UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

SCENIC VIEW DAIRY, L.L.C., a limited liability company, and MICHAEL D. GEERLINGS, MARK A. LUCAS, and MICHAEL J. VAN DAM, individuals,

Defendants.
/

Case No. 1:10-CV-865

HON. GORDON J. QUIST

OPINION

In this case, the United States of America seeks to enjoin Scenic View Dairy, L.L.C., Michael D. Geerlings, Mark A. Lucas, and Michael J. Van Dam (referred to collectively as "Defendants"), from violating the Federal Food, Drug, and Cosmetic Act (the "FDCA" or the "Act"), 21 U.S.C. § 301 *et seq.*, which the United States alleges Defendants are violating in the following respects: (1) delivering adulterated food for introduction into interstate commerce, in violation of 21 U.S.C. § 331(a); (2) adulterating drugs while held for sale and after shipment in interstate commerce, in violation of 21 U.S.C. § 331(k); and (3) failing to comply with the requirements set forth in 21 U.S.C. § 360b(a)(4)(A) for the extra-label use of new animal drugs, in violation of 21 U.S.C. § 331(u). The United States has filed a motion for summary judgment and a motion to strike several of Defendants' affirmative defenses. The Court heard oral arguments on May 23, 2011. For the reasons set forth below, the Court concludes that the United States' motion to strike should be granted in part and denied in part and its motion for summary judgment should be granted. The proper scope of injunctive relief, however, remains to be decided.

I. FACTS

Scenic View is a limited liability company, formed under the laws of the State of Michigan, with its principal place of business located in Hamilton, Michigan. Scenic View owns and operates three separate dairy farms in West Michigan: the "Fennville Farm," the "Freeport Farm," and the "Gowen Farm." Scenic View says that it has about 10,000 cows at any one time. The individual Defendants are Michael D. Geerlings, who is president and majority owner of Scenic View, and Mark A. Lucas and Michael J. Van Dam, who manage the Fennville Farm and Freeport Farm, respectively, and are responsible for the daily operations at those farms, including the diagnosis and treatment of animals.[1] Defendant Lucas is also a member.

Although Scenic View's primary business is the sale of Grade A milk, it also sells cull cows for beef, shipping approximately 70 cows to slaughter for human consumption per week. The cows are sold, either directly or by auction, to slaughterhouses both in Michigan and in other states, including Pennsylvania and Wisconsin. Since 2002, the United States Department of Agriculture ("USDA") Food Safety and Inspection Service ("USDA-FSIS") has detected above-tolerance levels of new animal drug residues in the edible tissues of slaughtered animals alleged to have originated from Scenic View on eleven occasions. After nearly all residue violations, the FDA inspected the farm from which the cow was believed to have originated. The United States has submitted evidence supporting each violation, including collection and lab reports, as well as records from the follow-up inspections. For purposes of clarity, this evidence will be discussed as part of the Court's analysis, after the legal framework has been set forth.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(a). Material facts

[1] The Gowen Farm is managed by Jeremy A. Portell, who was originally named as a defendant, but who was dismissed by Stipulation and Order dated April 6, 2011.

are facts which are defined by substantive law and are necessary to apply the law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). A dispute is genuine if a reasonable jury could return judgment for the non-moving party. *Id.*

A court must draw all inferences in a light most favorable to the non-moving party, but may grant summary judgment when "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Agristor Financial Corp. v. Van Sickle*, 967 F.2d 233, 236 (6th Cir. 1992) (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 1356 (1986)).

III. DISCUSSION

The United States alleges that Defendants have violated three separate provisions of the FDCA – § 331(a), (k), and (u) – and contends that the Court should grant its motion for summary judgment as to all three. The Court will discuss each provision in turn.

A. Whether Defendants Have Violated 21 U.S.C. § 331(a) by Delivering Adulterated Food for Introduction into Interstate Commerce

Section 331(a) prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated." 21 U.S.C. § 331(a). This provision has three elements: "(1) the product in question must be a food; (2) the food must be adulterated; and (3) there must be an interstate commerce nexus." *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 42 (E.D.N.Y. 2001); *accord United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 754 (6th Cir. 1999). Defendants do not contest that their cattle qualify as "food" within the meaning of the Act nor that they deliver their cattle for introduction into interstate commerce.[2]

[2] Animals intended for slaughter have been held to constitute food within the meaning of the Act. *See United States v. Tuente Livestock*, 888 F. Supp. 1416, 1424 (S.D. Ohio 1995) (holding that live hogs raised for food and intended to be offered for slaughter are "food" as used in § 331(a)); *see also* FDA, Proper Drug Use and Residue Avoidance by Non-Veterinarians, Compliance Policy Guide ("CPG") § 615.200 ("FDA regards live animals raised for food as 'food' under the Act."), available at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074660.htm (last visited Aug. 11, 2011). In addition, as set forth in detail below, the Government has presented sufficient evidence that Defendants routinely sell and deliver cattle either directly or by auction to slaughterhouses located outside of Michigan.

Instead, the dispute here lies in whether the food is "adulterated" under the Act. The United States asserts that Defendants' food is adulterated under two separate provisions: 21 U.S.C. § 342(a)(2)(C)(ii) and 21 U.S.C. § 342(a)(4). As to each provision, the Court will begin by addressing the parties' legal disputes followed by a discussion of the evidence presented.

1. Adulteration under 21 U.S.C. § 342(a)(2)(C)(ii)

Under 21 U.S.C. § 342(a)(2)(C)(ii), food is adulterated "if it is or if it bears or contains . . . a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title." As a threshold matter, § 360b provides that a new animal drug is automatically considered unsafe prior to receiving FDA approval for its intended use. *See* 21 U.S.C. § 360b(a)(1)(A) ("A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of . . . section 342(a)(2)(c)(ii) of this title unless . . . there is in effect an approval of an application filed [with the FDA]."). To obtain FDA approval, a new animal drug must undergo an extensive application and approval process that requires the applicant to demonstrate that the drug is safe and effective when used in accordance with the proposed labeling. *See id.* §360b(b) and (d) (detailing the application process for new animal drugs and the requirements for approval); *see also* FDA, Proper Drug Use and Residue Avoidance by Non-Veterinarians, Compliance Policy Guide ("CPG") § 615.200 ("The pre-market approval process ensures that when animal drugs are used in accordance with the labeled directions (type of animal, medical conditions, dosage, route of administration, and any other precautions or instructions for the safe and effective use of the product, including withdrawal and milk discard times) milk, eggs, and the edible tissues of slaughtered animals treated with a drug will not contain potentially harmful or violative drug residues."). When an approved new animal drug is not used in accordance with its labeling, the use is referred to as being "extralabel." *See* 21 C.F.R. § 530.3(a) ("Extralabel use means actual use or intended use of a drug in an animal in a manner that is not in accordance with

the approved labeling."). Extralabel use "includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses." *Id.*

In its motion for summary judgment, the United States initially took the position that a drug is unsafe under§ 360b if the actual use varies from the FDA-approved use (i.e., an extralabel use) *and* such different use "(1) is not by or under the lawful order from a licensed veterinarian; or (2) results in any drug residue above an established safe level, safe concentration, or safe tolerance." (Pl.'s Mot. for Summ. J. at 17.) Thus, the opening brief focused solely on extralabel uses. In their response, Defendants asserted that a drug that is used in accordance with the label, but nonetheless results in an above-tolerance residue level, is not "unsafe" under § 360b. In its reply, the United States expanded its position somewhat by arguing that "whether Defendants' use of new animal drugs is on-label or extra-label, those drugs are unsafe under § 360b, and Defendant's food is adulterated under § 342(a)(2)(C)(ii), if such use results in an illegal drug residue." (Pl.'s Reply at 4.) The parties cite no case law, and chambers research reveals none, interpreting the Act with respect to either position.

In paragraph (1), § 360b begins with the following position:

> A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purpose of . . . section 342(a)(2)(c)(ii) of this title unless . . . there is in effect an approval of an application filed [with the FDA] with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such approved application.

§ 360b(a)(1)(A). Paragraph (4) addresses the safety of a drug when used in an extralabel manner:

> (A) Except as provided in subparagraph (B), if an approval of an application filed [with the FDA] is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for purposes of paragraph (1) . . . with respect to a different use or intended use of the drug . . . if such use or intended use --

> (i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and
>
> (ii) is in compliance with the regulations promulgated by secretary that establish the conditions for such different use or intended use.
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> ***
>
> (B) If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under subparagraph (A) may present a risk to the public health, the Secretary may --
>
> (i) establish a safe level for a residue of an animal drug when it is used for such different use authorized by subparagraph (A); and
>
> (ii) require the development of a practical, analytical method for the detection of residues of such drug above the safe level established under clause (i).
>
> The use of an animal drug that results in residues exceeding a safe level established under clause (i) shall be considered an unsafe use of such drug under paragraph (1).

21 U.S.C. §§ 360b(4)(A)-(B).

Turning to the regulations, 21 CFR Part 530 deals with extralabel uses of new animal drugs. Section 530.10, entitled "Provision permitting extralabel use of animal drugs," explains that a drug is not unsafe with respect to an extralabel use so long as such use is "[b]y or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient-relationship [which the regulations also define] . . . *and* in compliance with this part." The very next section, entitled "Limitations," explains that "*[i]n addition* to uses that do not comply with the provisions set forth in § 530.10, the following specific extralabel uses are not permitted and result in a drug being deemed unsafe . . . (d) Extralabel use resulting in any residue above an established safe level, safe concentration or tolerance." 21 C.F.R. § 530.11 (emphasis added).

As to extralabel uses, therefore, the Act and its regulations are clear. Any extralabel use results in the drug being deemed unsafe under § 360b unless it is by order of a licensed veterinarian

in the context of a valid veterinarian-client-patient relationship ("VCPR"), as it is defined in the Act; and even if it is by order of a veterinarian in the context of a VCPR, it is still unsafe under§ 360b if it results in an illegal tissue residue. 21 U.S.C. § 360b(a)(4)(A)-(B); 21 C.F.R. §§ 530.10 and 530.11(d). The Court agrees with the United States that, in accordance with the general rule that the party seeking the benefit of a statutory exemption bears the burden of establishing that entitlement, Defendants bear the burden of establishing that they fall with the VCPR exception for extralabel use. *See United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 366, 87 S. Ct. 1088, 1092 (1967) (noting the general rule); *see also United States v. Kanasco, Ltd.*, 123 F.3d 209, 211 (4th Cir. 1997) (following the general rule with respect to a different FDCA statutory exemption); *United States v. Rhody Dairy, L.L.C.*, No. C11-0065-RSM, 2011 WL 2792454, at *4 (W.D. Wash. July 14, 2011) (noting that the defendant-dairy farm had failed to present evidence that it fell within the VCPR exception).

As to uses that accord with the drug's approved labeling, the only references to tolerance levels in § 360b and the related regulations are found in the provisions dealing with extralabel uses. Also, the pre-approval process itself is designed to ensure that the drug is safe when used in accordance with its approved label. Thus, a new animal drug is not legally deemed to be unsafe with respect to uses that accord with the drugs approved labeling simply because there was a violative tissue residue.

Given this legal framework, what follows is a discussion of the evidence presented as to each alleged residue violations on a farm-by-farm basis. To begin with, the Court finds that documentary evidence the United States has presented, including collection reports, laboratory results, and FDA Form-483s, are admissible as public records under Fed. R. Evid. 803(8)(C), which exempts from the hearsay rule "factual finding resulting from an investigation made pursuant to authority granted by law." This rule is based upon "the assumption that a public official will perform his duty

properly," and, thus, admissibility is presumed in the first instance, with the burden on the party opposing admission to demonstrate unreliability. *Ellis v. Int'l Playtex, Inc.*, 745 F.2d 292, 301 (4th Cir. 1984); *see also United States v. Midwest Fireworks Mfg. Co.*, 248 F.3d 563, 566 (6th Cir. 2001) (noting the "presumption of admissibility" that applies to public records and affirming admissibility of, among other things, laboratory test results prepared by the Consumer Products Safety Commission). The Court finds Defendants' generalized claims of untrustworthiness insufficient to overcome the presumption. *See Fujisawa Pharm. Co. v. Kapoor*, No. 92 C 5508, 1999 WL 543166, at *2 (N.D. Ill. July 21, 1999) (admitting an FDA Form-483 as a public record over defendant's general allegations of untrustworthiness).

(i) The Freeport Farm

On November 26, 2008, the USDA-FSIS collected a tissue sample from a cow with back tag number 34LL9096 and ear tag number13[3], in which laboratory tests identified a Penicillin residue of 0.10 ppm in the animal's kidney, which exceeds the 0.05 ppm tolerance level codified at 21 § C.F.R. § 556.510(a). (Pl's Mot. for Summ. J. Exs. 4-Q, 4-T, 4-V.) The FDA identified the cow as having been delivered from Defendants' Freeport Farm on November 25, 2008, to a livestock auction in Michigan for sale for use in human food, where it was purchased by a Pennsylvania slaughterhouse. (*Id.* Exs. 4-V and 4-Q at SVD_000000824.)

In response, the FDA inspected the Freeport Farm between August 11 and October 1, 2009. (Carter Decl. ¶ 23, Pl.'s Mot. for Summ. J. Ex. 4; *Id.* Ex. 4-W at SVD_000000760.) During the inspection, Defendant Van Dam admitted in a sworn affidavit that the identified cow had originated from Scenic View and had been treated with 40 cc of Penicillin on November 10, 2008, and 20 cc each of the following three days, even though, given the cow's weight, it should not have received

[3] The back tag is a tag that the auction house puts on the cow, while the ear tag is a tag that Defendants place on their cows (also referred to as "farm tag"). (*See* Supplemental Carter Decl. ¶ 4 n.1, Pl.'s Reply Ex. 2)

more than 14 cc according to the labeled dosage. (*Id.* Ex. 4-T.) Defendant Van Dam also admitted that Scenic View "routinely" administered Penicillin in 20 cc and/or 40 cc dosages, despite the labeled dosage of 1 cc per 100 pounds. (*Id.*) Finally, Defendant Van Dam admitted that he does "not always record the dosage and route of administration" in the treatment records or in any other documents. (*Id.*) During the investigation, the FDA investigator obtained copies of the treatment records for the subject cow as well as those of six additional cows. (*Id.* Exs. 4-S and 4-U.) In none of those records did Defendants routinely document the route of administration, dosage given, or withdrawal time. (*Id.*)

Following the investigation, the FDA investigator issued a FDA Form-483 to Defendant Van Dam, which summarized the investigator's findings as follows: (1) Defendants had caused an above-tolerance residue level through use of a new animal drug contrary to its labeling; (2) Defendants' extralabel use of Penicillin was without benefit of a valid VCPR; and (3) Defendants failed to maintain adequate treatment records because they did not routinely document route of administration or dosage given. (*Id.* Ex. 4-W.)

Defendants do not contest having administered extralabel dosages of Penicillin, but assert that they did so based upon protocols in place at the time, which were established in conjunction with veterinarians. (Defs.' Response at 14; Van Dam Decl. ¶ 16, *Id.* Ex. 7.) The Court assumes that Defendants are attempting to assert that their extralabel use falls within § 360b's VCPR exception. The Court need not determine whether Defendants' have presented sufficient evidence to meet their burden of establishing the existence of a valid VCPR, however. As set forth above, even where an extralabel use is by order of a veterinarian in the context of a VCPR, the drug is still deemed unsafe under§ 360b if the extralabel use results in an illegal tissue residue. 21 U.S.C. § 360b(a)(4)(A)-(B); 21 C.F.R. §§ 530.10 and 530.11(d). Because Defendants' extralabel use of Penicillin resulted in an above-tolerance residue, the drug is deemed "unsafe" under § 360b, and the

food containing that drug "adulterated" under 21 U.S.C. § 342(a)(2)(C)(ii), regardless of whether a VCPR relationship existed.[4]

On June 21, 2007, the USDA-FSIS collected a tissue sample from a cow with back tag number 34LL2679, which had been delivered from the Freeport Farm to a Michigan livestock auction where it was purchased by a Michigan slaughterhouse that routinely ships meat in interstate commerce. (Carter. Decl. Exs. 4-X and 4-Z.) Laboratory tests identified Sulfadimethoxine residue of 0.24 ppm and 0.20 ppm in the animals liver and muscle, respectively, (Pl.'s Mot. for Summ. J. Ex. 3-D at SVD_000001254), both of which exceed the 0.1 ppm tolerance level codified at 21 C.F.R. § 556.640(b)(1). On October 19, 2007, the USDA-FSIS collected a tissue sample from a cow with ear tag number 683 that had been delivered from the Freeport Farm to a Michigan slaughterhouse that routinely ships meat in interstate commerce. (Carter Decl. Exs. 4-Y and 4-Z.) Laboratory tests identified a Penicillin residue of 0.24 ppm in the animal's kidney, (Givens Decl. Ex. 3-D at SVD_000001241), which exceeds the 0.05 ppm tolerance at 21 C.F.R. § 556.510(a).

As a result, the FDA inspected the Freeport Farm between December 18, 2007 and January 7, 2008. (Carter Decl. ¶ 31.) During the investigation, the FDA investigator obtained treatment records for both of the cows in question, none of which routinely documented withdrawal periods, dosages, or route of administration. (*Id.* Exs. 4-CC and 4-DD.) After the inspection, the FDA investigator issued a Form-483, which, among other things, documented the investigator's observation that Defendants' treatment records were inadequate because they failed to consistently document route of administration, dosage, and withdrawal times.

As to the June sample, Defendants assert that there is a genuine issue of material fact as to whether the cow originated from Scenic View because the FDA has only identified the cow

[4]Indeed, as to this sample, Defendants concede that, assuming the tissue sample did originate from a Scenic View cow and the tests were properly done, "§ 342(a) may have been violated." (Defs.' Reply at 14.)

according to its back tag number, which is the number the auction house assigns, and not the ear tag number, which is the number Defendants use to identify the cattle on their farms. The Court disagrees. First, during the inspection, Defendant Van Dam admitted in a sworn affidavit to having delivered 17 dairy cows to auction that day, including a cow identified by back tag 34LL2679, but that without the ear tag number, he could not be sure exactly which of the 17 cattle delivered that day corresponded to that back tag number. (*Id.* Ex. 4-BB.) Moreover, the Government has submitted other documentation evidencing that the subject cow originated from Scenic View, including the sworn affidavit of the auction house manager, (Defs.' Reply Ex. 2-1 at SVD_000001110), and a copy of the check Scenic View received for the 17 head of cattle, which specifically identifies a cow with back tag number ending in 679. (*Id.* at SVD_0000001111.)

Nonetheless, the Court agrees with Defendants, that as to the June sample, a genuine issue of material fact exists about whether Scenic View caused the violative residue level because none of the treatment records for the 17 head of cattle indicate treatment with Sulfadimethoxine. The Government contends, and Defendant Van Dam admitted in the sworn affidavit, that what may have happened is that the cow was treated with Sulfadimethoxine but Defendants failed to record the treatment; and because they forgot to record it, no one checked the withdrawal time prior to delivering the cattle. (*Id.* Ex. 4-BB.) Yet, with no admission or actual evidence of an extralabel dosage of Sulfadimethoxine, a question of fact exists.

As to the October sample, Defendants do not contest that the cow was treated with an extralabel dosage of Penicillin. (*See* Defs.' Reply at 14 ("These cattle were given extra-label dosages of penicillin . . . and assuming the test results were properly done, § 342(a) may have been violated.").) Although the cow's treatment records do not evidence Penicillin having been administered, they do indicate that the cow was being treated for swollen legs, (Pl.'s Mot. for Summ. J. Ex. 4-DD at SVD_000001172), and Defendant Van Dam admitted in his sworn affidavit that

Defendants "routinely" medicate animals with Penicillin if they have swollen legs. (*Id.* Ex. 4-BB.) Defendants do argue, however, that the extralabel dosage of Penicillin was given based upon protocols in place at the time. The Court assumes that Defendants are again attempting to assert that their admitted extralabel use as to the October sample falls within the VCPR exception. Yet, because the extralabel use resulted in a violative tissue residue, the Court need not determine whether Defendants' have presented sufficient evidence to meet their burden in this regard. 21 U.S.C. § 360b(a)(4)(A)-(B); 21 C.F.R. §§ 530.10 and 530.11(d).

Accordingly, as to the Freeport Farm, the Court finds no genuine issue of material fact that Defendants' extralabel use of new animal drugs resulted in violative residue levels as to the November 26, 2008, and October 19, 2007, samples. As a result, those drugs are deemed "unsafe" under § 360b, and the food containing them "adulterated" under § 342(a)(2)(C)(ii), regardless of whether the extralabel use was by order of a veterinarian in the context of a valid VCPR. 21 U.S.C. § 360b(a)(4)(A)-(B); 21 C.F.R. §§ 530.10 and 530.11(d).

(ii) Gowen Farm

On November 7, 2006, the USDA FSIS collected tissue samples from two dairy cows, which laboratory tests identified as containing above-tolerance residue levels as follows: (1) Sulfadimethoxine residue of 0.57 ppm and 0.38 ppm found in the liver and kidney, respectively, both of which exceed the 0.1 ppm tolerance level codified at 21 C.F.R. § 556.640(b)(1), and Penicillin residues of 0.51 ppm and 0.08 ppm found in the kidney and liver, respectively, both of which exceed the 0.05 ppm tolerance level codified in 21 C.F.R. § 556.510(a), all found in a dairy cow with back tag 34XL6295; and (2) Sulfadimethoxine residue of 0.78 ppm and 0.57 ppm found in the liver and muscle, respectively, which exceeds the 0.1 ppm tolerance, in a dairy cow with back tag 34XL6290. (Pl.'s Mot. for Summ. J. Exs. 4-GG, 4-HH, 4-KK, and Ex. 3-D at SVD_000001257.) On November 8, 2006, the USDA-FSIS collected a tissue sample from a dairy

cow with back tag number 34RA6293, which laboratory tests identified as having Sulfadimethoxine residue of 0.23 ppm and 0.185 ppm in the animal's liver and muscle, respectively, both of which also exceed the 0.1 ppm tolerance. (*Id.* Exs. 4-FF and Ex. 3-D, SVD_000001257.) The USDA identified all three cows as having been delivered by Scenic View's Gowen Farm, on November 6, 2006, to a livestock auction in Michigan for sale for use in human food, where they were purchased by a Wisconsin slaughterhouse and Michigan slaughterhouse that routinely ships in interstate commerce. (*See id.* Exs. 4-FF, 4-GG, 4-HH, 4-KK.)

In response, the FDA inspected the Gowen Farm from January 23 to 25, 2007. (Carter Decl. ¶ 37, Pl.'s Mot. for Summ. J. Ex. 4; *Id.* Exs. 4-KK, 4-MM.) During the inspection, Gowen Farm manager Jeremy Portell admitted in a sworn affidavit to having sold eight cattle to auction on November 6, 2006, including three cows with back tag numbers 34RA6293, 34XL6290, and 34XL6295. (*Id.* Ex. 4-KK.) Portell also admitted that all eight cows had been treated with Penicillin and Sulfadimethoxine as recently as October 30, 2006, when the withdrawal times identified on the drugs' labels were 10 and 7 days respectively and that he "did not check the proper withdrawal times for these 8 head" before selling them to auction. (*Id.*) Thus, Portell admitted to extralabel use of these drugs by failing to follow the labeled withdrawal times. During the investigation, the investigator obtained the treatment records for all eight cows, none of which documented the routes of administration, dosage given, or withdrawal periods. (*Id.* Ex. 4-LL.)

After the inspection, the investigator issued to Defendant Geerlings an FDA Form-483 which summarized the investigator's observations as follows: (1) Defendants' extra-label use of new animal drugs had caused above-tolerance residue levels as to all three cows identified above; (2) Defendants failed to systematically review treatment records prior to offering animals for slaughter to assure that appropriate withdrawal times have been observed; and (3) Defendants failed to maintain adequate treatment records because their records failed to identify the dosage administered, route of administration, or withdrawal times. (*Id.* Ex. 4-MM.)

While not denying extralabel use as to any of the three cows, Defendants again assert that there is a genuine issue of material fact about whether any of the three cows actually originated from Scenic View because the FDA only identified the cows by their back tag numbers, but not the ear tag numbers. (Defs.' Resp. at 12.) The Court rejects this argument. To begin, Portell admits in the sworn affidavit that he sold the cows with the aforementioned back tag numbers, but that without the ear tag numbers he could not be sure exactly which of the eight cattle sold that day corresponded to the specific back tag numbers as all eight were treated with the drugs in question. (Pl.'s Mot. for Summ. J. Ex. 4-KK.) Even without this admission, the Government has submitted other documentation identifying the cows as having originated from the Gowen Farm, including the sworn affidavit of the auction house manager and a copy of the check Defendants received for the sale of the eight cattle, which specifically identifies the cows by the aforementioned back tag numbers. (Pl.'s Reply Ex. 2-4 at SVD_000001343 and 1349.)

Defendants also argue that even if the three cows did originate from Scenic view, the cows were treated under the verbal orders of the Gowen Farm's veterinarian. (Defs.' Resp. at 12.) Again, the Court assumes that Defendants are attempting to assert that their extralabel use falls within the VCPR exception. The Court need not determine whether Defendants' have presented sufficient evidence to meet their burden in this regard, however, because even where an extralabel use is under order of a veterinarian in the context of a VCPR, the drug is still deemed unsafe under§360b if it results in an illegal tissue residue. 21 U.S.C. § 360b(a)(4)(A)-(B); 21 C.F.R. §§ 530.10 and 530.11(d).

Accordingly, the Court finds no genuine issue of material fact that as to all three November 2006 samples originating from the Gowen Farm, Defendant's extralabel use of new animal drugs resulted in violative residue levels. As a result, the drugs are deemed "unsafe" under § 360b, and the food containing them "adulterated" under § 342(a)(2)(C)(ii), regardless of whether the extralabel use was by order of a veterinarian in the context of a valid VCPR.

(iii) Fennville Farm

On August 12, 2009, the USDA-FSIS identified an above-tolerance Sulfadimethoxine residue in a tissue sample collected from a cow that had been delivered from the Fennville Farm to a livestock auction in Michigan where it was purchased by a Pennsylvania slaughterhouse for use in human food. (Carter Decl. ¶¶ 5-6, Pl.'s Mot. for Summ. J. Ex. 4; *Id.* Ex. 4-A.) The USDA lab report identified Sulfadimethoxine residues of 0.151 ppm and 0.125 ppm in the animal's liver and muscle, respectively, (*Id.* Ex. 4-A at SVD_000000104), which exceed the applicable tolerance level of 0.1 ppm codified at 21 C.F.R. § 556.640(b)(1).

In response, the FDA inspected the Fennville Farm between January 25 to February 2, 2010. (Carter Decl. ¶ 5.) During the inspection, the FDA investigator obtained a letter dated October 28, 2009, from David Haverdink, Scenic View's Chief Operations Officer, to the Pennsylvania slaughterhouse, in which Haverdink admits that the cow had in fact been sent from Scenic View and that, although the cow had been held for the length of time recommended on the drug's label, because it was given a "larger dose then what the drug dosage called for," the retention time should have been longer. (*Id.* Ex. 4-F.) The FDA investigator also obtained Scenic View treatment records for the cow, which indicate that the cow had been treated with Sulfadimethoxine for foot rot, but do not indicate the dosage given, withdrawal time, or route of administration. (*Id.* Ex. 4-D.)

After the inspection, the FDA investigator issued a Form-483 to Defendant Lucas which summarized the investigator's observations as follows: (1) Defendants had caused an illegal tissue residue through use of Sulfadimethoxine contrary to its labeling and (2) Defendants failed to have an adequate system to control administration of drug treatments to its animals because their treatment records failed to indicate the actual dosage given for each treatment. (*Id.* Ex. 4-G.)

Defendants assert that the label-required dosage and withdrawal times were followed and point the Court's attention to the United States' Exhibit 4-B, which is another evaluation form

completed by the investigator after the inspection. The form asks the inspector to identify the "primary" factor causing the violation from a list of several possibilities including an extralabel use (such as administering a higher than recommended dosage or not following the labeled route of administration), from which the investigator selected "Unable to Determine." (*Id.* Ex. 4-B at SVD_000000039.) Therefore, Defendants assert, "the Government (by its own admission) has failed to prove a violation" as to the August 12, 2009 sample. (Defs.' Resp. at 13.)

The Court finds that, as to the August 12, 2009 sample, a genuine issue material fact exists about whether Defendants' use of Sulfadimethoxine was, in fact, extralabel. Given the Court's conclusion that a drug is not "unsafe" under § 360b with respect to uses that accord with the drug's label, but nonetheless results in a violative tissue level, the Court will ignore the August 12, 2009 sample for purposes of determining whether Defendants' food is adulterated under § 342(a)(2)(C)(ii). In addition, the Court will ignore the alleged 2002 violations, both of which Defendants contend are time-barred. Nonetheless, because the Court has already concluded that Defendants' extralabel use of new animal drugs resulted in violative residue levels on at least five other occasions, the United States is still entitled to summary judgment as to its claim that Defendants' food is "adulterated" under § 342(a)(2)(C)(ii).

2. Adulteration under 21 U.S.C. § 342(a)(4)

Under 21 U.S.C. § 342(a)(4), a food is deemed adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." To prove adulteration under this provision, the Government need not show that the food has actually become dangerous to health, only that it may have been; the standard is a "reasonable possibility" of injury. *See Blue Ribbon*, 179 F. Supp.2d at 44; *United States v. H.B. Gregory Co.*, 502 F.2d 700, 704 (7th Cir. 1974); FDA, CPG § 600.200 ("The 'may have been rendered injurious to health' standard requires a reasonable possibility of injury.").

The United States alleges that Defendants do not maintain adequate drug treatment records because they do not regularly document dosage, routes of administration, or withdrawal periods, and that this failure constitutes insanitary conditions whereby their food may be rendered injurious to health. Defendants argue that the United States' "rather novel" interpretation of "insanitary conditions" is both contrary to the common understanding of the term, which typically describes such as things as insect infestation, mold, or filth, and is inconsistent with § 350c of the Act, which, Defendants assert, specifically exempts farms from the Act's record-keeping requirements.

The Court concludes that Defendants are not exempt from all record-keeping requirements under the Act by virtue of §350c(b). That provision, which was enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002), after the events of September 11th, 2001, provides as follows:

> The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary *to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals*. The Secretary shall take into account the size of a business in promulgating regulations under this section.

21 U.S.C. § 350c(b). Not only do Defendants fail to present any authority interpreting the provision so as to exempt farms from any and all record-keeping requirements, but, on its face, the provision focuses on a particular type of record – those identifying the immediately previous source and subsequent recipient of foods – not record-keeping as a whole. Moreover, subsection (d)(1) specifically provides that §350c "shall not be construed . . . to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this chapter." *Id.*

The question, then, is whether, as the United States alleges, the failure to maintain adequate drug treatment records can constitute "insanitary conditions" under the Act. In this regard, the United States' proffered interpretation of "insanitary conditions" is not as "novel" as Defendants suggest. Since at least 1993, the FDA has interpreted the term not only as encompassing more than "filth or bacteria," but in the context of holding food-producing animals, specifically to include a lack of adequate control measures such as the failure to maintain adequate drug treatment records. *See* FDA, CPG § 615.200 (explaining that FDA may regard live animals raised for food as adulterated under § 342(a)(4) where illegal residues are identified and inadequate control systems, including the failure to maintain adequate treatment records, are documented). "In FDA's view, failure to maintain adequate controls with respect to use of animal drugs could result in a reasonable possibility of injury to human health because illegal drug residues often result from a lack of such controls, and illegal drug residues could have adverse toxilogical effect on consumers, ranging from acute to chronic reactions." *Id.*

The Court agrees with the FDA's interpretation. Administering drugs to animals without adequate control measures, including the failure to maintain adequate treatment records, creates a reasonable possibility that edible tissues from those animals may be rendered injurious to human health. *See Rhody Dairy*, 2011 WL 2792454, at *2 (concluding that the failure to maintain records of drug administration constitutes "insanitary conditions" under § 342(a)(4)); *see also United States v. Nova Scotia Food Prods. Corp.*, 417 F. Supp. 1364, 1369 (E.D.N.Y. 1976), *rev'd on other grounds*, 568 F.2d 240 (2d Cir. 1977) (explaining that the term "insanitary" "is given operative content only by reference to the purpose of subsection (a)(4), that is, to provide against *whatever* condition of processing may render the product injurious to health *or* contaminate it will filth." (emphasis added)); *United States v. Articles of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798, 89 S. Ct. 1410, 1418 (1969) ("[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be

given a liberal construction consistent with the Act's overriding purpose to protect the public health.").[5]

Having concluded that the failure to maintain adequate treatment records can constitute "insanitary conditions" under § 342(a)(4), the Court also rejects Defendants' contention that there is a genuine issue of material fact as to the adequacy of their records. Defendants assert that they keep an electronic record of all medical treatments for their cows that identifies the ailment/injury being treated, medication given, treatment dates, and other related information. (Defs.' Reply at 4.) Defendants admit that they do not routinely record route of administration, dosage, or withdrawal time in their treatment records, but assert that they need not do so because the information is already part of their standard protocol and, therefore, already known by Scenic View employees without reference to a particular cow's record. (*Id.*)

The adequacy of Defendants' record-keeping is an issue of law, not fact. *See Rhody*, 2011 WL 2792454, at *2. The Court notes that since at least 1993, the FDA has published in its Compliance Policy Guide what it views as an adequate treatment record: one that, "at a minium, identifies the animal(s) treated (individual animals, pens, lots, etc.), the date(s) of treatment, the drug(s) administered, who administered the drug(s), the amount administered, and the withdrawal time prior to slaughter." FDA, CPG § 615.200. Moreover, even ignoring the 2002 inspection,

[5]Citing the general rule of statutory construction that a specific provision controls ones of more general application, Defendants also assert that the Government is barred from seeking relief under § 342(a)(4)'s "insanitary conditions" provision, when the real concern is violative residue levels, which is already specifically addressed by § 342(a)(2)(C)(ii) and its related regulations. The Court disagrees. The cases on which Defendants rely for this proposition involve situations in which applying the more generally applicable provision would effectively render the more specific provision a nullity. *See United States v. Turner*, 602 F.3d 778, 782 (6th Cir. 2010); *Edward D. Rollert Residuary Trust, Genesee Merchants Bank & Trust Co. v. Comm'r*, 752 F.2d 1128, 1132 (6th Cir. 1985). However, reading § 342(a)(4)'s "insanitary conditions" so as to encompass the failure to maintain adequate control measures does not render § 342(a)(2)(C)(ii) a nullity. That is, on the one hand, a dairy farm could cause a residue violation through the extralabel use of drugs, in violation of § 342(a)(2)(C)(ii), and yet maintain adequate treatment records in general. On the other hand, a dairy farm could keep inadequate treatment records, leading to a reasonable possibility that the edible tissues from its slaughtered animals may be rendered injurious to health, even if the USDA-FSIS has yet to identify a violative tissue residue. To be sure, given its limited resources, the USDA-FSIS is only able to screen approximately 3.4% of dairy cows offered for slaughter. (Supplemental Vaugh Decl. ¶ 20, Pls.' Supplemental Br. Ex. 3.) Thus, for any given animal containing an illegal residue, the likelihood that the USDA-FSIS will actually catch it is quite low. In the Court's view, the two provisions are better viewed as working together to protect against edible tissues containing unsafe levels of drug residue from being introduced into the nation's food supply. This same rationale applies to the Government's claims under § 331(k) and § 331(u).

which Defendants allege is time-barred, the FDA issued a Form-483 to Defendants after several other inspections, all of which notified Defendants that their treatment records were inadequate because they failed to routinely document dosage, route of administration, and withdrawal time. Yet, Defendants refused to bring their record-keeping into compliance.

In addition, while this case was stayed, the FDA once again inspected Defendants' Freeport and Fennville Farms, and discovered additional evidence relating to the inadequacy of Defendants' record-keeping. For example, Defendant Van Dam admitted during the Freeport inspection that Scenic View keeps no records whatsoever relating to its use of two highly potent and dangerous new animal drugs: Xylazine and Tolazine. (Second Vaughn Decl. ¶¶ 16-17, Pl.'s Supplemental Br. Ex. 3.) The drugs are used in connection with the treatment of left displaced abomasums ("LDA"), which is a condition in which "the abomasum (a compartment of the stomach in ruminants) becomes displaced to the left of the rumen (another stomach chamber) and upwards when its muscular wall loses tone and the stomach becomes filled with gas." (*Id.* ¶ 16.) Defendants estimate that 75% of cattle receiving an LDA treatment require the use of Xylazine (for sedation purposes) and, of those 75%, approximately 20-25% are also given Tolazine. (Manual Lopez Decl. ¶ 6, Defs.' Supplemental Resp. Ex. 8.) Defendants have a prescription to use these drugs, which sets forth a thirty-day withdrawal time for Tolazine and a four-day withdrawal time for Xylazine. (Defs.' Supplemental Br. Ex. 79-A. at SVD_000002837.) Because Defendants make no record when they use these drugs, however, they can only guess about whether or not these withdrawal times apply to any given cow that has received an LDA treatment. For example, Defendants sold a cow with ear tag number 148 to auction on February 22, 2011, even though its treatment records show that it had received an LDA treatment just one day before. (Pl.'s Supplemental Br. Ex. 4-A and 4-B.) Defendants submit the affidavit of the herdsman who performed the LDA procedure stating that he is "confident" that the cow was not given Xylazine or Tolazine in connection with the treatment.

(Manual Lopez Decl. ¶ 14, Defs.' Supplemental Resp. Ex. 8.) But the mere fact that the herdsman must guess raises serious concerns about the adequacy of Defendants' record-keeping.

Moreover, other treatment records obtained during the most recent inspections show that two cows at the Freeport Farm received Ampicillin treatment for eight days, when the label specifies a seven-day treatment period. (Campbell Decl. ¶ 8, Pls.' Supplement Br. Ex. 4; *Id.* Exs. E and F.) Defendants admit that their treatment protocol for Ampicillin was not followed, but assert that this "minor discrepancy" never posed any threat to the nation's food system because one of the cows was never sold and the other was held for 20 days after the last treatment of Ampicillin. (Defs.' Supplemental Resp. at 9; Van Dam Decl. ¶ 6, *Id.* Ex. 5.) Regardless of whether either of these cows actually entered the nation's food supply, this is yet another example of how Defendants' lack of adequate control measures constitutes insanitary conditions. Again, under § 342(a)(4), the Government need not prove that Defendants' food has actually become dangerous to health, only that it *may* have. The standard is a "reasonable possibility" of injury. *Blue Ribbon*, 179 F. Supp. 2d at 44.

In short, the Court finds that Defendants' bare assertion that their treatment records are adequate is insufficient to counter the evidence presented by the United States in this regard. Defendants' failure to maintain adequate controls for their administration of animal drugs constitutes insanitary conditions that create a reasonable possibility that edible tissues from their animals may be rendered injurious to human health. *See Rhody Dairy*, 2011 WL 2792454, at *2 (concluding that the defendant-dairy farm lacked adequate control measures where they failed to document dosages, route of administration, the person administering the drug, and withdrawal times, even though, as here, the defendant-dairy farm contended that such information was already part of its standard protocol). Therefore, Defendants food is also "adulterated" under 21 U.S.C. § 342(a)(4).

Accordingly, the Court finds that Defendants have delivered for introduction into interstate commerce food that is adulterated in violation of 21 U.S.C. § 331(a).

B. Whether Defendants have violated 21 U.S.C. § 331(k)

The United States next asserts that Defendants have violated § 331(k) by adulterating drugs while held for sale and after shipment in interstate commerce. That provision, in full, prohibits the following conduct:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. § 331(k). The purpose of this provision is "to safeguard the consumer from the time [drug] is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer." *H.B. Gregory,* 502 F.2d at 704 (citing *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92, 84 S. Ct. 559, 563 (1964)). To establish its claim, the United States must demonstrate that (1) the act in question occurred while the drug was held for sale and after having been shipped in interstate commerce; and (2) that the act resulted in the drug being adulterated. *United States v. Evers*, 643 F.2d 1043, 1047 (5th Cir. 1981). The Court will address the two in reverse order.

1. An Act that Results in the Drug Being Adulterated

Defendants' argue that § 331(k) only prohibits conduct related to the destruction of labeling. That is, Defendants argue that the "doing of any other acts" language is limited to acts of the same general nature as those specifically enumerated in the same section, i.e., alteration, mutilation, destruction, obliteration or removal of labels. As the Supreme Court made clear when faced with this argument in 1964, however, such an interpretation of the § 331(k) is contrary to both its text and legislative history. *Wiesenfeld Warehouse Co.*, 376 U.S. at 88-89, 84 S. Ct. at 562; *see also* H.R.

Rep. No. 80-807 (1947) (Pl.'s Reply Ex. 1 at 3) (explaining that the "any other act" language is purposefully broad in scope and "not limited by the preceding enumeration of forbidden acts with respect to labeling" and penalizes "among other acts resulting in adulteration . . . the act of holding articles under insanitary conditions whereby they may become contaminated with filth or rendered injurious to health").

The question then is whether Defendants have engaged in conduct that causes its drugs to be adulterated. Under 21 U.S.C. § 351(a)(5), a drug is deemed adulterated if "it is a new animal drug which is unsafe within the meaning of section 360b." Because, as discussed above, the Court finds that Defendants' extralabel use of new animal drugs results in the drugs being deemed unsafe under § 360b, those acts also result in the drugs being adulterated for purposes of § 331(k).

2. The Acts Occurred While those Drugs were "Held for Sale" and After Shipment in Interstate Commerce

The United States argues that the "held for sale" requirement is satisfied if the product can be shown to have been used for any purpose other than Defendants' personal consumption. Because Defendants hold drugs to administer to their animals, rather than for their own personal consumption, they hold drugs for sale within the meaning of the Act. Defendants argue that the "held for sale" element is not satisfied because (1) the first time their cows can be considered "held for sale" is after they have been shipped to auction, which is *after* Defendants have administered drugs, and (2) they do not "sell" drugs to their cows.

To begin, the question is not whether the offending conduct took place while Defendants' *cows* were held for sale, but while Defendants held the *drugs* for sale. The United States' claim here is that Defendants adulterated *drugs* while held for sale and after shipment in interstate commerce. In addition, "[i]t is well established that the terms 'while held for sale' as they appear in the Federal Food, Drug, and Cosmetic Act have been given by courts an expansive rather than technical

construction." *United States v. Articles of Animal Drug Containing Diethylstilbestrol*, 528 F. Supp. 202, 204 (D. Neb. 1981). In fact, courts have interpreted the term to cover bailees storing food in warehouses, *Wiesenfeld Warehouse Co.*, 376 U.S. at 92, 84 S. Ct. at 563-64; physicians holding drugs or medical devices for use in the treatment of patients, *Evers*, 643 F.2d at 1050 and *United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975); and bakery owners holding adulterated flour even though they planned to sell bread and rolls made from the flour rather than the flour itself, *United States v. Cassaro, Inc.*, 443 F.2d 153, 155 (1st Cir. 1971). Indeed, several Courts have agreed with the United States' interpretation that the "held for sale" language is satisfied if the item is used for any purpose other than personal consumption. *See, e.g.*, *Articles of Animal Drug Containing Diethylstilbestrol*, 528 F. Supp. at 205; *United States v. Articles of Device (Acuflex; Pro-Med)*, 426 F. Supp. 366, 368 n.3 (W.D. Penn. 1977); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1521 (E.D.N.Y. 1984).

Given these broad interpretation of § 331(k), as well as the FDCA in general, the Court finds that the drugs Defendants administer to their cattle are "held for sale" within the meaning of § 331(k). *See Rhody Dairy*, 2011 WL 2792454, at *3 (holding the same with regard to new animal drugs held on a diary farm). Defendants do not contest that they receive the drugs after shipment in interstate commerce. Therefore, the Court concludes that Defendants have violated § 331(k) by adulterating drugs while held for sale and after shipment in interstate commerce.

C. Whether Defendants have Violated § 331(u)

Section 331(u) prohibits "[t]he failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A)." 21 U.S.C. § 331(u). As discussed above, § 360b(a)(4)(A) authorizes the extralabel use of new animal drugs only where such use is (1) by written or oral order of a veterinarian in the context of a valid VCPR *and* (2) such use complies with the regulations establishing conditions for extralabel use, including 21 C.F.R. §

530.11(d)'s prohibition of any extralabel use that results in violative tissue residues. *See* 21 U.S.C. § 360(b)(a)(4)(A) and 21 C.F.R. § 530.11(d). Regardless of whether Defendants have met their burden with regard to the former, because their extralabel use results in violative tissue residues they have failed to comply with the latter. Accordingly, the Court finds that Defendants have failed to comply with 21 U.S.C. § 331(u).

In addition, the Court finds Defendants have not established that their extralabel use of new animal drugs is by order of a licensed veterinarian within the context of a valid VCPR. The regulations define a valid VCPR as one in which:

> (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or other caretaker) has agreed to follow the instructions of the veterinarian;
>
> (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
>
> (3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

21 C.F.R. 530.3(i).

Defendants assert that, in consultation with veterinarians, they have established protocols for treating certain ailments, which the farm managers and herdsmen use to diagnosis the animal, elect treatment options, and provide drug-specific information such as route of administration, dosage, and withdrawal times. (Defs.' Reply at 4; *Id.* Geerlings Affidavit Ex. 1 ¶¶ 4-7.) In addition, veterinarians visit the farms approximately once every two weeks and as necessary to address specific health issues. (*Id.* and Portell Decl. ¶ 7, *Id.* Ex. 2.) Defendants have submitted the affidavit of veterinarian, Dr. Dale McKenzie, affirming that "[i]n the past, [he has] consulted with

Scenic View's farm managers regarding treatment protocols." (*Id.* Ex. 3 ¶ 22.) Dr. McKenzie states that his relationship with Scenic View began in 2001, but also admits that was not available on a regular basis between September 2007 and April 2009. (*Id.* ¶ 7.)

The United States has submitted copies of Defendants' protocols, which were obtained during the most recent inspections of the Freeport and Fennville Farms. (*See* Pl.'s Supplemental Br. Ex. 4-D.) The United States alleges that the protocols are inadequate to support Defendants' extralabel use. Specifically, the United States points to 21 C.F.R. § 530.20(a)(2)(i), entitled "Conditions for permitted extralabel animal and human drug use in food-producing animals." That regulation provides that, before any extralabel use may be permitted, the veterinarian must "[m]ake a careful diagnosis and evaluation of the conditions for which the drug is to be used." 21 C.F.R. § 530.20(a)(2)(i). By virtue of this regulation, the United States alleges, veterinarians must be substantially involved in the diagnosis of the animals before extralabel use may permitted. The United States concedes this may be done through implementation of both diagnostic and treatment protocols along with regular follow-up to ensure that the protocols are being properly applied. Yet, Defendants' protocols contain no diagnostic criteria whatsoever. (Pl.'s Suppl. Br. in Support of Summ. J. Ex. 4-D.) Defendants assert that they are not required to maintain diagnostic protocols, only treatment protocols. That is, according to Defendants, it does not matter whether their herdsmen are misdiagnosing cows and are, therefore, ineffective with their medical treatments, but whether the appropriate withdrawal times are being followed when drugs are used.

The Court finds that the United States has the better side of the argument based upon the language of the regulations requiring the veterinarian's "careful diagnosis," 21 C.F.R. § 530.20(a)(2)(i), as well as other regulations such as 21 C.F.R. § 530.5(a)(6), which requires the veterinarian to keep records of the number of animals treated in an extralabel manner, which could not be done if the diagnosis are made by laypersons without sufficient involvement of the veterinarian.

D. Injunctive Relief

The United States asks the Court to enjoin Defendants' violations of § 331 pursuant to 21 U.S.C. § 332(a), which expressly authorizes such relief. Where, as here, Congress specifically authorizes the granting of injunctive relief, the Court need not consider the traditional equitable factors, such as irreparable harm, that apply to private litigants in equity. *See United States v. Szoka*, 260 F.3d 516, 523-34 (6th Cir. 2001). Instead, to be entitled to injunctive relief, "the government must show that defendants have violated the FDCA and that there is some reasonable likelihood that the violations may recur." *Blue Ribbon*, 179 F. Supp. 2d at 50; *Rhody*, 2011 WL 2792454, at *5 (same) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S. Ct. 894, 898 (1953)).

The Court finds that injunctive relief is warranted in this case. Defendants' violative conduct not only extends to all three farms, but has continued over several years despite repeated notices from the FDA that Defendants needed to bring their operation into compliance and how they could do so. *See United States v. Kasz Enters., Inc.*, 855 F. Supp. 534, 544 (D.R.I. 1994) (finding injunctive relief to be "particularly appropriate" in that the defendant's FDCA violations were "systematic and ongoing, notwithstanding repeated warnings by the FDA"); *Commodity Futures Trading Comm'n v. Hunt*, 591 F.2d 1211, 1220 (7th Cir. 1979) ("When the violation has been founded on systematic wrongdoing, rather than an isolated occurrence, a court should be more willing to enjoin future misconduct."). Despite Defendants' contention that injunctive relief is inappropriate because they no longer or rarely use the new animal drugs that caused the residue violations at issue here, the extent of Defendants' past violations gives rise to an inference that future violations are likely to occur. *See Blue Ribbon*, 179 F. Supp. 2d at 50 ("The probability of future violations may be inferred from past unlawful conduct."); *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 177 (1987) (same); *Commodity Futures*, 803 F.2d at 1251 (same). And finally, the Court rejects Defendants' contention that injunctive relief is inappropriate because,

although they may have violated the Act in the past, their record is still better than other farms and quite good when considering the size of Scenic View's overall operation. The FDCA does not provide for any sort of large-producer type exception and the Court declines the invitation to create one. *See United States v. Lazere*, 56 F. Supp. 730, 733 (N.D. Iowa 1944) (rejecting a defendant's argument that injunctive relief under the FDCA was inappropriate because he was doing the best he could to avoid insanitary conditions, explaining that the FDCA "does not provide that parties shall avoid doing such things if it is possible, it provides that it shall not be done at all").

All of that being said, however, the Court is concerned about the scope of the injunction submitted by the United States. The Court's experience as a lawyer and a judge is that injunctive orders often come with unintended consequences. It is not the Court's intent to put Scenic View out of business. This company has many cows to take care of, and we cannot always expect perfection. However, the nature of the products being sold by Scenic View, if insanitary for example, have the potential of creating disaster for individuals and even loss of confidence in the nation's food supply. In addition, the Court takes to heart the fact that individual defendants, to a large extent, are dependent upon Scenic View's record-keeping systems, something over which they probably have no great control. The Court would not want them to be deprived of their opportunity for work as herdsmen on other farms if they are not personally responsible for the wrongful conduct of Scenic View. The Court is also concerned about the length of the injunction. It seems to the undersigned that if the record-keeping is put into compliance as a system and by the individuals, then the problems will be largely solved. At that point, Scenic View could be placed on the same inspection routine, warnings, and penalties as other similarly farms. Therefore, the Court does not see the necessity of a permanent injunction. And, of course, the Court could be wrong in all of this.

In lieu of filing additional briefs regarding injunctive relief, the parties shall, within 28 days, submit a proposed agreed injunction. If the parties cannot agree upon the wording of an injunction,

the parties shall, instead of submitting the agreed upon injunction, each submit their own proposed injunction within the same 28 days. In that event, each party shall have an additional 7 days to file a brief setting forth objections to the other party's proposal and the rationale behind their own proposal.

Finally, without knowing the specific facts and background of injunctions entered by other district courts, this Court is not too impressed with the fact that such injunctions exist. For examples

- Is there any legal or factual rationale for the specific wording of the injunction?
- Was the injunctions the result of a settlement?
- How big were the farms?
- What were the problems?
- Could the problems have been remedied in another manner?
- Does the United States inspect these farms on a regular basis?

E. The United States' Motion to Strike

One day before it filed its motion for summary judgment, the United States filed a motion to strike the following affirmative defenses from Defendants' Amended Answer pursuant to Fed. R. Civ. P. 12(f): (1) the claims may be barred by an applicable statute of limitations; (2) the claims may be barred by the doctrine of laches, estoppel and/or waiver; (3) the allegations and relief sought fail since any conduct was that of others over which Defendants had no right of control; (4) the claims fail for failure to permit cure; and (5) the claims against the individuals in this matter fail because it was impossible or impracticable for those individuals to avoid those violations. In their reply to the motion to strike, Defendants agreed to withdraw the waiver, estoppel and failure to permit cure affirmative defenses. As to the remaining affirmative defenses, the Court notes that motions to strike affirmative defenses, although generally disfavored, are within the sound discretion of the Court. *Ameriwood Indus. Int'l Corp. v. Arthur Andersen & Co.*, 961 F. Supp. 1078, 1984

(W.D. Mich. 1997). "An affirmative defense is insufficient if, as a matter of law, the defense cannot succeed under any circumstances." *Id.*

1. Statute of Limitations

The United States alleges that its FDCA claims are not bound by a statute of limitations and thus, this defense cannot succeed under any circumstances. Defendants concede that the FDCA itself does not provide a statute of limitations, but assert that both of the 2002 residue violations are, nonetheless, barred by the general four-year statute of limitations set forth in 28 U.S.C. § 1658(a). Section 1658 provides that "[e]xcept as otherwise provided by law, a civil action arising under an Act of Congress enacted after the date of enactment of this section [December 1, 1990] may not be commenced later than 4 years after the cause of action accrues." 28 U.S.C. § 1658(a). The Supreme Court has interpreted § 1658 so as to apply to claims (1) arising under a federal statute enacted after December 1, 1990 or (2) "made possible" by a post-1990 amendment to a pre-existing statute. *Jones v R.R. Donnelley & Sons Co.*, 541 U.S. 369, 382, 124 S. Ct. 1836, 1845 (2004).

Congress amended the FDCA with the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA"), Pub. L. No. 103-396, 108 Stat. 4153 (October 22, 1994), with stated purpose of "clarify[ing] the application of the Act with respect to alternate uses of new animal drugs." AMDUCA added 21 U.S.C. § 331(u), one of the three FDCA provisions the United States alleges Defendants have violated, as well as 21 U.S.C. § 360b(a)(4), on which the United States also relies to support its claims. The Court need not determine as a matter of law, however, whether the United States' claims were "made possible" under AMDUCA because, as set forth above, even ignoring both of the 2002 residue violations, the Court finds that the United States is entitled to summary judgment as to all of its claims.

2. Laches

The United States argues that laches cannot be applied against it in a civil suit, such as this, to protect the public interest. *See Utah Power & Light Co.*, 243 U.S. 389, 409, 37 S. Ct. 387, 391

(1917) ("As a general rule, laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest."). Defendants raise no argument to the contrary. The Court concludes that the defense should be struck. *See Hatchett v. United States*, 330 F.3d 875, 887 (6th Cir. 2003) ("It is well established that the Government generally is exempt from the consequences of its laches."); *United States v. Angell*, 292 F.3d 333, 338 (2d Cir. 2002) ("[L]aches is not available against the federal government when it undertakes to enforce a public right or protect the public interest.").

3. Lack of Control

The United States asks the Court to strike Defendants' affirmative defense that the claims must fail because "any conduct was that of others over which Defendants had no control or right of control." (Aff. Def. 4.) Defendants assert that each farm manager is only responsible for the medical treatment of diary cattle on *his* farm; hence, it would be unfair to enjoin Mr. Lucas, for example, based upon violations that occurred at the Gowen or Freeport Farms. Because the Court has determined that FDCA violations occurred at all three farms, this argument is moot.

4. Impossibility

Finally, the United States asks the Court to strike Defendants' claim of impossibility, citing cases holding that impossibility is not a recognized defense to civil claims for injunctive relief under the FDCA. *See e.g.*, *United States v. Lazere*, 56 F. Supp. 730, 732 (N.D. Iowa 1944). Defendants respond that they are not arguing that they cannot avoid future violations based upon impossibility, but that, as to the August 11, 2009 sample at least, it was impossible to avoid the above-tolerance residue as Defendants complied with the drug's labeling and, yet, a violative residue level nonetheless resulted. Because the Court has ignored the 2009 sample for purposes of this motion, this argument is also moot.

Accordingly, the Court will deny in part and grant in part the United States' motion to strike. It is granted as to the defense of laches, but denied in all other respects.

CONCLUSION

For the foregoing reasons, the Court concludes that the United States' Motion for Summary Judgment (docket no. 22) should be granted and that the United States' Motion To Strike Defendants' Second, Third, Fourth, Fifth, and Sixth Affirmative Defenses should be granted in part and denied in part.

A separate Order will issue.

Dated: September 1, 2011

/s/ Gordon J. Quist
GORDON J. QUIST
UNITED STATES DISTRICT JUDGE