UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>MICHAEL P. FERRY, INC., a corporation, and MICHAEL P. FERRY, an individual<br><br>Defendants. | ) | CIVIL ACTION NO. _____<br><br>COMPLAINT FOR PERMANENT INJUNCTION |

Plaintiff, the United States of America, by Carmen M. Ortiz, United States Attorney for the District of Massachusetts, 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 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.

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

## DEFENDANTS

4. Defendant Michael P. Ferry owns Michael P. Ferry, Inc., a Massachusetts corporation that operates a livestock business from a farm located at 729 Gifford Road, Westport, Massachusetts ("Defendants' farm"), within the jurisdiction of this court.

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

6. Defendant Ferry is the most responsible person at Defendants' farm, and is involved in every aspect of the farm's operations, including purchasing, hauling, feeding, treating, and selling livestock, and record keeping.

7. Defendants deliver and cause the delivery of food for introduction into interstate commerce. For example, Defendants sell cattle that are delivered for slaughter for use as human food to a slaughterhouse located in Whitehall, New York.

8. Defendants medicate their cows in Massachusetts with new animal drugs that have been shipped in interstate commerce, including but not limited to flunixin, penicillin, and sulfamethazine that were manufactured in Ontario, Canada, Northern Ireland, and Le Sueur, Minnesota, respectively.

9. Defendants cause the adulteration of drugs while such drugs are held for sale after shipment in interstate commerce by failing to follow the FDA approved labeling and/or veterinary prescription for such drugs when administering them to their cows.

## STATUTORY AND REGULATORY PROVISIONS

10. The drugs that Defendants use to treat their cattle, including, but not limited to, flunixin, penicillin, and sulfamethazine, are new animal drugs within the meaning of 21 U.S.C. § 321(v).

11. 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).

12. A new animal drug's conditions for use are set forth in the drug's labeling and are published by regulation. 21 C.F.R. Parts 520 – 529, 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"), and 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 period"). 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 ("dosages"). 21 U.S.C. § 360b(i).

13. 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 labeling, 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 extra-label 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.

14. 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 who are susceptible to antibiotics may experience severe allergic reactions as a result of ingesting food containing out-of-tolerance antibiotic levels. Furthermore, food containing above-tolerance antibiotic levels contributes to the development of antibiotic-resistant strains of bacteria in those who eat or handle food containing residues of such drugs.

15. A new animal drug detected in an animal's tissue at a level above the tolerance set by FDA or in a species for which its use is not approved is unsafe within the meaning of 21 U.S.C. §§ 360b(a)(1), (a)(4).

16. 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).

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

18. 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).

## Defendant's Violations of the Act

### June 2014 Inspection

19. FDA most recently inspected Defendants' farm from June 4 through 26, 2014, as a follow-up to laboratory testing by the United States Department of Agriculture ("USDA") that detected illegal levels of residue in a dairy cow that Defendants sold for slaughter. Specifically,

USDA's laboratory testing detected illegal levels of flunixin, penicillin, and sulfamethazine in the cow's muscle, liver, and kidneys.

20. The FDA investigator observed and documented numerous violative conditions during the June 2014 inspection, including, but not limited to, the following:

a. Defendants used an animal drug in a manner contrary to label directions without benefit of a veterinarian's prescription issued pursuant to a valid veterinarian-client-patient relationship. Specifically, Defendants administered animal drugs, including, but not limited to, flunixin, penicillin, and sulfamethazine without following the dosage limitations contained on the drug's labeling and/or without written authorization from a licensed veterinarian;

b. Defendants failed to maintain adequate treatment records. Specifically, Defendants' treatment records do not note the drug withdrawal times, dosage, or the route of administration;

c. Defendants failed to systematically review treatment records prior to offering an animal for slaughter for human food, to ensure that drugs have been used only as directed and that appropriate withdrawal times have been observed. Specifically, Defendants did not review the drug treatment records before offering their cows for slaughter for use as food; and

d. Defendants failed to maintain adequate drug inventory records.

21. At the close of the June 2014 inspection, FDA investigators issued a Form FDA 483, List of Inspectional Observations, to Defendant Michael Ferry, documenting violative conditions at Defendants' farm, including those described in paragraph 20.

Prior Warnings by FDA

22. Defendants have a long history of violating the Act. Many of the violations observed during FDA's most recent inspection of Defendants' farm, described in paragraph 20, are the same as, or similar to, violations observed by FDA during prior inspections in 2013 and 2011. At the close of each of these inspections, FDA provided Mr. Ferry with a Form FDA 483 documenting the observed violations.

23. In August 2011, FDA issued a Warning Letter to Defendants that documented their poor animal husbandry practices, unlawful extra-label drug use, and the presence of unlawful drug residues found in three separate bob veal calves that Defendants sold for slaughter for use as human food. The Warning Letter also stated that failure to correct these violations may result in regulatory action, including an injunction.

24. On October 29, 2013, FDA held a regulatory meeting with Defendants to discuss persistent violative conditions observed during FDA's 2013 inspection and additional instances of unlawful drug residues found in Defendants' cattle. FDA personnel warned Defendants that failure correct these violations may result in regulatory action, including an injunction.

Warnings and Laboratory Testing by USDA

25. Since 1999, USDA has issued at least nine warning letters to Defendants relating to violative drug residues in the edible-tissues of food producing animals that Defendants sent for slaughter.

26. Throughout this period, USDA collected tissue samples from dairy cows and bob veal calves that Defendants sold for slaughter for use as human food and analyzed those samples for drug residues.

27. USDA's testing on multiple occasions since 2004 revealed illegal residues of the new animal drugs flunixin, penicillin, sulfamethazine, neomycin, and gentamicin in Defendants' cows and calves. Such laboratory results establish that Defendants either did not administer the drugs in a manner consistent with the dosage, withdrawal period, and/or other use requirements set forth in each drug's approved labeling, or that Defendants did not maintain sufficient records to ensure that the animals they sold for use as food were free of illegal drug residues.

28. Since 2004, the drug residues found in cattle sold by Defendants for slaughter for use as food are as follows:

| **Sample Date** | **FSIS Sample Form Number** | **Animal** | **Drug Residue** | **Tissue** | **Residue (ppm)** | **Tolerance (ppm)** |
|---|---|---|---|---|---|---|
| 11/13/2013 | 100644613 | Dairy cow | Flunixin | Liver | 0.808 | 0.125 |
| | | | Flunixin | Muscle | 0.0274 | 0.025 |
| | | | Penicillin | Kidney | 0.0794 | 0.05 |
| | | | Sulfamethazine | Liver | 0.976 | 0.1 |
| | | | Sulfamethazine | Muscle | 0.527 | 0.1 |
| 02/06/2013 | 100382594 | Bob veal | Sulfamethazine | Liver | 0.16 | 0.1 |
| | | | | Muscle | .154 | 0.1 |
| 01/13/2011 | 576161 | Bob veal | Neomycin | Kidney | 11.59 | 7.2 |
| 11/04/2010 | 576765 | Bob veal | Gentamicin | Kidney | Positive | n/a |
| 07/21/2010 | 576554 | Bob veal | Neomycin | Kidney | 11.51 | 7.2 |
| 03/18/2010 | 517121 | Bob veal | Neomycin | Kidney | 8.47 | 7.2 |
| 02/04/2010 | 514152 | Bob veal | Neomycin | Kidney | 11.17 | 7.2 |
| 02/25/2009 | 531300 | Dairy cow | Neomycin | Kidney | 9.76 | 7.2 |
| 12/22/2004 | 298661 | Dairy cow | Penicillin | Kidney | 3.59 | 0.05 |
| | | | Penicillin | Liver | 0.53 | 0.05 |

29. USDA repeatedly warned Defendants about their illegal practices. Between 2005 and 2014, USDA sent Defendants multiple residue violation letters, stating that the agency had found violative drug residues in cattle that Defendants offered for slaughter. The letters warned

that violative residues in the edible tissues of animals cause the food to be adulterated under the Act, and that continued violations may lead to enforcement action by USDA or FDA.

## DEFENDANTS' CONDUCT AND VIOLATIONS

### Defendants Violate 21 U.S.C. § 331(a)

30. Because of Defendants' 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 animals sold for slaughter by Defendants for use as food contained drug residues in amounts above the levels permitted by law.

31. Defendants, without an order from a licensed veterinarian within the context of a veterinarian-client-patient relationship, administered new animal drugs, including, but not limited to, flunixin, penicillin, and sulfamethazine, to their animals and failed to comply with the drugs' approved withdrawal requirements, route of administration, and/or dosage requirements. A new animal drug used in a manner that fails to conform to the drug's approved conditions of use, without a prescription from a licensed veterinarian within 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' use of new animal drugs resulted in illegal residues and caused the drugs to be unsafe within the meaning of 21 U.S.C. § 360b(a)(1).

32. Because the edible tissues of animals sold for slaughter by Defendants 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).

33. 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).

34. 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 within 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).

35. Because the extra-label new animal drug use by Defendants caused illegal drug residues, Defendants do not comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

36. 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 new animal drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(5).

37. Defendants violate 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: (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 food (edible tissues of animals) has been held under insanitary conditions whereby it may have been rendered injurious to health.

Defendants Violate 21 U.S.C. § 331(k)

38. Defendants purchase, receive, and use new animal drugs, within the meaning of 21 U.S.C. § 321(v), to treat their dairy cows and veal calves, including, but not limited to, flunixin, penicillin, and sulfamethazine.

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

40. Defendants, without an order from a licensed veterinarian within the context of a veterinarian-client-patient relationship, do not comply with indications for use, withdrawal requirements, route of administration, and/or dosage requirements when administering new animal drugs after shipment in interstate commerce. 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).

41. Defendants' extra-label use of new animal drugs results in residues above an established safe level, safe concentration, or tolerance. Such drugs, therefore, are deemed 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).

42. In light of the conduct described above, 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) by using such drugs in ways that are inconsistent with their approved conditions of use while such drugs are held for sale after shipment in interstate commerce.

Defendants Violate 21 U.S.C. § 331(u)

43. 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 within 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).

44. Defendants violate 21 U.S.C. § 331(u) by failing to comply with the requirements in 21 U.S.C. § 360b(a)(4)(A) regarding the extra-label use of new animal drugs.

Likelihood of Future Violations

45. Despite numerous warnings from two federal agencies, as described above, Defendants continue to violate the Act. Based on Defendants' repeated violations, especially in the face of these warnings, the United States 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).

## 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); 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, 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 _____ day of _____, 2015.

Respectfully submitted,

BENJAMIN C. MIZER
Acting Assistant Attorney General

JONATHAN F. OLIN
Deputy Assistant Attorney General

Carmen M. Ortiz
United States Attorney

MICHAEL S. BLUME
Director

/s/ David Sullivan
DAVID SULLIVAN
Trial Attorney
United States Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044-0386
Telephone: (202) 514-0516
Fax: (202) 514-8742
Bar No.: Louisiana 27303

Of Counsel:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

PERHAM GORJI
Deputy Chief Counsel for Litigation

SCOTT A. KAPLAN
Associate Chief Counsel for Enforcement
United States Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
WO 31-4579
Silver Spring, MD 20993
301-796-8576