999 inspection, FDA issued Defendant Roderick a Form FDA 483 documenting the observations listed in paragraph 22.

24. The Maryland Department of Agriculture (“MDA”), in accordance with its contract with FDA, inspected Defendants’ operations in 2004, 1997, and 1996. Each MDA inspection was prompted by USDA laboratory reports identifying Defendants’ sale for use as human food an animal containing illegal drug residues. At the close of each inspection, MDA documented violations the same as, or similar to, violations observed by FDA during the May 2009, October 2007, and September 1999 inspections, including Defendants’ failure to: (1) follow pre-slaughter withdrawal periods; (2) maintain treatment records; and (3) obtain extra-label prescriptions from a licensed veterinarian. MDA also discussed these violations with Defendants.

LABORATORY TESTING

25. USDA collected tissue samples from animals that Defendants sold for slaughter for use as food and analyzed those samples for drug residues. Between 1996 and 2009, USDA found illegal antibiotic residues in tissue samples collected from eight of Defendants’ animals. The edible tissues of these eight animals contained unlawful amounts of penicillin, sulfadimethoxine, oxytetracycline, gentamicin, sulfamethazine, and flunixin. These results demonstrate that Defendants did not administer the drugs consistent with the dosage, withdrawal period, species limitations, and/or other use requirements set forth in the drugs’ labeling.

26. Defendants sold cattle and calves for slaughter for use as human food with the following illegal drug residues:

Sample Date	USDA Sample #	Drug Residue	Tissue	Residue Level (PPM)	Tolerance (PPM)
09/24/1996	308627	Penicillin	Kidney	0.30	0.05
01/07/1997	337711	Sulfadimethoxine	Liver	0.81	0.10
			Muscle	0.89	0.10
06/11/1997	269488	Oxytetracycline	Muscle	3.10	2
			Liver	22	6
			Kidney	46	12
02/24/1998	283041	Gentamicin	Kidney	0.5	0.00
02/23/1999	270177	Gentamicin	Kidney	2.60	0.00
11/11/2003	435010	Gentamicin	Kidney	8888 ¹	0.00
07/26/2007	503199	Sulfamethazine	Liver	131.89	0.0
			Muscle	179.88	
03/17/2009	531348	Flunixin	Liver	0.2085	0.125

DEFENDANTS' CONDUCT AND VIOLATIONS

27. Defendants' poor record-keeping practices, inadequate inventory system, and improper administration of drugs have resulted in Defendants' sale for use as human food of: (1) cattle and calves that were treated with new animal drugs in a manner contrary to the instructions for use set forth in the drugs' approved labeling; and (2) the edible tissues of animals containing new animal drugs in amounts above the levels permitted by law.

28. The presence in food of new animal drug residue above the legally-prescribed limit

¹ USDA uses "8888" to indicate that residues were found, but not quantified.

establishes that a new animal drug has been used in a manner inconsistent with the approved conditions of use for such drug. A new animal drug used in a manner that fails to conform to the drug's approved conditions of use is deemed unsafe under 21 U.S.C. § 360b(a)(1).

29. Because Defendants sold for use as human food edible tissues of cattle and calves containing unsafe new animal drugs within the meaning of 21 U.S.C. § 360b(a)(1), the cattle and calves, and their edible tissues, are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii).

30. Defendants' poor record-keeping practices, inadequate inventory system, and improper administration of drugs constitute insanitary conditions whereby the edible tissues of their cattle and calves may have been rendered injurious to health and cause the animals and edible tissues thereof to be adulterated within the meaning of 21 U.S.C. § 342(a)(4).

31. Because Defendants use new animal drugs in ways that are inconsistent with the drugs' approved conditions of use, which renders the drugs unsafe within the meaning of 21 U.S.C. § 360b(a)(1), Defendants cause such drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(5).

32. Because Defendants use new animal drugs in a manner that results in residues above the established tolerances, Defendants do not comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

33. Because Defendants use new animal drugs in a manner that does not accord with the drugs' approved conditions for use and that is not pursuant to a lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, Defendants do not comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

34. Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced into

interstate commerce, and delivering or causing to be delivered for introduction into interstate commerce, food that is adulterated: (1) within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii) because the food contains unsafe new animal drugs; and (2) within the meaning of 21 U.S.C. § 342(a)(4) because the cattle and calves have been held under insanitary conditions whereby their edible tissues may have been rendered injurious to health.

35. Defendants violate 21 U.S.C. § 331(k) by causing new animal drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), by using the drugs in ways that are inconsistent with their approved conditions of use, while such drugs are held for sale after shipment in interstate commerce.

36. Defendants violate 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).

PRIOR NOTICE

37. Defendants are well aware that their practices violate the Act. On numerous occasions, FDA, USDA, and MDA have warned Defendants, both orally and in writing, that their conduct violates the law, and have emphasized the importance of compliance with the Act. At the conclusion of each OCF inspection in 2009, 2007, and 1999, FDA issued Form FDA 483s to Defendant Roderick and discussed the documented violations with him.

38. FDA issued Defendant Roderick a Warning Letter, dated January 16, 2008, advising him that he had offered for sale for use as human food a bob veal calf whose tissues were found to contain illegal sulfamethazine residues and that Defendants hold animals under conditions that could allow medicated animals bearing potentially harmful drug residues to enter the food supply.

39. USDA repeatedly warned Defendants about their illegal practices. Between October 1996 and April 2009, USDA sent eight letters to Defendant Roderick stating that USDA found violative drug residues in cattle offered for slaughter by Defendants. The letters warned that violative drug residues in the edible tissues of animals cause the food to be adulterated under the Act and that continued violation could lead to criminal or injunctive action by USDA or FDA.

40. At the conclusion of each OCF inspection in 2004, 1997, and 1996, MDA documented Defendants' violations and discussed the same with Defendant Roderick.

41. Despite numerous warnings from FDA, USDA, and MDA, Defendants continue to violate the Act, as shown by the results of FDA's most recent OCF inspection. Based on Defendants' repeated violations in the face of these warnings and Defendant Roderick's recent statement that he does not intend to maintain treatment or drug inventory records, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), and (u) and continue to pose a significant risk to the public health.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under the provisions of 21 U.S.C. § 332(a), 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 notice of the Court's order from, directly or indirectly:

A. violating 21 U.S.C. § 331(a) by introducing, delivering, or causing the introduction or 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); and

B. violating 21 U.S.C. § 331(k) by doing or 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); and

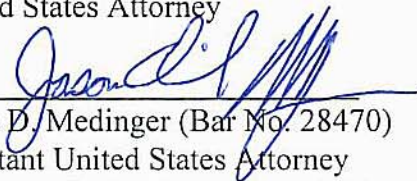
II. Order Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order to cease introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, any article of food within the meaning of 21 U.S.C. § 321(f), and 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, unless and until the defendants bring their operations into compliance with the law to the satisfaction of FDA; and

III. 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 3rd day of November, 2009.

Respectfully submitted,

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By: /s/ 
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