TESTIMONY OF HILARY WOOD
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BEFORE THE SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES:
REGARDING THE SAFEGUARD AMERICAN FOOD EXPORTS ACT OF 2019
January 27, 2020

I. QUALIFICATIONS OF FRONT RANGE EQUINE RESCUE

Front Range Equine Rescue (FRER) is a Colorado-based nonprofit group incorporated under Section 501(c)(3) of the Internal Revenue Code. FRER is actively involved in the rescue, rehabilitation and adoption to good homes of domestic and wild horses found at auctions and destined for slaughter; and in educational efforts regarding the health and safety dangers of horse slaughter.[1] Since 1997, FRER has assisted thousands of horses through its rescue and educational programs. While some of FRER's horses are surrendered by their owners or received after being abandoned, many are rescued from livestock auctions; others are purchased at feed lots before they are sent to slaughter.

For over a decade, FRER has been involved in an objective, science- and fact-based analysis of all relevant issues surrounding the discussions of horse slaughter in the public discourse. For example, FRER surveyed horse owners, equine-related business, and equine veterinarians around the country in order to compile a list of commonly-used drugs administered to American horses.[2] In connection with this list, FRER obtained sworn statements from many veterinarians and individuals involved in the equine industry, that most of the drugs on the list of drugs were given to the majority of American horses. The indisputable conclusion from FRER's analysis of drug administration to American horses is that it would be illegal, and threaten human

[1] For the purposes of this testimony, "slaughter" of horses refers solely to the slaughter of horses for human consumption.

[2] See attached Exhibit A.

health, to eat the meat of almost every American horse that goes to slaughter, because of the dangers of ingesting their flesh.

In addition to its rescue efforts, and as part of its analysis of all aspects affecting the slaughter of American horses, FRER has engaged in an examination of the laws, legal principles, and specifically the jurisdiction of federal agencies over horse slaughter. As part of that analysis, FRER representatives have been engaged in discussions with both the Food and Drug Administration and the U.S. Department of Agriculture and its Food Safety and Inspection Service.

FRER's work in this area has also included analyses of the environmental dangers of horse slaughter operations, as well as the economic analysis of the viability of horse slaughter operations in America.

II. THE FDA REGULARLY EXERCISES ITS AUTHORITY OVER FOOD ANIMALS

The value of the SAFE Act's prohibitions is validated directly by the Food and Drug Administration ("FDA"), which has asserted its legal authority in this area, and which has made it clear that the use of unapproved substances in horses means that those horses cannot be slaughtered for human consumption. That is, the FDA already considers horses who have received unapproved substances to be prohibited from use for human consumption – because of the dangers inherent in eating their meat. When dealing specifically with a dealer of horses who was selling horses treated with such substances, FDA has confirmed that "sending treated horses to slaughter for human consumption is illegal."[3] The SAFE Act will codify that agency practice and make clear that Congress desires to prevent the distribution of potentially dangerous horse meat.

FDA, throughout its history, has confirmed its jurisdiction over live animals who will be slaughtered and turned into food. The FDA has long concluded, as memorialized in hundreds of official, publicly-available warning letters, that food derived from animals who lack complete

[3] U.S. Food and Drug Administration Establishment Inspection Report and Warning Letter, Ronald Andio, DBA Patron Farms, LLC, 4/03/2012 - 4/30/2012, attached hereto as Exhibit B.

treatment records may have been rendered injurious to health, and is, therefore, adulterated under the FDCA.[4] And the evidence FRER has obtained for years remains undisputed -- that Americans do not raise their horses to become food and do not maintain complete treatment records for them. Consequently, horse meat from virtually all American horses is adulterated; the FDA is one of the agencies responsible for ensuring that adulterated or unsafe meat, and the animals whose flesh will be turned into that meat, not be placed in the stream of commerce.

The FDA routinely issues warning letters to producers and sellers of adulterated meat, based on both the presence of violative drug residues[5] and "insanitary" conditions for live animals found on the property of producers. The FDA has issued warning letters based on insanitary conditions at least as far back as 1996, the earliest date for which warning letters are available on the FDA's website[6], up to the present day. In 2012 and 2013 alone, the FDA issued over 130 warning letters for violations of the FDCA based on insanitary conditions.[7] FDA maintains a page on its website with these reports, which run up through just a few months ago.[8]

Most of the warning letters based on insanitary conditions cite the producers of food animals (cows and horses) – the individual or entity that raises the animal to become food – for procedures with respect to the live animals on the producer's property. In the majority of these

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[4] 21 U.S.C. § 342(a)(4) ("A food shall be deemed to be 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. . . .").

[5] 21 U.S.C. 342(a)(2)(C)(ii) ("A food shall be deemed to be adulterated . . . if it is or if it bears or contains . . . a new animal drug (or conversion product thereof) that is unsafe [as defined by the FDCA and related regulations]. . . .").

[6] *See, e.g.*, U.S. Food and Drug Administration Warning Letter, Bottasso Dairy 12/27/1996, No. 29-53315, *available at* http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/1996/UCM065184.pdf (finding insanitary conditions based on lack of system to track medication status of animals, assure animals have been withheld from slaughter for appropriate time to deplete drug residues, assure drugs are used consistent with labeling, and determine quantities of drugs are accounted for).

[7] All FDA warning letters are available on the FDA's website at the following link: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm (last visited Jan. 24, 2020). The Warning Letters cited in this Testimony are simply examples of the hundreds of times the FDA has confirmed its statutory and regulatory authority over live animals who may one day become meat.

[8] *Id.*

warning letters, the FDA cites the producer's "fail[ure] to maintain complete treatment records," which amounts to "hold[ing] animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply[,]"[9] as a basis for concluding that food from those animals is adulterated. Other warning letters issued to producers based on insanitary conditions cite their "fail[ure] to systematically review treatment records prior to offering an animal for slaughter for human food to assure that drugs have been used only as directed and that appropriate withhold times have been observed" as a basis for concluding that meat from those animals is adulterated.[10]

In other words, FDA, exercising its jurisdiction over live animals intended to be turned into meat, found the meat would be unsafe and adulterated simply because of the failure to maintain complete treatment records.[11] The FDA asserts that the lack of complete medical records creates too great of a risk that banned and other dangerous substances would enter the food supply. Because there are incomplete treatment records for virtually every single American

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[9] *See, e.g.*, U.S. Food and Drug Administration Warning Letter, Three L Farm 12/19/13, No. NYK-2014-14, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm379652.htm.

[10] *See, e.g.*, U.S. Food and Drug Administration Warning Letter, Van Erk Dairy LLC 12/3/13, No. CIN-14-412782-05, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm377803.htm. *See also* U.S. Food and Drug Administration Warning Letter, Bernick's Registered Holsteins 10/1/12, No. MIN 13-01, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323204.htm (citing adulteration based on insanitary conditions for failure "to have an effective system to control administration of drug treatments to your animals and to ensure that treatments are recorded by your employee"); U.S. Food and Drug Administration Warning Letter, Marcellina Dairy 12/26/12, No. DEN-13-5-WL, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm334764.htm ("You failed to maintain and review complete and accurate treatment records for medicated animals that are sold for food."); U.S. Food and Drug Administration Warning Letter, Meerland Dairy LLC 11/27/12, No. CIN-13-375558-04, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm336397.htm (citing failure "to adequately segregate treated animals to prevent them from being sold for slaughter for food"); U.S. Food and Drug Administration Warning Letter, Head Farms 11/19/13, No. NYK-2014-7, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm375679.htm ("Your treatment records lack the indication for use, route administered, dosage frequency, duration of treatment, and the drug withdrawal time for meat.").

[11] Christ S. King 4/11/12 Warning Letter (bob veal calf), Exh. C; Brouillette Farm, Inc. Warning Letter 6/11/12, Exh. D (cow); John Malcore Livestock LLC 6/27/12 Warning Letter, Exh. E (steer).

horse who goes to slaughter, the FDA's ruling means that *all* American horse meat is illegal and adulterated. The SAFE Act ensures that this dangerous product will not reach the public, in alignment with FDA's primary purpose. The FDCA prohibits not only the "introduction" (sale) of adulterated food into interstate commerce but also its "delivery for introduction."[12] Therefore, in addition to producers of adulterated meat, the FDA has authority to penalize other individuals and entities throughout the supply chain who deal with live animals, including dealers, veterinarians, and slaughterhouses, for violating the FDCA.[13] For example, the FDA cites dealers of food animals for failing to implement a system to trace animals to their producers, determine from the producers what drugs the animals have received and when they were administered, and withhold the animals from slaughter in order to "deplete potentially hazardous" drug residues.[14]

III. THE FOOD AND DRUG ADMINISTRATION HAS JURISDICTION OVER HORSES BEING TRANSPORTED FOR SLAUGHTER[15]

Congress enacted the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ *301 et seq*. (the "FDCA") in order to guarantee the safety of food to the consuming public, and created the

[12] 21 U.S.C. § 331(a).

[13] *See id.*; *see also* FDA Compliance Program Guidance Manual, Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods at 21-22, 28, *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113433.pdf.

[14] *See, e.g.*, U.S. Food and Drug Administration Warning Letter, Himmelspach, William W. 12/4/13, No. SEA 14-02, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm378035.htm; U.S. Food and Drug Administration Warning Letter, Ronald Andio, DBA Patron Farms, LLC 7/9/12, No. CIN-12-312058-26, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm313462.htm.

[15] While horse slaughter is currently prohibited by virtue of limitations in the federal budget, American horses are still potentially subject to slaughter in America, should the budget allocations change. Additionally, while horses cannot be slaughtered in America, most states do not prohibit the consumption of horse meat, so that the import of horse meat into America is possible. And that meat may actually be from American horses, whose meat, as established above, is both unsafe, adulterated, and potentially dangerous for consumers.

FDA to fulfill this purpose.[16] When harmful substances are present in foods, the FDA must enact rules and regulations that provide procedures to determine which foods contain harmful substances or are otherwise unsafe.[17] Among other responsibilities, the FDA must approve all food additives.[18] If these substances cannot be safely used, then the FDA must prohibit their presence in food or remove the offending products from the marketplace.[19]

The FDA also must identify drugs that are prohibited for use in animals that will be slaughtered for meat. For example, 21 C.F.R. §§ 520.23-520.264 list dosage limits for drugs administered to animals, and many of the drugs listed can *never* be used in animals intended for human consumption. *See, e.g.*, 21 C.F.R. § 520.1720A-E (prohibiting the use of phenylbutazone tablets and boluses, granules, paste, gel, and powder in animals slaughtered for food). Many of the animal drugs regulated by the FDA may not be administered to animals slaughtered for human consumption; if they are given, the animal cannot be used for meat. *See, e.g.*, *id.* And many of these drugs are commonly given to horses. *See id.*; Exhibit A.

A. Application to Horse Meat

"Adulterated" foods are unsafe and cannot be sold to the public.[20] The FDCA establishes the standard for adulteration and the basis upon which a finding of adulteration can be made.[21] Food is adulterated if, among other reasons, it bears or contains "any food additive that is unsafe" or "any new animal drug (or conversion product thereof) that is unsafe" or "if it is otherwise unfit for food. . . ."[22] Food additives are substances, excluding new animal drugs

[16] 21 U.S.C. § 393 (2006).

[17] 21 U.S.C. § 342.

[18] *See id.*; 21 U.S.C. § 348; *see also* 21 C.F.R § 570.38 (explaining the process for determining whether a substance is a food additive).

[19] 21 U.S.C. §§ 331(a)-(c), § 348. The statutory scheme covers the specific issues raised in the SAFE Act. *See*, *e.g.*, 21 U.S.C. §§ 331, 348, 360b.

[20] 21 U.S.C. §§ 331, 342.

[21] 21 U.S.C. § 342; *see also* 21 U.S.C. § 348 (establishing the process for regulating food additives); 21 C.F.R. § 570.38 (establishing the process for regulating food additives).

[22] 21 U.S.C. § 342(a)(2)(C)-(a)(3); *see also* § 348 (food additives); § 360b (new animal drugs).

among other categories, which are intended or reasonably expected to become a component or otherwise affect the characteristics of any food, including any substance intended for use in producing, processing, or treating the food.[23] New animal drugs are drugs intended for use for animals other than human beings.[24] The FDA has jurisdiction over the safety of all food sold to the public, including horse meat.[25]

Horse meat that contains an additive or comes from a horse that was treated with a new animal drug is presumed unsafe and its sale is prohibited unless the FDA has approved the additive or new animal drug. If horse meat contains an additive, the FDCA automatically deems it adulterated and unsafe unless there is in effect a regulation prescribing the conditions under which the additive may be safely used and the additive is used in conformity with the regulation.[26] Similarly, if horse meat contains a new animal drug, it is automatically deemed adulterated and unsafe as a matter of law unless there is in effect an approved application for use of the drug and the use conforms to the approved application.[27]

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[23] 21 U.S.C. § 321(s).

[24] 21 U.S.C. § 321(v).

[25] 21 U.S.C. § 679 (declaring that the FDA has the full authority conferred by the FDCA to regulate food, notwithstanding the Meat Inspection Act's conferral of authority over meat inspection to the USDA and FSIS); FDA Directive 565.100, FDA Jurisdiction Over Meat and Poultry Products (U.S.D.A. 2005), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074588.htm (explaining that food additives used in meat are subject to both FDA and USDA jurisdiction); FSIS Factsheet, Additives in Meat and Poultry Products (2008), *available at* http://www.fsis.usda.gov/Factsheets/Additives_in_Meat_&_Poultry_Products/index.asp (explaining that the FSIS and USDA share responsibility for the safety of food additives used in meat); FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, pp. 49, 50 (U.S.D.A. 2005), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113433.pdf (prescribing guidelines for FDA inspection of food animals).

[26] 21 U.S.C. § 348(a)(2). Other exceptions exist for additives "intended solely for investigational use by qualified experts" and additives that are "food contact substances." 21 U.S.C. § 348(a)(1), (3).

[27] 21 U.S.C. § 360(b)(1)(a). Other exceptions exist for conditionally approved applications, which are available only for "a minor use or a minor species" 21 U.S.C. § 360ccc; 21 U.S.C. § 360b(a)(B)-(C). Horses are not "minor species." *See* 21 U.S.C. § 321(oo).

B. Screening of animals for exposure to banned substances

The FDA, along with the FSIS, is responsible for inspecting meat to protect consumers from harmful residues.[28] FDA jurisdiction extends not only to meat but also to food-producing animals that will become meat. For example, in 1995, a court held that the FDA had the authority under the FDCA to inspect live hogs.[29] Specifically, the FDA conducts investigations of potentially harmful residues reported by the FSIS to determine the parties responsible for the tissue residue violation and for introducing the adulterated food into interstate commerce.[30] According to the FDA, most violations involving illegal drug residues result from animal producers' use of drugs for unapproved purposes, as well as failure to comply with drug withdrawal times and other label warnings.[31]

With most of the drugs listed on Exhibit A, there is no "withdrawal time" at all and the label clearly indicates that the use of those drugs are absolutely prohibited for animals who will be slaughtered. Thus, once an animal has been given those drugs at any time during its life, the law prohibits its processing into meat. Given the FDA's mandate to protect the public from potentially dangerous food products, this total ban must be because of the FDA's determination that sufficient risk exists any time those drugs are administered.

Consequently, the FDA focuses on obtaining evidence of "poor husbandry practices" of live animals, requiring inspectors to describe in their inspection report "**at least**" the following: all drugs on the premises, other drug-containing products that could have been used, where and how the drugs are stored, who administers medication, identification systems and quarantine practices, medication records (if they exist), and how the producer determines that withdrawal

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[28] FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, p. 6 (U.S.D.A. 2005).

[29] *United States v. Tuente Livestock*, 888 F. Supp. 1416, 1423 (S.D. Ohio 1995). *See also* 21 U.S.C. § 321(f)(1), (3) (defining "food" to include "articles used for food or drink for man" and "articles used for components of any such article"); *Otis McAllister & Co. v. U. S.*, 194 F.2d 386, 387 (5th Cir. 1952) (holding that unprocessed coffee beans are food).

[30] FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, p. 6 (U.S.D.A. 2005).

[31] *Id.*

times are met.[32] The FDA may also investigate other individuals involved with animals who may be suspected to potentially be slaughtered, including "a hauler, buyer, dealer, auction barn, veterinarian, or slaughter house."[33]

In conducting on-site investigations of potentially harmful residues in live animals intended for human consumption, the FDA focuses on repeat violators—those who sell a slaughtered animal whose carcass is found to contain a violative concentration of a drug within a year of a first violation.[34] As resources allow, the FDA also conducts on-site inspections for first-time violators in response to FSIS reports of violative tissue residues evidencing (1) the presence of particularly dangerous drugs in food-animals, (2) the intentional misuse of a drug, or (3) a complete disregard for the withdrawal period (the "criteria").[35]

If the FDA is aware of an initial residue violation but the violation does not satisfy the above criteria, "then resource constraints do not allow for an FDA investigation."[36] The FSIS reports violative residues on a "single-animal basis" for the FDA to investigate. As FSIS analysis of tissue samples may be limited to identification of a single drug, food animals that (1) contain violative residues, (2) which meet the above criteria, and (3) are not tested by the FSIS may not be reported to the FDA.[37]

Enforcement measures taken against violators of the FDCA range from no FDA action to criminal prosecution. When the FSIS obtains evidence of an initial violation that does not meet the criteria, the FDA takes no action.[38] When the initial violation fits the criteria, the FSIS sends a Violation Notification Letter, which serves as an FDA warning to the producer who is shipping

[32] *Id.* at 19-20 (emphasis in original).

[33] *Id.* at 6.

[34] *Id.* at 10.

[35] *Id.*

[36] *Id.* (emphasis in original).

[37] *See id.* at 18.

[38] *Id.* at 10, 28.

animals with violative residues.[39] Similarly, the FSIS and FDA issue Warning Letters, such as those previously discussed in this testimony, to repeat violators.[40] While the possibility of further enforcement, injunctions, or penalties, exist, the agency's workload limits its ability to address all violators. Meanwhile, potentially dangerous meat, that imperils consumer health, may be placed into the stream of commerce.

The SAFE Act removes this large gap between violations and enforcement, and the lack of detection based on detailed on-farm evaluations, and ensures the elimination of dangerous products being dumped into the marketplace, international and domestic. Given the unknowns around the dangers of horse meat, this law presents the closest thing to an assurance that the public will be protected from this threat.

IV. THE SPECIAL TREATMENT OF HORSES BEFORE SLAUGHTER MEANS THEIR MEAT IS ADULTERATED AND UNSAFE FOR HUMAN CONSUMPTION

Traditional food animals, such as cows, pigs, and chickens, are raised in a controlled, heavily regulated environment, and their owners, handlers, and all involved individuals know that they were born to be turned into meat. In stark contrast to that controlled environment, American horses are raised for a variety of purposes, *none* of which is to become meat. While producers of traditional food animals comply with food safety rules, owners of horses do not even consider food safety rules. And whereas producers of traditional food animals maintain complete treatment records, as a good husbandry practice and to avoid producing adulterated food, owners of horses do not maintain these records. Therefore, virtually all American horses lack complete treatment records, are held "under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply," and are therefore prohibited from being processed into meat, and deemed "adulterated".[41]

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[39] *Id.* at 28.

[40] *Id.* at 29.

[41] *See, e.g.*, U.S. Food and Drug Administration Warning Letter, Three L Farm 12/19/13, No. NYK-2014-14.

And even for those horse owners who do keep records, if those records were accessible, they would show that a laundry list of medications and treatments prohibited for use in food animals were regularly given to these horses. The veterinarians with whom FRER has spoken do keep records, and they have confirmed that virtually all American horses have been administered substances banned for use in food animal production.

The conditions in which horses are raised exemplify the concerns the FDA has had about situations where drug histories are unmonitored. American horses are raised for numerous purposes— for sports and competitions, to be companions, sources of recreation, and tools of labor or to roam free in open fields, and are treated more like dogs and cats than cows, pigs, and chickens. When horses are injured, ill, or otherwise in need of medical attention or treatment, their owners administer a variety of substances to keep them healthy, strong, and free of pests. Because American horse owners do not consider their horses to be potential food, they administer these substances without regard to their effects on someone who later consumes their horses' flesh.[42] Moreover, horse owners are unlikely to keep complete treatment records for their horses and unlikely to convey treatment histories to future owners of their horses. Because of these facts, according to the FDA, horses are raised and held under conditions that are "so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply."[43] If highly regulated food animals (like cows and pigs) whose owners lack complete treatment records for their animals (but may have had some treatment records) are adulterated, then horses whose owners lack virtually any treatment records are, without a doubt, also adulterated.[44]

The FDA confirmed this interpretation of the statute when it cited the former owner of a bay thoroughbred gelding horse for holding the horse "under conditions that [we]re so

[42] *See* Exhibit A.

[43] *See* 21 U.S.C. § 342(a)(4).

[44] *See* Christ S. King 4/11/12 Warning Letter, Exh. C; Brouillette Farm, Inc. 6/11/12 Warning Letter, Exh. D; John Malcore Livestock LLC 6/27/12 Warning Letter, Exh. E.

inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply."[45] Like the cases above, the FDA found that meat from horses held by this farm was adulterated because (1) the horses were held under inadequate conditions, which included the owner's failure to obtain the horse's medication status from the prior owner and (2) tissue from the horse tested positive for phenylbutazone and clenbuterol, each of which is banned for administration to horses intended for human consumption.[46] To avoid future violations, the FDA suggested that the owner, Ronald Andio, implement a system to determine whether horses he obtains have been medicated, when they have been medicated, and with which drugs they have been medicated.[47]

Given Andio's known conduct, these suggestions are likely futile: in order to sell horses, he lied when he said a horse he sold "had not been administered any drugs or vaccines or treated with any substances not permitted for use in food processing equine in the last 180 days prior to your purchase of this animal."[48] This type of fraud is widespread, and Andio's actions are unsurprising. Although federal inspectors may lack the resources to investigate the conditions under which all other American horses are raised and held, these horses still exist. They are held in similar conditions. And their meat is similarly adulterated.

The FDA has stated and is certainly correct that producers of food animals can avoid selling animals and meat with violative residues by obtaining knowledge of each animal's complete treatment history. Similarly, producers can avoid selling animals that are adulterated from the conditions in which they are raised by obtaining complete treatment histories for their animals. But as explained above, this collection of information is impossible with American horses so that they, due to the purposes for which they are raised and the conditions in which

[45] Patron Farms, LLC 7/9/12 Inspection Report and Warning Letter, Exh. B.

[46] *Id.*

[47] *Id.*; *see also* McGovern Farm, Inc., Department of Health and Human Services Warning Letter 6/28/12 CMS # 318279, attached as Exh. F (recommending similar measures to avoid the future sale of adulterated animals).

[48] Patron Farms, LLC 7/9/12 Warning Letter, Exh. B.

they are raised, are adulterated under 21 U.S.C. § 342(a)(4). And the SAFE Act will prevent the sale of dangerous meat, and the slaughter of animals whose meat would be potentially harmful to consumers.

In light of these facts, horse meat from American horses is unsafe and subject to condemnation by the FDA, pursuant to the applicable statutes. The SAFE Act's protections will relieve FDA of the large burden of monitoring horse dealers in the inevitable act of buying and selling horses for slaughter without obtaining complete treatment records and slaughter facilities in the inevitable act of purchasing horses for slaughter without obtaining complete treatment records.

V. CURRENT PROCEDURES DO NOT PROTECT THE PUBLIC

The SAFE Act is the only guarantee that dangerous horse meat, in violation of FDA and FSIS requirements, will not enter the market. FSIS has a Compliance Guide for Residue Prevention, that is intended to detect dangerous residues of commonly used drugs in food animals.[49]

The Compliance Guide recognizes that without information regarding the origins of animals sent for food production, federal agencies, slaughterhouses, and the public cannot possibly obtain the information necessary to protect the food supply. These entities and individuals rely heavily on self-regulating, easily identifiable producers who can be monitored and re-evaluated on an ongoing basis. This does not and cannot happen with horses who go to slaughter, because (as explained above, and is undisputed) they come from a constantly revolving set of unknown and effectively unidentifiable individual horse owners who are not involved in commercial production and who almost certainly have no understanding of the drug restrictions for food animals. Nor do these individuals have any reason to believe they should be concerned with the drugs their horses are given. And because these original owners of horses that end up as food are unknown, the agencies cannot accurately evaluate the drugs given to

[49] *See* https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/residue-guidance (last visited Jan. 25, 2020).

them in order to compile a reasonable list of drugs for which to test. This difference between commercial animals and horses destroys the most important link in the FDA's ability to monitor the improper administration of drugs to horses used for meat, because FDA has no ability to ascertain the identities of current owners of horses who will become meat in the future. These problems, which are emphasized by the issues raised in FSIS' Compliance Guide, counsel strongly for Congressional intervention with the SAFE Act, which will remove all of these unknowns.

Undisputed evidence establishes that horses are given an extensive array of drugs that are completely prohibited for use in horses who will become meat. Once the horses are given those drugs, they should never be shipped to slaughter. The federal government's National Residue Program cannot address this problem, because it only looks for detectable remaining amounts of drugs – and only a fraction of the drugs identified as being regularly given to American horses.[50] However, if a drug is completely banned, neither the testing protocols nor any kind of residue-related test will be sufficient to keep those horses out of the market.

Nor can FDA rely on the representations of the final sellers of horses for slaughter, because they virtually never have any connection with or knowledge of the original owners, or the lives of the horses before they are sold for slaughter. Such individuals and companies, often known as "killer buyers," purchase the horses at auctions just prior to selling them to slaughter. There have been multiple reports of falsified documentation of the required forms (including the conduct cited in FDA's Warning Letters). Even if the forms are accurately filled out, however, the information cannot be complete, because in almost every circumstance the seller has no facts regarding the original owner of the horses.

Without the SAFE Act, the threat to consumers remains significant. With the SAFE Act, the problem (outside of violations of the law) will be almost solved.

[50] Additionally, testing is only done on select organs at select times on horses, so that it can easily miss drug residues in other tissues.

VI. THE SAFE ACT CREATES NO NEGATIVE CONSEQUENCES

Proponents of horse slaughter often argue that slaughterhouses offer the only humane alternative for old, sick, disabled, or "unwanted" horses.[51] However, the USDA has confirmed the findings of a study concluding that more than ninety-two per cent of horses sent to slaughter are healthy.[52] Proponents also argue that horse slaughter is a more humane end for "unwanted" horses than abandonment and starvation. This position ignores proven alternatives to horse slaughter that control the horse population and allow horses to pass their final days peacefully.

Anticipating the day when legislation like the SAFE Act might be passed, a series of safety nets for horses have been, and continue to be, developed in preparation for a time when there is a ban on both (1) domestic slaughter of American horses for human consumption, and (2) the transport of American horses to other countries for slaughter.

All of these programs are viable potential contributors to what can and will be a safe and successful integration of horses into settings where they will be provided with optimal welfare, and where they will not negatively impact the public or the environment.

The solutions outlined below demonstrate there are no "unwanted" horses and the only way to truly test these existing programs is to enact the bans.[53]

1. Because the USDA has determined that 92.3 per cent of horses going to slaughter are in good condition, they could live productive lives under basic care if they were not sent to

[51] The Horse Slaughter Arguments, https://www.habitatforhorses.org/the-horse-slaughter-arguments/ (last visited April 19, 2019).

[52] Horses for Life Foundation, https://www.horsesforlife.org/why-ban-horse-slaughter.html (last visited January 27, 2020).

[53] FRER has also been a leader for well over two decades in showing exactly how successful such alternative to slaughter can be – FRER's Stop the Backyard Breeder program was a model for many others who then took on gelding reimbursement programs; the Trails End program showed how a partial reimbursement for humane euthanasia when needed could help owners do the right/responsible thing for end of life decisions (and other groups have provided similar types of assistance); its training evaluation work inspired many who were not doing the same and horses have become more adoptable to qualified homes when rescues offer this. And FRER's educational programs that teach responsible horse care and ownership have impacted thousands as have similar programs offered by rescue and non-rescue horse groups alike.

slaughter. They could be sold, donated, or rehomed. And the same study showed that 6 per cent of the horses going to slaughter were in poor enough condition that humane euthanasia – not slaughter -- was the proper approach with them. In fact, there is no demonstrable correlations between malnutrition or starving and horses going to slaughter. Horse slaughter has always been an option, but there have also always been starving horses, and some owners might even keep starving horses out of fear of them going to slaughter. Various independent rescue organizations, as well as coalitions of rescues, have already formed responsible plans in anticipation of a slaughter ban. These groups envision, and are prepared to institute the programs discussed below:

a) Sanctuary/rescue for horses in need (both short and long-term plans)

b) Fostering horses, and providing care, shelter, nutrition and safety for them through adoption services

c) Rehabilitation and training,

d) Direct adoptions to qualified lifetime caregivers (whether private or rescue groups)

e) Education on rehoming horses safely

f) Where absolutely necessary because of irremediable suffering, humane euthanasia and burial support.

There are many private groups and individuals around the country outside of non-profit rescues and sanctuaries who provide similar services to keep horses from slaughter.

2. The equine industry, which is valued in the tens of billions of dollars annually, has the means and motivation to help fund programs supporting any horses in need. The industry also has the ability to send the message of reducing overbreeding, and thus reducing the number of horses in need of support.

By encouraging its constituents to keep horses or safely rehome them, the industry will increase revenues that would otherwise be lost by horses who go to slaughter. That is, the money lost on care of healthy horses is a significant lost financial opportunity for the industry, as long as an infinite slaughter pipeline is open.

3. Horse owners, given the attention that horse slaughter has been given in the past several years, have become more educated when re-homing their horses and are seeking humane solutions as opposed to auctions and slaughter. The following options are in place and being utilized and their use can be increased once the bans are in place:

a) Sales to evaluated, private owners, who may be located through a broad network in any community, including other horse enthusiasts, veterinarians, farriers, boarding facilities, feed and tack stores, trail-riding groups, breed associations, 4-H and Pony Clubs, trainers and friends. Commonly-used websites like Petfinder.com, Equine.com, Dreamhorse.com and TheHorse.com (as well as reliable Facebook and other social media outlets are already in existence and available for this type of use).

b) Lease of horses to another horse owner/enthusiast. Leases like this are not uncommon and typically involve the lessee paying a portion of the horse's monthly board expenses in exchange for spending time with the horse. Leasing is a great way to relieve financial strain without giving up the horse.

c) Donations. More than 500 organizations across the country accept donated horses for use in various programs that benefit communities—including therapeutic riding centers for inner city kids, mentally disabled individuals, or mental trauma victims, police department mounted units, summer youth camps, prison programs, veteran therapy programs, university riding programs, or similar equine assisted therapy programs.

d) There are nearly 700 U.S. horse rescues and sanctuaries that take in horses with the intention of adopting them out to new homes or providing a lifetime of care. The Homes for Horses Coalition is one of many groups of horse rescues and professionals actively working to provide care and homes to horses in need and promote responsible horse ownership. There are also specialized facilities dealing only with horses that are rescued in equine abuse cases, and that serve to rehabilitate and then adopt out those horses.

e) The Humane Society of the United States formed the Responsible Horse Breeders Council, composed of breeders that will take back any horse they have bred who becomes

homeless or is at risk for slaughter. Some breeds also maintain databases for owners who want to be contacted if a horse they've owned or bred needs a home. Many individuals and groups who rescue horses have contacted former owners/breeders when tracing a horse's tattoo for example. Those horses very often are placed back to those former owners.

f) Gelding clinics and grants for subsidized gelding are also offered by a number of groups. Gelding clinics and grants have clearly shown that providing free or low-cost gelding of stud colts and stallions works. Many rescues across the country have offered such programs at one time or the other.

g) Very few horses may require it, but humane euthanasia is a ready option. The cost of humane euthanasia and carcass removal is equal to or less than one month's care in most parts of the country and is a part of responsible horse ownership. Companies throughout the country offer equine crematory services and rendering/carcass disposal services that will remove deceased horses from an owner's property. Euthanasia clinics and grants have given horse owner's incentive to do "the right thing" when humane euthanasia is appropriate. Providing free or low-cost euthanasia keeps horses from being dumped into the slaughter pipeline or suffering additional abuse.

4. The horse slaughter industry is fueled in part by certain practices that could be reduced through education, intervention, and substitution:

a) Reduce the use of horses in industries that discard "used" horses, such as horseracing and show industries, with responsible breeder incentives.

b) Improve adoptions through increased gentling/training programs for the BLM's wild horse program to ensure that adopted horses do not end up going to slaughter;

c) Provide horse owners with rehoming tips on how to safely place a horse with a new owner.

d) Strengthen and support equine welfare laws giving animal control officers better education on horse abuse issues.

When slaughter of American horses ends, it will create many job openings while those horses are being absorbed into people's lives. Thus, the humane solutions will also promote more attention to responsible horse care and welfare. Here are some examples of job opportunities that will expand or open up with the influx of horses:

a) Trainers for riding, show horses;

b) Boarding facilities;

c) Equine veterinarians and increase in equine veterinary research and curricula;

d) Gentling and training of wild horses;

e) Equine assisted therapy, including therapeutic riding, Wounded Warrior programs and programs for autistic youth.[54] And horseback riding is a way for injured individuals to regain motor skills, build and strengthen muscles, and improve balance. Because of their demeanors, horses also can become trusting, steady partners;

f) Equine summer camp programs;

g) Equine centers for trail riding, training, year-round riding and boarding;

h) Farriers and other equine professionals;

i) A variety of community-based programs that utilize horses including guest ranches and eco-sanctuaries (focused on wild horses); and

j) Educators with respect to horse care, horse responsibilities, and horse welfare.

Finally, many states and municipalities operate horse rescues, rehoming organizations, and sanctuaries. These facilities offer short and long-term stays for horses in need. They often operate as non-profits and may contain an educational component whereby the public is able to interact with the horses and learn about the different animals and their unique stories.[55]

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[54] *See, e.g.*, Paige Cerulli, *Horses for Heroes: How Horses Help Wounded Warriors*, https://www.wideopenpets.com/horses-for-heroes-how-horses-help-wounded-warriors/ (last visited April 19, 2019).

[55] *See, e.g.* Equine Advocates Rescue & Sanctuary is a Field of Dreams for Horses, https://www.equineadvocates.org/sanctuary/ (last visited April 19, 2019).

Taking a more expansive view of maintaining healthy and manageable wild horse populations, horse contraception is also the obvious, humane, accepted key to addressing wild horse overpopulation concerns.[56] Horse contraception can be administered by injecting a mare with a contraceptive vaccine that triggers her immune system to reject fertilization.[57] Scientists are also working on longer-term solutions.[58]

VII. HORSE SLAUGHTER IS A CRUEL ACT, AND CANNOT BE ACCOMPLISHED HUMANELY

Ignoring every bit of evidence that has been presented to the federal agencies, the American people, and the courts over the last 15 years, horse slaughter advocates have developed a false rhetoric, claiming that slaughter in a slaughterhouse, for an American horse, is "humane euthanasia." Nothing could be further from the truth, as detailed below. It should be easy for this Committee to see the false foundation for any argument that slaughter is a feasible alternative to any problem, and to also immediately appreciate that any group claiming that horse slaughter is "humane" are urging Congress to endorse some of the cruelest acts that can be committed to horses. The arguments of any one that slaughter is humane is proof positive that they have no concern at all for animal welfare or animal cruelty.

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[56] *See*, *e.g.*, Rutberg, A. *et al.*, "Contraceptive efficacy of priming and boosting doses of controlled-release PZP in wild horses", *Wildlife Research* (April 27, 2017), at http://dx.doi.org/10.1071/WR16123 (accessed Jan. 27, 2020); Turner, J.W. Jr. *et al.*, "Porcine zona pellucida (PZP) immunocontraception of wild horses (Equus caballus) in Nevada: a 10 year study", *Reprod Suppl.* 2002;60:177-86 at https://www.ncbi.nlm.nih.gov/pubmed/12220157 (accessed Jan. 27, 2020); Killian, G. *et al.*, "Long-Term Efficacy of Three Contraceptive Approaches for Population Control of Wild Horses", *Proc. 22nd Vertebr. Pest Conf.* (R. M. Timm and J. M. O'Brien, Eds.) (Univ. of Calif., Davis. 2006), 67-71 ("Three years of study on mustang mares treated with immunocontraceptive vaccines and an IUD suggest that they are safe and effective.") at https://www.aphis.usda.gov/wildlife_damage/nwrc/publications/06pubs/miller062.pdf (accessed Jan. 27, 2020).

[57] *Id.*

[58] *Id.*

A. Commercial Horse Slaughter Cannot Be Accomplished Without Horrendous Treatment of the Horses.

From their acquisition at livestock auctions and other sources to the slaughterhouse, horses destined for human consumption are subject to mistreatment and cruelty. Their transportation from the livestock auction to the slaughter facility is often long and grueling, because they are cramped in trucks that do not accommodate their physical requirements and unique temperaments.[59] At slaughter facilities, horses are often subject to appalling abuse before and during their slaughter. Some horses are even slaughtered while still conscious. Each aspect of this treatment increases the possibility that their meat is inappropriate for consumption under a number of FDCA and FDA regulations.

Poor conditions during the transportation of horses result in slaughter facilities filled with frightened, food- and water-deprived, sick and injured horses. Federal law requires transported horses to be off-loaded for food and water every twenty-eight hours, but horses are often transported continuously for over thirty hours.[60] Some horses arrive at slaughterhouses with their backs broken or other serious injuries.[61] And the lack of proper food and water in already weakened horses can lead to further injuries and death during extended transport. According to a 1999 study of sixty horses transported for slaughter, one animal had to be removed from the transport trailer after twelve hours of transport, dying two days later.[62] The fifty-nine arriving horses sustained a total of eighty-one injuries.[63]

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[59] *See* C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999) ("Horses tend to travel longer distances to slaughter than other livestock, because there is a limited number of equine slaughterhouses.") *available at* http://jas.fass.org/content/77/11/2925.

[60] T.H. Friend, *A Review of Recent Research on the Transportation of Horses*, J. ANIM. SCI. 79:E32-E40 (2001) ("Continuous transport of slaughter horses for 30 hours is common, and some trips last 36 hours or longer.") *available at* http://jas.fass.org/content/79/E-Suppl/E32.

[61] *See* 151 CONG. REC. H4247 (horses are "transported in excess of 1,000 miles in the most inhumane conditions perceived").

[62] C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999) *supra* Note 59.

[63] *Id*.

The mistreatment continues at the end of the transport phase. Many horses are not given hay or water in overnight holding pens.[64] Many of the horses in holding pens are "downers" – animals too sick or injured to stand up and walk, some of whom may be dragged or pushed into the pen.[65] Some of these ill, diseased, and injured animals are unfit for food under the FDCA and should not be slaughtered for human consumption.[66]

Because they frighten more easily than cows, horses are unsuited to be processed at a slaughter plant. As horses are more sensitive to odors than cows, the scent of blood that necessarily exists in the slaughter facility exacerbates their fright. Some horses slip and fall in the stun box. As a result of their keen perception and subsequent fear, horses are more likely to injure themselves trying to escape the slaughter plant.

Under federal law, horses must be rendered unconscious prior to slaughter,[67] but because of their natural agility and flight instinct, many horses are improperly stunned and remain conscious when they are hoisted to have their throats cut.[68] According to a recent report, almost half of the horses going to slaughter had to be stunned more than once.[69] The desire to slaughter as many horses as quickly as possible inevitably contributes to the inaccuracy and cruelty of the slaughtering process.

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[64] *See Pasture to Plate: A Report by the Canadian Horse Defence Coalition on Equine Slaughter*, p. 5 (July 2011), *available at* http://canadianhorsedefencecoalition.files.wordpress.com/2011/12/pasture-to-plate.pdf ("*Pasture to Plate*") (accessed Jan. 27, 2020).

[65] *See* Gary D. Anderson & Don R. Lee, *Salmonella in Horses: A Source of Contamination of Horse Meat in a Packing Plant Under Federal Inspection*, 31 Applied and Environmental Microbiology 661 (1975) ("[S]laughter horses have usually been trucked for extensive distances. Many times they are injured or unhealthy, housed poorly, fed and watered improperly, and sometimes held for long times, as much as a week, in dirty confined pens at the slaughter plant.") *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC291172/.

[66] *See* 21 U.S.C. § 342(a)(5) ("A food shall be deemed adulterated if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.").

[67] *See* Humane Methods of Slaughter Act, 7 U.S.C. § 1902(a).

[68] *See* 151 CONG. REC. S10,220 (daily ed. June 8, 2005) ("horses sometimes remain conscious throughout the slaughter process").

[69] *Pasture to Plate*, *supra* Note 64, at 4.

The USDA has documented appalling cruelty at slaughter plants, including gruesome descriptions and photographs of the mistreatment inherent in horse slaughter.[70] The examples cited in this section, which are only those that were discovered and occurred in a small sampling of plants, speak volumes for the absolute terror that slaughterhouses are for horses, and the danger to them and to the public in processing them for meat.

B. Horse Slaughter Leads to Other Public Health Problems.

Not only does horse slaughter pose danger to those who consume the meat and inflict cruelty upon the horses, but horse slaughter facilities also harm the environment, overwhelm local governments, diminish quality of life, and threaten public health. There has been a growing and overwhelming public sentiment that horse slaughter for human consumption should be ended, and to prohibit related activities which have detrimental impacts on the health, safety, environment, and welfare of humans living in proximity to horse slaughter plants. In connection with the last of the Texas horse slaughter facilities, local residents were fed up with "the extreme disregard" shown by the companies that owned the facilities towards the citizens in the communities in which they were located.[71]

Every one of the last three American horse slaughterhouses[72] wreaked environmental havoc by dumping blood, entrails, urine, feces, heads, and hooves into local systems,

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[70] *See*, *e.g.*, USDA, Food Safety & Inspection Service, Noncompliance Record Noncompliance Record Nos. 00 18-2005-8243 (Apr. 4, 2005) ("Nine horses were overcrowded in the alleyway causing undue excitement which was further exacerbated when two more employees from the kill floor began yelling and hitting these horses causing the one in the end of the line to slip and fall."); 0013-2006-8243 (Oct. 9, 2006) ("horse was down" . . . "in the upper middle compartment of a pot bellied trailer" and "[o]ther horses within the compartment were trampling the downed horse"); 0006-2007-8243 (Jan. 24, 2007).

[71] Jane Allin, *When Horse Slaughter Comes to Town*, p. 3 (Mar. 2011), *available at* http://www.horsefund.org/resources/When_Horse_Slaughter_Comes_to_Town_Updated_March_2011.pdf ("*When Slaughter Comes to Town*"); *Life In A Slaughter Town: Kaufman, Texas*, pp. 4, 10, *available at* http://galleries.forbes.com/gallery/Life_in_a_Slaughter_Town%3A_Kaufman,_Texas#image=03PB6Ww0dV53u&view=filmstrip ("*Life In A Slaughter Town*").

[72] The last three horse slaughterhouses in America, which closed in 2007, were in DeKalb, Illinois (Cavel), Kaufman, Texas (Dallas Crown), and Fort Worth, Texas (Beltex).

overwhelming waste water infrastructures and leading to numerous environmental violations.[73] According to the former mayor of Kaufman, Texas, where the Dallas Crown plant was located, the problems were epidemic, including (1) a pervasive and horrible odor in the vicinity of the plant; (2) multiple violations of the plant's industrial waste permit; (3) denial of access to city inspectors for waste water testing; (4) transportation of slaughter refuse in leaking containers without covers, leading to horse parts falling into the road; (5) blood flowing in nearby ditches; and (6) bones and blood in front of the facility and in neighboring yards, attracting dogs and other animals.[74] Dallas Crown also left a 600-gallon container filled with blood and horse parts outside its facility, generating a stench and attracting flies and vermin.[75] In 2003, the container spilled outside the plant, emptying blood into a ditch, and, from there, into the ground.[76]

In addition to all of the other benefits the SAFE Act will provide – here and abroad – it will also prevent further environmental pollution caused by a dangerous and cruel practice that provides no benefits at all.

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[73] *See When Slaughter Comes to Town*, *supra* Note 71, at 3. *See also* Eckhoff, Vickery, "*Horse Slaughterhouse Investigation Sounds Food Safety and Cruelty Alarms*," *Forbes*, Dec. 6, 2011, *available at* http://www.forbes.com/sites/vickeryeckhoff/2011/12/06/horse-slaughterhouse-investigation-sounds-food-safety-and-cruelty-alarms/.

[74] Former Mayor Paula Bacon, Open Letter to State Legislatures Considering Pro-Horse Slaughter Resolutions (Feb. 2009), *available at* http://www.animallawcoalition.com/horse-slaughter/article/686 ("Paula Bacon Letter"); *see also* Eckhoff, Vickery, "Texas Mayor Paula Bacon Kicks Some Horse Slaughter Tail," *Forbes*, Jan. 10, 2012, *available at* www.forbes.com/sites/vickeryeckhoff/2012/01/10/texas-mayor-paula-bacon-kicks-some-tail/ (accessed Jan. 15, 2012).

[75] *Life In A Slaughter Town, supra* 71, at 9.

[76] *See id.*

Exhibit A

BANNED AND DANGEROUS SUBSTANCES COMMONLY GIVEN TO HORSES SENT TO SLAUGHTER

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
1.	**Acepromazine**	Anti-anxiety/tranquilizer Previously used in humans, but use discontinued	*See also* Citak A, Soysal DD, Uçsel R, Karaböcüoglu M, Uzel N., *Seizures associated with poisoning in children: tricyclic antidepressant intoxication*, PEDIATR INT. 48(6):582-585 (2006) (Two children suffered cardiac arrest from intoxication from acepromazine and died.).
2.	**Acetazolamide**	Diuretic for horses. Used to treat epilepsy and benign intracranial hypertension in children and adults.	Acetazolamide (sulfonamide) induces metabolic alkalosis and is contraindicated in patients with hyperchloremic acidosis, angle-closure glaucoma, kidney and liver disease, and in patients with Addison's disease. Fatalities have occurred (rare) due to Stevens-Johnson syndrome (diffuse rash that sloughs), toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitizations may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of hypersensitivity or other serious reactions occur, discontinue use of this drug. Caution is advised for patients receiving concomitant high-dose aspirin and Acetazolamide, as anorexia, tachypnea, lethargy, coma and death have been reported. http://www.drugs.com/pro/acetazolamide.html
3.	**Acriflavine**	Blue-Kote (topical ointment, antiseptic, protective wound dressing) http://www.drugs.com/vet/dr-naylor-blu-kote.html Not for use on animals intended for food. http://www.horsesuppliesplus.com/antiseptics.html	Acriflavine is an ingredient found in Blue-Kote, which is itself labeled "not for use on animals intended for food." The dangers for humans who ingest this substance are unknown.
4.	**Altrenogest**	Regu-Mate (altrenogest/oral progestin) (growth promoter) 21 CFR § 520.48: - "Do not use in horses intended for human consumption." "Do Not Use In Horses Intended For Human Consumption." http://www.drugs.com/vet/regu-mate-solution.html	Active harmful ingredients (residue): Progestin. Progestin is used in the mini-pill to prevent contraception so progestin could result in an aborted fetus in a pregnant woman. Progestin along with estrogens are pro-thrombotic meaning that they cause deep blood clots, including venous thrombosis and cerebral thrombosis. http://www.nejm.org/doi/full/10.1056/NEJM200105173442007 Combined with estrogens, progestin increases the risk of breast cancer and cardiovascular problems.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			http://www.whi.org/findings/ht/eplusp_3yr.php Increased stroke risk. http://www.whi.org/findings/ht/ealone_stroke.php HUMAN WARNINGS Skin contact must be avoided as Regu-mate® (altrenogest) Solution 0.22% is readily absorbed through unbroken skin. Protective gloves must be worn by all persons handling this product. Pregnant women or women who suspect they are pregnant should not handle Regu-mate® (altrenogest) Solution 0.22%. Women of child bearing age should exercise extreme caution when handling this product. Accidental absorption could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water. http://www.drugs.com/vet/regu-mate-solution.html
5.	**Aluminum hydroxide**	Strepvax II (component in equine vaccine) Used in humans for gastrointestinal problems, ulcers. http://www.drugs.com/vet/strepvax-ii.html	WARNINGS/PRECAUTIONS May cause constipation. Caution with renal failure; prolonged use may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of dialysis encephalopathy and osteomalacia syndromes. Caution with normophosphatemic patients; prolonged use may result in hypophosphatemia if phosphate intake is inadequate. ADVERSE REACTIONS Constipation, dialysis osteomalacia, hypophosphatemia. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1544 Can cause constipation, confusion, loss of appetite, and muscle weakness. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001056/
6.	**Amikacin**	Antibiotic 21 CFR § 529.56 - "Do not use in horses intended for human consumption"	Antibiotics are potentially dangerous to humans who either have allergies or sensitivities to them. Additionally, the use of antibiotics in food animals, and the subsequent ingestion by humans of those animals, has the potential to create antibiotic resistance in humans, which can cause significant problems for humans upon subsequent illness.
7.	**Amoxicillin**	Antibiotic	Infections and Infestations: Mucocutaneous candidiasis. Gastrointestinal: Nausea, vomiting, diarrhea, black hairy tongue, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Hypersensitivity Reactions: Anaphylaxis Serum sickness-like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, hypersensitivity vasculitis and urticaria have been reported. Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted, but the significance of this finding is unknown. Hepatic dysfunction including cholestatic

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			jaundice, hepatic cholestasis and acute cytolytic hepatitis have been reported. Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness have been reported rarely. Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been rarely reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases. http://www.drugs.com/sfx/amoxicillin-side-effects.html
8.	**Ampicillin sodium**	Antibiotic for treatment of respiratory tract infections (pneumonia and strangles) and skin and soft tissue infections (abscesses and wounds), when caused by susceptible organisms. 21 CFR § 522.90c - "Do not use in horses intended for human consumption."	COMMON SIDE EFFECTS Inflammation and redness of the tongue; irritation of mouth or throat; mild diarrhea; nausea; second infection; vomiting. SEVERE SIDE EFFECTS Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); bloody stools; severe diarrhea; stomach pain/cramps; vaginal irritation or discharge. http://www.drugs.com/sfx/ampicillin-side-effects.html See also side effects for ampicillin injection: •upset stomach, diarrhea, vomiting, mild skin rash More severe: •severe skin rash, itching, hives, difficulty breathing or swallowing, wheezing, unusual bleeding or bruising, headache, dizziness, seizures, sore mouth or throat http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601133.html Material Safety Data Sheet ("MSDS") for ampicillin sodium salt: Toxic Effects on Humans: Hazardous in case of ingestion, of inhalation. http://www.sciencelab.com/msds.php?msdsId=9925610
9.	**Aspirin**	Aspir-paste http://www.drsfostersmith.com/1/1/10913-aspir-paste-by-oral-x.html Reduces joint, muscle, and lameness pain.	WARNINGS/PRECAUTIONS Avoid in children or teenagers for chickenpox or flu symptoms; Reye's syndrome may occur. May cause severe allergic reaction (hives, facial swelling, asthma, shock) and stomach bleeding. Avoid in asthma, stomach problems that persist or recur, ulcers, or bleeding problems. ADVERSE REACTIONS Allergic reaction, hives, facial swelling, asthma, shock. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=195

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			Can cause excessive bleeding in those taking warfarin; http://stroke.ahajournals.org/content/40/5/1944.full Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); black or bloody stools; confusion; diarrhea; dizziness; drowsiness; hearing loss; ringing in the ears; severe or persistent stomach pain; unusual bruising; vomiting. http://www.drugs.com/sfx/aspirin-side-effects.html
10.	**Avermectin A1a, 5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)-**	Farnam Ivercare (dewormer) http://msds.farnam.com/m001116.htm Ivercare Paste is labeled "Do not use in horses intended for food purposes." http://www.drugs.com/vet/ivercare-paste-1-87.html	A hazardous component of the Farnam Ivercare dewormer product. http://msds.farnam.com/m001116.htm Links to the toxicological literature here: http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=14145#x50 http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+toxline:@term+@rn+65195-51-9+@OR+@all
11.	**Benzyl alcohol**	Equipoise Equipoise Injectable http://www.drugs.com/vet/equipoise-injectable-can.html	ADVERSE REACTIONS Pruritis, erythema, pyoderma, ocular irritation. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Benzyl+alcohol
12.	**Boldenone undecylenate**	Equipoise injectable 21 CFR § 522.204 - "Do not administer to horses intended for human consumption." Equipoise injectable (boldenone undecylenate injection) is recommended as an aid for treating debilitated horses when an improvement in weight, haircoat or general physical condition is desired. http://www.drugs.com/vet/equipoise-injectable-can.html	Boldenone undecylenate is a steroid ingredient in Equipose (for horses). It is not indicated for use in humans but appears to have off-label uses as a bodybuilding steroid. Known side effects consist of: nausea, leukopenia, symptoms resembling a peptic ulcer, acne, excitation (commonly referred to as roid rage), sleeplessness, chills, vomiting, diarrhea, hypertension, prolonged blood clotting time, increase in libido. Females had reported menstrual irregularities, post-menopausal bleeding, increased sex drive, swelling of the breasts, hoarseness or deepening of the voice, and enlargement of the clitoris. Men had reported acne, gynocomastia, and increased aggression. http://www.anabolicsmall.com/equipoise.html Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
13.	**Butorphanol**	For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.	COMMMON SIDE EFFECTS Dizziness; drowsiness; dry mouth; light-headedness; nasal irritation; nausea; runny nose; sore throat; stuffy nose; trouble sleeping; unpleasant taste; vomiting.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		21 CFR § 522.246 - "Do not use in horses intended for human consumption."	SEVERE SIDE EFFECTS Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blurred vision; burning, numbness, or tingling; change in the amount of urine produced; chest pain; confusion; ear pain; fainting; fast, slow, or irregular heartbeat; flushing; hallucinations; mental or mood changes (agitation, anxiety, depression); restlessness; ringing in the ears; seizures; severe or persistent dizziness, drowsiness, or light-headedness; severe or persistent headache or trouble sleeping; shortness of breath; slow, shallow, or difficult breathing; tremors; unusual swelling. http://www.drugs.com/sfx/butorphanol-side-effects.html
14.	**Butoxy Polypropylene Glycol**	Farnam Bronco Gold (fly spray) http://msds.farnam.com/m001650.htm Farnam Endure Fly Spray http://msds.farnam.com/m000080.htm Farnam Endure Sweat-Resistant http://msds.farnam.com/m001046.htm Farnam Tri-Tec 14 http://msds.farnam.com/m000490.htm Farnam Wipe (fly control	In 2002, a woman in Oklahoma was hospitalized after using Pyranha fly spray on horses. Her face was distorted, and her words slurred. She reportedly had leg problems, tremors, memory problems. The medical toxicologist's conclusion was that the patient, a professional horse trainer, developed a complex neurotoxic movement disorder following sensitization to a product that contained 33% /butoxypolypropylene glycol/ BPG. Adverse reactions and side effects of ingestion are unknown.
15.	**Carbadox**	Antibiotic used for growth promotion purposes (generic)	Not permitted for use in food-producing animals in Australia (http://www.apvma.gov.au/registration/not_permitted.php) Or in Canada, or the European Union. (http://www.hc-sc.gc.ca/dhp-mps/vet/faq/faq_mrl-lmr-eng.php#a6) Not for human use. http://www.drugs.com/pro/mecadox.html Chronic health effects, including cancer, mutagenic effect, changes in lung function. Accidental ingestion may cause serious harm or be fatal. MSDS SUPPLIER http://datasheets.scbt.com/sc-204668.pdf
16.	**Ceftiofur Crystalline Free Acid**	Excede (antibiotic) For the treatment of lower respiratory tract infections in horses. 21 CFR § 522.313a	Intended for use in horses which are non-food animals. Because this indication for this new animal drug is not intended for use in food producing animals, there is no data pertaining to drug residues in food (i.e., human food safety). WARNINGS

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		- "Do not use in horses intended for human consumption." http://www.excede.com/Excede.aspx?country=US&drug=XT&sec=100&species=EQ	Not for use in humans. For use in animals only. Consult a physician in case of accidental human exposure. Do not use in horses intended for human consumption. http://animalhealth.pfizer.com/sites/pahweb/US/EN/Products/Documents/Combined%20Full%20PI%20(8_5x11)%20-%20EXEQ0110014.pdf
17.	**Ceftiofur Sodium**	Ceftiflex powder For treatment of respiratory infections in horses. 21 CFR § 522.313c - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/ceftiflex.html	Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposure to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth, and clothing. http://www.drugs.com/vet/ceftiflex.html
18.	**Chloramphenicol**	Chlor-500 Chlor-1000 Chloramphenicol 1% Ointment "Not for use in animals that are raised for food production. Must not be used in meat, egg, or milk-producing animals. 21 CFR § 520.390a; 520.390c; 522.390; 524.390. http://www.drugs.com/vet/chlor-500-can.html http://www.drugs.com/vet/chlor-1000-can.html http://www.drugs.com/cdi/chloramphenicol.html http://www.drugs.com/vet/chloramphenicol-1-ophthalmic-ointment-can.html	Some medicines may interact with Chloramphenicol: •Anticoagulants (e.g., warfarin) because side effects, including risk of bleeding, may be increased. •Hydantoins (e.g., phenytoin) or sulfonylureas (e.g., glyburide) because the actions and side effects of these medicines may be increased. •Medicines that may decrease your bone marrow (e.g., cancer chemotherapy) because the risk of serious side effects, such as low blood platelet levels and low white blood cell counts, may be increased. Chloramphenicol has caused severe and sometimes fatal blood problems (e.g., anemia, low blood platelets, low white blood cell counts). Leukemia has also been reported after use of Chloramphenicol. Blood problems have occurred after both short-term and long-term use of Chloramphenicol. Do not use chloramphenicol if safer, effective medicines can be used. http://www.drugs.com/cdi/chloramphenicol.html Prohibited for use in food-producing animals in the European Union.
19.	**Chloroform**	Anesthetic	The IARC (International Agency for Research on Cancer) classifies chloroform as possibly carcinogenic to humans. http://monographs.iarc.fr/ENG/Monographs/vol73/mono73.pdf
20.	**Cimetidine**	Prevention and prophylaxis of	ADVERSE REACTIONS

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		gastrointestinal irritation and ulcers	Diarrhea, headache, dizziness, somnolence, reversible confusional states, reversible impotence, increased serum transaminases, rash, gynecomastia, blood dyscrasias. WARNINGS/PRECAUTIONS Reversible confusional states reported, especially in severely ill patients. Increased risk of developing confusional states with advancing age (≥50 yrs), renal and/or hepatic impairment. Risk of hyperinfection of strongyloidiasis in immunocompromised patients. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1440
21.	**Clenbuterol**	Beta-agonists used for growth promotion purposes Prohibited from any use in any food-producing animal. http://www.farad.org/eldu/prohibit.asp	Not approved for human use. http://www.deadiversion.usdoj.gov/drugs_concern/clenbuterol.htm
22.	**Copper Naphthenate**	Kopertox Treatment of thrush. 21 CFR § 524.463 - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/kopertox.html http://www.sciencelab.com/msds.php?msdsId=9923553	Toxic to central nervous system, blood, and kidneys. May produce vomiting, headache, shock, jaundice, kidney damage, nervous system damage, liver damage.
23.	**Crude Liver Extract**	Liver 7 injection http://www.drugs.com/vet/liver-7-injection.html	FDA cautions against the use by humans of any animal organ extract. http://www.healthline.com/natstandardcontent/liver-extract
24.	**Cupric Sulfate**	Proudsoff (ointment for control and removal of proud flesh) Not for use on animals intended for food. http://www.drugs.com/vet/proudsoff.html	Harmful if swallowed. May cause gastrointestinal tract irritation with nausea, vomiting, diarrhea, metallic taste, burning sensation in the stomach or epigastrum, abdominal pain, and possible gastrointestinal tract bleeding. May affect metabolism, liver (liver damage, jaundice), blood, urinary system (kidney damage, hematuria, hemoglobinuria, albuminuria), behavior/nervous systems (somnolence, tremor, psychosis, muscle weakness, coma), cardiovascular system (lowering of blood pressure, dysrhythmia).
25.	**Cypermethrin**	Farnam Endure Sweat-Resistant (fly spray http://msds.farnam.com/m000080.ht	"Pyrethroid ingestion gives rise within minutes to a sore throat, nausea, vomiting and abdominal pain. There may be mouth ulceration, increased secretions and/or dysphagia. Systemic effects occur 4-48 hours after exposure. Dizziness, headache and fatigue are common, and palpitations, chest tightness and blurred vision less

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		m	frequent. Coma and convulsions are the principal life-threatening features. Most patients recover within 6 days. . . ." S.M. Bradberry *et al.*, *Poisoning Due to Pyrethroids*, Toxicol Rev. 24(2):93-106 (2005) (quoting abstract). Potential organ damage. http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/cypermet-ext.html
26.	**Dapsone**	Dermatitis skin problems in horses. Acne treatment in humans.	Adverse effects include agranulocytosis, aplastic anemia, leucopenia, thrombocytopenia, hemolysis, and other blood dyscrasias have been reported after treatment. It may cause significant reduction in leukocytes, platelets, or hemopoiesis. Caution with glucose-6-phosphoate dehydrogenase (G6PD) deficiency, methemoglobin reductase deficiency, or hemoglobin M, and those who are exposed to other agents or conditions such as infection or diabetic ketosis capable of producing hemolysis. Toxic hepatitis and cholestatic jaundice reported after use. Liver function tests must be monitored if there are any abnormalities. Can cause muscle weakness. Peripheral neuropathy, nausea and vomiting, abdominal pain, and pancreatitis may occur. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Dapsone
27.	**Deodorized Kerosene**	Component in Farnam Repel Xp (fly spray). http://msds.farnam.com/m000031.htm	Ingestion may cause aspiration hazard, nausea, fatigue, pulmonary edema, central nervous systemepression, convulsions and loss of consciousness. http://www.sciencestuff.com/msds/C1955.html
28.	**Deslorelin**	Used for inducing ovulation within 48 hours in ovulating mares. 21 CFR § 522.533 - "Do not use in horses intended for human consumption."	Deslorelin stops the production of certain sex hormones in horses, and has never been approved for use on humans. If it was approved, it would be for a small targeted complement of the human population with identified diseases related to the production of too much of certain sex hormones, but could otherwise produce unwanted hormonal effects and responses.
29.	**Detomidine Hydrochloride**	Dormosedan Pain relief and sedative for minor surgery. Also used in humans for sedation in intensive care and surgery conditions. 21 CFR § 522.536; 529.536 - Not for use in horses intended for food." - "Do not use in horses intended for human consumption." http://www.dormosedan.com/	Can cause hypotension, hypertension, bradycardia, dry mouth, respiratory depression, tachycardia, nausea and vomiting, atrial fibrillation, fever, hyperglycemia, anemia, hypovolemia, hypoxia, atelectasis. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2848

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
30.	**Dexamethasone**	Dexium injection Anti-inflammatory drug. 21 CFR § 522.540 - (d)(4) (sterile aqueous solution). "Not for use in horses intended for food." - (e)(5) (sterile aqueous solution). "Not for use in horses intended for food." 21 CFR § 522.542 - "Not for use in horses intended for food." http://www.drugs.com/vet/dexium-injection.html Steroid for humans.	Adverse reactions include fluid/electrolyte disturbances, muscle weakness, osteoporosis, peptic ulcer, pancreatitis, ulcerative esophagitis, impaired wound healing, headache, psychic disturbances, growth suppression (pediatrics), glaucoma, hyperglycemia, weight gain, nausea, malaise. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=798 Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
31.	**Dichloromethane**	Furall Antibacterial http://msds.farnam.com/m000394.htm	If eaten, this drug can cause gastrointestinal irritation with nausea, vomiting and diarrhea. May cause kidney damage. May cause central nervous system depression, characterized by excitement, followed by headache, dizziness, drowsiness, and nausea. Advanced stages may cause collapse, unconsciousness, coma and possible death due to respiratory failure. May cause carboxyhemoglobinemia. Dichloromethane has been treated as a carcinogen in California since 1988 and it may also have adverse reproductive effects. http://www.sciencelab.com/msds.php?msdsId=9948&code=SLM2677
32.	**Diclazuril**	Clinacox Antiprotozoal Used to treat infections leading to myoencephalitis. 21 CFR § 520.606 - "Do not use in horses intended for human consumption."	Administered to some AIDS patients, but effects in humans largely unknown.
33.	**Diclofenac Sodium**	Surpass (topical) Arthritis treatment in humans and horses. 21 CFR § 524.590 - "Do not use for horses intended for human consumption." http://www.drugs.com/vet/surpass-	May cause hypertension, edema, or heart failure. Some individuals with prior gastrointestinal disease may be hypersensitive to the drug's effects. Potential kidney failure and danger for patients with renal disease. May cause anaphylactic reactions; may harm fetus in utero. Maycause liver problems. May cause anemia and affect blood. May cause abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea and vomiting, gastrointestinal ulcers, renal function abnormalities, anemia, dizziness, edema, elevated liver enzymes. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Diclofenac+Sodium

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		topical-cream.html	
34.	**Diflubenzuron**	Equitrol II Fly control http://www.drugs.com/vet/equitrol-ii-feed-thru-fly-control.html	May cause anemia.
35.	**Dimethylsulfoxide**	Topical application for sprains, soreness; may also be injected or combined with other drugs for administration. Limited treatment use in humans -- used as a topical application to reduce acute swelling due to trauma. 21 CFR § 524.660a - Dimethyl sulfoxide solution - "Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food." 21 CFR § 524.660b - Dimethyl sulfoxide gel - "Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food." http://www.webmd.com/vitamins-supplements/ingredientmono-874-DMSO%20(DIMETHYLSULFOXIDE).aspx?activeIngredientId=874&activeIngredientName=DMSO%20(DIMETHYLSULFOXIDE)	May cause headache, dizziness, drowsiness, nausea, vomiting, diarrhea, constipation, breathing problems, vision problems, blood problems, and allergic reactions. Also may harm the liver and kidneys. http://www.webmd.com/vitamins-supplements/ingredientmono-874-DMSO%20(DIMETHYLSULFOXIDE).aspx?activeIngredientId=874&activeIngredientName=DMSO%20(DIMETHYLSULFOXIDE) MSDS available here: http://www.sciencelab.com/msds.php?msdsId=9927347
36.	**Dimetridazole** (generic)	Bactericidal Antibacterial	Withdrawn from European market because of dangers of gastrointestinal problems, potential for cancer. http://www.bioagrimix.com/msds/36/36280/3628007.pdf
37.	**Di-n-propyl isocinchomeronate**	Fly control products:	High toxicity – classified as a carcinogenic Pesticide Action Network (PAN) "Bad Actor".[1]

[1] "PAN Bad Actor pesticides" belong to a "most toxic" set of pesticides identified by the Pesticide Action Network and Californians for Pesticide Reform (CPR). These pesticides are at least one of the following: known or probable carcinogens, as designated by the International Agency for Research on Cancer (IARC), U.S. EPA, U.S. National Toxicology Program, and the state of California's Proposition 65 list; reproductive or developmental toxicants, as designated by the state of

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Flysect Super-7 repellent spray Flysect Super-C Mosquito Halt http://www.drugs.com/vet/flysect-super-7.html http://msds.farnam.com/m000811.htm http://www.drugs.com/vet/flysect-super-c.html http://www.drugs.com/vet/mosquito-halt-repellent-spray-for-horses.html	www.pesticideinfo.org/Detail_Chemical.jsp?Rec_id=PC2798
38.	**Dipropyl isocinchomeronate**	Farnam Roll-On Repellent (fly spray) http://msds.farnam.com/m000018.htm	High toxicity – PAN Bad Actor. Carcinogenic. www.pesticideinfo.org/Detail_Chemical.jsp?Rec_id=PC2798
39.	**Domperidone**	In horses, used for treatment of toxicity from fescue grass that affects pregnancies. In humans, used to increase bowel contractions and combat nausea and vomiting caused by other drugs. 21 CFR § 520.766 - "Do not use in horses intended for human consumption." http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm235691.htm	FDA has warned that this drug passes into breast milk and should not be used in nursing human mothers. Side effects include dizziness, dry mouth, nervousness, flushing, irritability, insomnia, stomach cramps, hot flashes and leg cramps, chest pain, slow/fast/irregular heartbeat, swelling of the feet or ankles, difficulty urinating, swelling of the breasts or discharge from the nipple in men or women, menstrual changes, sexual difficulties. May affect absorption and action of other drugs, and interact with other drugs. http://www.medicinenet.com/domperidone-oral/article.htm
40.	**Doxycycline**	Antibiotic for horses and humans. http://www.drugs.com/cdi/doxycycline-capsules.html	Dangerous for pregnant women; may cause tooth problems, gastrointestinal symptoms, autoimmune syndrome, renal problems.

California's Proposition 65 list; neurotoxic cholinesterase inhibitors, as designated by California Department of Pesticide Regulation, the Materials Safety Data Sheet for the particular chemical, or PAN staff evaluation of chemical structure (for organophosphorus compounds); known groundwater contaminants, as designated by the state of California (for actively registered pesticides) or from historic groundwater monitoring records (for banned pesticides); pesticides with high acute toxicity, as designated by the World Health Organization (WHO), the U.S. EPA, or the U.S. National Toxicology Program.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
41.	**Doxylamine succinate**	Antihistamine Anticholinargic 21 CFR 520.784 - "Not for use in horses intended for food."	Not to be combined with other antihistamines. Can cause multiple adverse side effects.
42.	**Equine Influenza vaccine**	Killed virus vaccine	Not intended for human use and no testing on human ingestion of this vaccine.
43.	**Equine Rhinopneumonitis – Influenza vaccine**	Killed virus vaccine Prestige II with Havlogen (vaccine) http://intervetus.naccvp.com/?m=product_view&id=1047348	Not intended for human use and no testing on human ingestion of this vaccine.
44.	**Estradiol**	Female hormone for management of reproductive functions in horses, and for relief of menopausal symptoms in humans Estradiol Cypionate in Oil Estradiol enanthate; Estradiol benzoate	Risk of cancer is among the multiple potential negative side effects related to the unapproved and uncontrolled use of this synthetic female hormone. Other side effects include headaches, dizziness, breast pain, increased risk for yeast infections, flu-like symptoms, arthritic pain, hair loss, gastrointestinal problems including nausea or vomiting, and incidences of spotting in between periods or other menstrual irregularities. May be unsafe for people with blood disorders, heart disease, obesity, seizure disorders or certain allergies.
45.	**Eucalyptus Oil**	Scarlet Oil Wound Dressing http://www.drugs.com/vet/scarlet-oil.html Labeled "Not for use on animals intended for food."	Potential side effects include seizures, poisoning, drowsiness, morbidity in children, central nervous system, depression.
46.	**Fenbendazole**	Dewormer (Panacur) Equi-bits Panacur Paste Panacur Power Pac Panacur Suspension Safe-Guard Safe-Guard Power-Dose 21 CFR § 520.905a - "Do not use in horses intended	No human formulation, and adverse effects on humans who eat this dewormer, that directly affects the gastrointestinal tract, are unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		for human consumption."	
47.	**Firocoxib**	Equioxx Non-steroidal anti-inflammatory drug (NSAID). 21 CFR § 520.930; 522.930 - Firocoxib paste. - "Do not use in horses intended for human consumption." http://www.equioxx.com/	There is no approved use of this drug for humans and so any adverse effects on humans who ingest this drug are completely unknown. Firocoxib is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
48.	**Flunixin**	NSAID: Banamine (solution or paste) (pain killer) Flunazine injectable Flu-nix D injection Flunixamine 21 CFR § 520.970 - Granules - "Do not use in horses intended for human consumption." 21 CFR § 522.970 - Injectible - "Do not use in horses intended for human consumption."	Flunixin is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
49.	**Flunixin Meglumine**	NSAID: Flunazine injectable Flu-nix D injection Flunixamine Labeled: Not for use in horses intended for food. http://www.drugs.com/vet/flunixin-meglumine-injection.html http://www.drugs.com/vet/flunazine-injectable-solution.html http://www.drugs.com/vet/flu-nix-d-	This is also one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		ivx.html http://www.drugs.com/vet/flunixamine.html	
50.	**Furaltadone**	Antibacterial http://www.chemblink.com/MSDS/MSDSFiles/139-91-3_Sigma-Aldrich.pdf	May cause cancer in humans, but very little known about effect on humans because the drug has not been tested on humans and the potential side effects upon ingestion are unknown.
51.	**Furazolidone**	Antibacterial: Furall Furox Aerosol Powder Used in humans as an anti-diarrheal 21 CFR § 524.1005 - "Not for use in horses intended for food." http://msds.farnam.com/m000394.htm http://www.drugs.com/vet/furazolidone-aerosol-powder.html Federal law prohibits the use of this product in food-producing animals.	Contains chemicals known to the state of California to cause cancer. Should only be taken under strict medical oversight; dangerous if taken with alcohol, when pregnant, or for individuals with certain blood disorders. Adverse effects include headache, stomach upset, nausea, vomiting, dizziness or weakness, fever, skin rash, itching, muscle aches, flushing, breathing trouble. This medication may cause the urine to turn brown in color.
52.	**Furosemide**	Diuretic: Lasix Used in humans and horses	May cause pancreatitis, jaundice, anorexia, paresthesias, ototoxicity, blood dyscrasias, dizziness, rash, urticaria, photosensitivity, fever, thrombophlebitis, restlessness. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Furosemide
53.	**Gentamicin sulfate solution**	Antibiotic: Gentamicin solution Do not use for horses intended for human consumption. http://www.drugs.com/vet/gentamicin-sulfate-solution.html 21 CFR § 529.1044a - "Do not use in horses intended for human consumption."	Can cause severe hearing and kidney problems. May cause dizziness, vertigo, ringing in the ears, hearing loss, numbness, muscle twitching or weakness, difficulty breathing, decreased urination, rash, itching, or sore throat. Interaction and potential harm with other drugs can cause adverse reactions.
54.	**Gentian violet**	Blue-Kote	Usually used topically on humans. Unknown side effects upon ingestion.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Topical ointment, antiseptic, protective wound dressing. Not for use on food producing animals. http://www.drugs.com/vet/dr-naylor-blu-kote.html http://www.drnaylor.com/index.php?option=com_content&task=blogcategory&id=20&Itemid=47 "Not for use on animals intended for food." http://www.horsesuppliesplus.com/antiseptics.html	
55.	**HCl**	Component of Dexium injection http://www.drugs.com/vet/dexium-injection.html	Very hazardous if touched; not fully tested on humans; may be fatal if inhaled or swallowed. Causes irritation and burning, ulceration, or perforation of the gastrointestinal tract and resultant peritonitis, gastric hemorrhage and infection. Can also cause nausea, vomiting (with "coffee ground" emesis), diarrhea, thirst, difficulty swallowing, salivation, chills, fever, uneasiness, shock, strictures and stenosis (esophogeal, gastric, pyloric). May affect behavior (excitement), the cardiovascular system (weak rapid pulse, tachycardia), respiration (shallow respiration), and urinary system (kidneys- renal failure, nephritis). Acute exposure via inhalation or ingestion can also cause erosion of tooth enamel.
56.	**Hyaluronate sodium**	Arthritis treatment Legend Legend injectable 21 CFR § 522.1145 - "Do not use in horses intended for human consumption." - "Not for use in horses intended for food." http://www.bayerdvm.com/products/legend/legend.cfm http://www.drugs.com/vet/legend-multi-dose-hyaluronate-sodium-injectable-solution.html	May cause gastrointestinal tract information with nausea and vomiting. It may affect blood (normocytic anemia, change in leukocyte count), metabolism, behavior (ataxia, convulsions), respiration (respiratory stimulation), and urinary system. The toxicological properties of this substance have not been fully investigated. http://www.sciencelab.com/msds.php?msdsId=9924276
57.	**Hyaluronic acid sodium salt**	Polyglycan	May cause gastrointestinal irritation, affect blood, metabolism and behavior. The dangers upon ingestion by humans has not been fully investigated.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		For use only as a surgical lavage in animals not intended for food use. http://www.medi-vet.com/Polyglycan.aspx Also used in race horses prior to a race.	
58.	**Hydroxyzine Pamoate**	Anti-anxiety in humans and preoperative sedation. Antihistamine, anti-itching and sedative in animals. http://www.drsfostersmith.com/product/prod_display.cfm?pcatid=20678	May impair mental and physical abilities in elderly, may potentiate other medications, and not for use by pregnant or nursing mothers. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1096
59.	**Hyoscine butylbromide**	Buscopan Scopolamine Antispasmodic; colic pain relief. http://www.drugs.com/vet/buscopan-sterile-solution-can.html	Potential adverse effects include blurred vision, severe allergic reactions, confusion, urinary problems, and mood changes. www.drugs.com/sfx/scopolamine-side-effects.html
60.	**Isoflurane**	Surgical anesthetic 21 CFR § 529.1186 - "Do not use in horses intended for human consumption."	MSDS reports no information on toxicity upon ingestion.
61.	**Isoparaffinic Petroleum Solvent**	Fly Control: Farnam Bronco Gold (spray) Farnam Wipe http://msds.farnam.com/m001650.htm http://msds.farnam.com/m000490.htm	Unknown human toxicity and side effects after ingestion.
62.	**Ivermectin**	Dewormers: Agri-mectin Paste Bimectin Paste Equell Paste	Can act for up to twelve months; carcinogenicity not studied; not recommended for pregnant women; distributes into breast milk. Adverse reactions include pruritus, edema, papular/pustular/frank urticarial rash, fever, axillary/cervical/inguinal lymphadenopathy, arthralgia/synovitis, limbitis, tachycardia, peripheral edema, leukopenia, eosinophilia

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Equimax Farnam Ivercare Horse Health Ivermectin Ivercare paste ProMetin E™ Paste Zimecterin Gold Zimecterin Paste Also found in human anthelmintic compounds 21 CFR § 520.1192 - Paste - "Do not use in horses intended for human consumption." 21 CFR § 1194 - Meal - "Do not use in horses intended for human consumption." 21 CFR § 1195 - Liquid - "Do not use in horses intended for human consumption." 21 CFR §1198 - Ivermectin and praziquantel paste - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/agri-mectin-paste-1-87.html http://www.drugs.com/vet/agri-mectin-paste-1-87.html http://www.davisandlawrence.com/1-x-6-08-g.html http://www.horsehealthusa.com/details/Equell-Paste/37-105.html http://www.equimaxhorse.com/	http://www.pdr.net/search/searchResult.aspx?searchCriteria=ivermectin

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
63.	**Ketoprofen**	NSAID: Ketofen Used as NSAID in horses and humans. 21 CFR § 522.1225 - "Not for use in horses intended for food." http://www.drugs.com/vet/ketofen.html	Ketoprofen is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
64.	**Levothyroxine Sodium**	Thyro-L Thyroid replacement hormone. http://www.drugs.com/vet/thyro-l.html	This artificial thyroid hormone can exacerbate thyroid and hypertension problems in susceptible individuals. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Levothyroxine+Sodium
65.	**Luprostiol**	For control of reproductive cycles and inducing termination of pregnancy. 21 USC § 522.1290 - solution - "Do not use in horses intended for human consumption." - "Labeling shall bear the following statements: Warning: Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early states, women may be unaware of their pregnancies..."	Dangerous for children, pregnant and lactating mothers, individuals with respiratory problems. Can cause hormonal effects when taken.
66.	**Mepivacaine**	Anesthetic 21 CFR § 522.1372 - "Not for use in horses intended for human consumption."	Because this is an injectable drug, studies have not been done on the dangers of ingestion.
67.	**Methocarbamol**	Robaxin Muscle relaxant in animals and humans.	Potential adverse reactions include lightheadedness, dizziness, drowsiness, nausea, urticaria, pruritus, rash, conjunctivitis, nasal congestion, blurred vision, headache, fever, seizures, syncope, flushing. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Methocarbamol

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.petplace.com/drug-library/methocarbamol-robaxin-v/page1.aspx	
68.	**Methyl Salicylate**	Scarlet Oil Wound dressing for horses. Muscle and joint pain relief in humans. Not for use on animals intended for food. http://www.drugs.com/vet/scarlet-oil.html	"When ingested, the highly concentrated liquid methyl salicylate in the form of wintergreen oil, as with other volatile oils, can induce vomiting and is a notorious source for severe, often fatal poisonings." http://www.drugs.com/npp/wintergreen.html Dangerous if used in conjunction with other analgesics, anticoagulants, steroids, NSAIDs, alcohol, and diuretics. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Methyl+Salicylate
69.	**Methylandrostenediol**	Methandriol Anabolic steroid Used as growth stimulator and steroid in horses and humans. http://www.drugs.com/international/methandriol.html	Can cause estrogenic (female hormone) and androgenic (male hormone) effects. Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
70.	**Methylprednisolone**	Human and horse steroid 21 CFR § 522.1410 - "Do not use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
71.	**Metronidazole**	Antibiotic in humans and horses (Flagyl) http://www.wedgewoodpetrx.com/learning-center/professional-monographs/metronidazole-for-veterinary-use-ab.html	This drug can cause gastrointestinal problems, serious allergic reactions in sensitive individuals, flu-like symptoms, seizures, encephalopathy, aseptic meningitis, peripheral neuropathy, nausea and vomiting, headache, anorexia and neutropenia. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Metronidazole
72.	**Moxidectin**	Quest Gel Quest Plus Antiparasitic (dewormers) Not for horses or ponies intended for human consumption. http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/	Very limited testing on humans – potential adverse effects still unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		ComplianceEnforcement/ucm168782.htm 21 CFR § 520.1452; 520.1463 - Gel - "Not for use in horses and ponies intended for food." http://www.drugs.com/vet/quest-plus-equine-oral-gel.html	
73.	**N-(2-Ethylhexyl)-5-norbornene-2,3-dicarboximide**	Bug Block (fly control) http://absorbine.org/products/flycontrol/bug-block-insecticide-repellent http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf	"Harmful if ingested." Bug Block fly control has multiple adverse effects if swallowed by humans. http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf
74.	**N-acetyl-D-glucosamine 10%**	Polyglycan Post-surgical lavage of joint compartments. "Do not administer to animals that are to be slaughtered for food." www.arthrodynamic.com/polyglycan/	Ingredient in Polyglycan, which includes warning: "For use only as a surgical lavage in animals not intended for food use." http://www.medi-vet.com/Polyglycan.aspx
75.	**Neomycin Sulfate**	Animax ointment Human and animal antimicrobial, anti-fungal steroid drug	May cause nausea and vomiting, diarrhea, malabsorption syndrome, nephrotoxicity, ototoxicity, neuromuscular blockage, neurotoxicity, fetal harm. Especially dangerous for individuals with certain diseases of the muscles. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=3174
76.	**Nitrofurantoin**	Equifur Antibacterial for urinary tract infections in horses and humans. This drug is not to be administered to horses that are to be slaughtered for use in food. http://www.drugs.com/vet/equifur-can.html	Adverse effects include hypersensitivity reactions, pulmonary/hepatic/psychotic reactions, peripheral neuropathy, nausea and vomiting, anorexia, dizziness, exfoliative dermatitis, anaphylaxis, hematologic abnormalities, cyanosis, angioedema, asthenia. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=383

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
77.	**Nitrofurazone**	Niderm Ointment Antibacterial ointment, burns, skin grafts. 21 CFR § 524.1580b - "Do not use in horses intended for human consumption." - "Federal law prohibits the use of this product in food-producing animals." Federal law prohibits the administration of this preparation to animals that produce food or that are intended for consumption as food. http://www.drugs.com/vet/niderm-ointment-can.html	Very toxic to humans. http://www.sciencelab.com/msds.php?msdsId=9926271
78.	**N-Octyl Bicycloheptene Dicarboximide**	Farnam Roll-On Repellent Fly spray http://msds.farnam.com/m000018.htm	According to the manufacturer, Farnam Roll-On Repellent is "harmful if swallowed."
79.	**Nystatin**	Antimicrobial, antifungal and steroid Animax ointment Mycostatin Bio-Statin For use in humans and horses with thrush.	Adverse reactions include oral irritation, sensitization, diarrhea, nausea and vomiting, gastrointestinal disturbances, rash, urticaria, Stevens-Johnson syndrome. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Nystatin See also: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000767/ http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682758.html
80.	**Omeprazole**	Treatment for ulcers in horses and humans. Gastrogard 21 CFR § 520.1615 - "Do not use in horses intended for human consumption." http://gastrogard.us.merial.com/faq.shtml	Adverse reactions include headache, diarrhea, abdominal pain, nausea and vomiting, fever, respiratory disorders, severe allergic reactions, irregular heartbeat, bruising and bleeding. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Omeprazole
81.	**Oxibendazole**	Anthelcide dewormer	"Do not allow product to enter drinking water supplies, waste water or soil."

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		21 CFR § 520.1638 - paste - "Not for use in horses intended for human consumption." 21 CFR § 520.1638 - Suspension - "Not for use in horses intended for human consumption." Not for use in horses intended for human consumption. http://www.drugs.com/vet/anthelcide-eq-equine-wormer-paste.html	http://www.seqchem.com/safetysheet.php?SQIndex=SRP012491o
82.	**Parachlorometaxylenol**	Scarlet Oil Not for use on animals intended for food. http://www.drugs.com/vet/scarlet-oil.html	May cause burning of mouth, throat and stomach, if ingested. http://surfactantsinc.com/pdf/Surcide%20PCMX-USP%20MSDS.pdf
83.	**Phenol**	Red-Kote Not for use on animals intended for food. http://www.drugs.com/vet/dr-naylor-red-kote.html	Phenol is considered to be quite toxic to humans via oral exposure. Anorexia, progressive weight loss, diarrhea, vertigo, salivation, a dark coloration of the urine, and blood and liver effects have been reported in chronically (long-term) exposed humans. Animal studies have reported reduced fetal body weights, growth retardation, and abnormal development in the offspring of animals exposed to phenol by the oral route. http://www.epa.gov/ttn/atw/hlthef/phenol.html
84.	**Phenylbutazone**	NSAID: Butazone 400 Butazone 1000 Butazone Concentrate Bute paste Butequine 21 USC §520.1770a - Tablets and boluses - Dogs and horses - "Do not use in horses intended for human consumption.." 21 USC § 522.1720	Serious and fatal adverse effects have been reported from ingestion of Phenylbutazone, including bone marrow suppression and aplastic anemia. Banned in America for human use. Nicholas Dodman, Nicolas Blondell, Ann M. Marini, "Association of phenylbutazone usage with horses bought for slaughter: A public health risk", FOOD AND CHEMICAL TOXICOLOGY 48 (2010) 1270–74. "Phenylbutazone is known to induce blood dyscrasias, including aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia and deaths. Hypersensitivity reactions of the serum-sickness type have also been reported. In addition, phenylbutazone is a carcinogen, as determined by the National Toxicology Program." http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm124078.htm Phenylbutazone is especially problematic for patients with a history of asthma attacks, hives, or other allergic reactions to aspirin or other NSAIDs. It also should be avoided by patients with peptic ulcer disease or poor kidney function, since this medication

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		- Injection - Dogs and horses - "Not for use in animals intended for food." http://horsebackmagazine.com/hb/archives/13184 http://www.farmvet.com/pc-1500-163-bute-paste-12-gm.aspx http://www.drugs.com/vet/butequine-can.html http://tuesdayshorse.wordpress.com/tag/cfia/	can aggravate both conditions. Phenylbutazone is generally used with caution in patients taking blood thinning medications (anticoagulants), such as warfarin (Coumadin), because of an increased risk of bleeding. Patients taking lithium can develop toxic blood lithium levels. Additionally, patients taking cyclosporine (Sandimmune) can develop kidney toxicity.
85.	**Piperonyl Butoxide**	Repel-XP Fly control Do not use on horses intended for human consumption. http://www.drugs.com/vet/repel-xp-emulsifiable-fly-spray.html	Potential dangers to humans are unknown: "Data are not available from accidental poisonings, occupational exposures, or epidemiological studies regarding the reproductive and developmental toxicity of piperonyl butoxide." npic.orst.edu/factsheets/pbotech.pdf Ingestion can cause vomiting and diarrhea. Pesticide Action Network North America. Piperonyl Butoxide, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC33240 The EPA classifies piperonyl butoxide as a group C carcinogen, a possible human carcinogen. Environmental Protection Agency. Reregistration Eligibility Decision for Piperonyl Butoxide. (June 2006). http://www.epa.gov/opp00001/reregistration/REDs/piperonyl_red.pdf
86.	**Polysulfated Glycosaminoglycan**	Adequan Joint treatment. 21 USC § 522.1850 - "Do not use in horses intended for human consumption."	Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this supplemental new animal drug. The drug is approved for use only in horses that are not to be used for food and is to be labeled "'Not for use in horses intended for food.'" http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm054846.htm Based on the formulation of the drug, humans could develop anaphylaxis or excessive bleeding as the sulfated proteoglycans are anticoagulants.
87.	**Ponazuril**	Antiprotozoal Marquis paste; Marquis 21 CFR § 520.1855 - Horses only - "Not for use in horses intended	Unknown side effects and adverse reactions in humans ingesting Ponazuril. "Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this supplemental new animal drug. The drug is approved for use only in horses that are not to be used for food and is to be labeled 'Not for use in horses intended for food.'" Freedom of Information Summary, Original New Animal Drug Application, NADA

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		for food." "Not for use in horses intended for food." http://www.drugs.com/vet/marquis-15-w-w-ponazuril-antiprotozoal-oral-paste.html	141-188 (Marquis), www.fda.gov/downloads/AnimalVeterinary/.../ucm117581.pdf
88.	**Prallethrin**	Insecticide Mosquito Halt Fly spray http://www.drugs.com/vet/mosquito-halt-repellent-spray-for-horses.html	Potential poisoning, headache, dizziness, nausea, and seizure. http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35755 "Pyrethroid ingestion gives rise within minutes to a sore throat, nausea, vomiting and abdominal pain. There may be mouth ulceration, increased secretions and/or dysphagia. Systemic effects occur 4-48 hours after exposure. Dizziness, headache and fatigue are common, and palpitations, chest tightness and blurred vision less frequent. Coma and convulsions are the principal life-threatening features. Most patients recover within 6 days. . . ." S.M. Bradberry *et al.*, *Poisoning Due to Pyrethroids*, Toxicol Rev. 24(2):93-106 (2005) (quoting abstract).
89.	**Praziquantel**	Dewormer For horses and humans Equimax Quest Plus Zimecterin Gold http://www.equimaxhorse.com/ http://www.drugs.com/vet/quest-plus-equine-oral-gel.html "Not for use in humans." (Zimecterin) http://www.zimecterin.com/ZimecterinGold/index.html?=50	Available by prescription only and to be taken only under the monitoring of a physician. Contraindicated for people with pre-exiting conditions involving the liver, kidney, or heart. Praziquantel may cause side effects including headache, dizziness, stomach pain, nausea, fever, itching, hives (especially serious). http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000474/ http://www.rxlist.com/biltricide-drug/patient-images-side-effects.htm
90.	**Prednisone**	Human and horse steroid 21 USC § 522.1890 - Horses, dogs and cats - "Not for use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
91.	**Prostaglandin**	Lutalyse solution Horse and human use – regulation of	Can cause unknown and unwanted hormonal effects, including termination of pregnancy, to individuals who ingest without knowing.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		female reproduction and other uses. This drug is not to be administered to horses that are to be slaughtered for use in food. http://www.drugs.com/vet/lutalyse-sterile-solution-can.html	
92.	**Pseudoephedrine HCl**	Tri-Hist Granules Not for use in horses intended for food. http://www.drugs.com/vet/tri-hist-granules.html	Can cause central nervous stimulation, insomnia, anxiety, dizziness, blurred vision, colitis, and psychosis when combined with other drugs.
93.	**Pyrantel Pamoate**	Exodus Paste Dewormer 21 CFR § 520.2044 - Horses and ponies - "Do not use in horses intended for human consumption." 21 CFR § 520.2043 - Horses and ponies - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/exodus-paste.html	Adverse reactions include abdominal cramps, nausea and vomiting, diarrhea, headache, dizziness. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2985
94.	**Pyridoxine HCl**	Liver 7 injection	Potential health effects after ingestion unknown. http://www.sciencelab.com/msds.php?msdsId=9924765
95.	**Pyrilamine Maleate USP**	Tri-Hist Granules Antihistamine (human and horse use) 21 CFR § 522.2063 - "Do not use in horses intended for food purposes." Not for use in horses intended for food. http://www.drugs.com/vet/tri-hist-granules.html	Many individuals with identified health conditions have hypersensitivities to antihistamines and the use of antihistamines is contraindicated in that portion of the population. http://www.drugs.com/pro/poly-hist-pd.html

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
96.	**Rabies vaccination**	Imovax Rabies Vaccine	The dangers of human ingestion are unknown.
97.	**Ractopamine hydrochloride**	Optaflexx 100 Premix Beta-agonist used for growth promotion purposes	A January 2012 article reported that ractopamine hydrochloride is "[f]ed to an estimated 60 to 80 percent of pigs in the United States, [and has] has sickened or killed more of them than any other livestock drug on the market." While the FDA has approved the drug for use in cows and pigs, many countries have banned it from food-producing animals, and the drug has never been tested on horses intended for human consumption. http://bottomline.msnbc.msn.com/_news/2012/01/25/10220221-dispute-over-drug-in-feed-limiting-us-meat-exports
98.	**Rhinopneumonitis vaccine**	5-way (vaccination) http://www.alpineanimal.net/page6263a3c5.html?inc=na	Unknown consequences for humans.
99.	**Ronidazole**	Antiprotozoal agent http://www.wedgewoodpetrx.com/items/ronidazole-capsule.html	Does not appear to have any human applications. Dangerous side effects in animals. Toxicity information and potential health effects are unknown. https://www.reagentworld.com/products/msds2.asp?proid_2=23072
100.	**Selenium**	Trace mineral supplement 21 USC § 522.2100 - "Do not use in horses intended for food."	Rare but potential side effects include nausea, vomiting, abdominal pain, hearing loss, fatigue, weight loss, muscle tenderness, heart failure, and allergic reactions.
101.	**Stanozolol**	Anabolic steroid Used in both animals and humans. 21 USC 522.2150 - "Not for use in horses intended for food." http://www.petplace.com/drug-library/stanozolol-winstrol/page1.aspx	Potential side effects of anabolic steroids are well-documented. Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain
102.	**Stilbenes**	Used in estrogen-related substances	Animals treated with these drugs are banned from meat production in the European Union. http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097
103.	**Strangles vaccine (Streptococcus Equi vaccine)**	Vaccination for *streptococcus equi* http://www.aaep.org/strangles.htm Pinnacle I.N. (strangles)	Dangers of human ingestion unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.drugs.com/vet/pinnacle-i-n.html	
104.	**Sucralfate**	Used to aid in healing gastrointestinal tract, ulcers, for humans and animals.	Adverse reactions include constipation, diarrhea, nausea and vomiting, pruritus, rash, dizziness, insomnia, back pain, headache, dry mouth, flatulence, gastric discomfort, indigestion, sleepiness. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Sucralfate
105.	**Sulfadiazine**	Tribrissen (oral) 400 paste 21 CFR § 520.2215 - "Do not use in horses intended for human consumption." 21 CFR § 520.2260a - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/tribrissen-400-oral-paste.html	Sulfadiazine has potential cross-sensitivity with other drugs in the same class. Some individuals will have blood cell destruction from the drug. It can also cause transient leukopenia, skin necrosis, skin discoloration, burning sensation, rash, interstitial nephritis, and other systemic reactions. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Sulfadiazine
106.	**Sulfamethoxazole Trimethoprim**	Antibacterial Bactrim, Septra	While these drugs are approved for human use, unnecessary ingestion of antibiotics is medically contraindicated. Additionally, adverse reactions include nausea and vomiting, anorexia, allergic skin reactions (*e.g.*, rash, urticaria), agranulocytosis, aplastic anemia, hepatitis, renal failure, hyperkalemia, aseptic meningitis, arthralgia, convulsions, cough.
107.	**Sunscreens**	Components in various fly spray products http://www.horse.com/ContentFiles/Associated_Content/ultrashieldexlabel.pdf	While sunscreens are used by humans, there is no substantial literature or studies on ingestion of sunscreens or their byproducts and metabolites.
108.	**Testosterone enanthate**	Uni-Bol Male sex hormone http://www.drugs.com/vet/uni-bol-can.html	The ingestion of male hormones, when not medically indicated, can create hormonal imbalances. Additionally, use may cause dangerous reactions in hypersensitive individuals or those with other illnesses. Can increase prostate and other problems in elderly men. Can also cause hormone-mediated reactions, fluid and electrolyte disturbances, nausea, cholestatic jaundice, alterations in liver function, headache, and anxiety. It is also designated as "not for use" in nursing mothers. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2017
109.	**Thiamine HCl**	Included in liver 7 injection http://www.drugs.com/vet/liver-7-injection.html	Hazardous in case of ingestion. http://www.sciencelab.com/msds.php?msdsId=9925232

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
110.	**Thyrostats**	Thyroid-related growth promotion Antithyroid agents for the purpose of growth promotion	Animals treated with these drugs are banned from meat production in the European Union. http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097.
111.	**Topazone Aerosol Powder**	Antibacterial Topazone Furox http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm137145.htm	Contains chemicals known to the state of California to cause cancer. Should only be taken under strict medical oversight; dangerous if taken with alcohol, when pregnant, or for individuals with certain blood disorders. Adverse effects include headache, stomach upset, nausea, vomiting, dizziness or weakness, fever, skin rash, itching, muscle aches, flushing, breathing trouble. This medication may cause the urine to turn brown in color.
112.	**Triamcinolone Acetonide**	Component in Animax ointment Antimmicrobial, anti-fungal, steroid (for thrush treatment) 21 CFR § 520.2483 - tablets - "Do not use in horses intended for human consumption." 21 CFR § 522.2483 - Suspension - "Do not use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
113.	**Trimethoprim**	Uniprim antibiotic Powder For treatment of *Streptococcus equi* ("Strangles") 21 CFR § 520.2611 - "Do not use in horses intended for human consumption." 21 CFR § 520.2613 - Trimethoprim and sulfadiazine powder - "Not for use in horses intended for food." "Do not use in horses intended for human consumption."	Trimethoprim is a strong antibiotic with multiple potential adverse reactions, adverse interactions with other drugs and hypersensitivities noted in individuals with various diseases and metabolic conditions. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000813/

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.drugs.com/vet/tribrissen-400-oral-paste.html http://www.drugs.com/vet/uniprim-powder.html	
114.	**West Nile virus**	Recombitek West Nile Vaccine http://www.drugs.com/vet/recombitek-equine-west-nile-virus-can.html	This vaccine has only been approved for use in horses and no data exists with respect to the safety of humans eating it, or meat from animals who have received it.
115.	**Xylazine**	Sedative Anased 21 CFR § 522.2662 - "Not for use in horses intended for food. - "Do not use in domestic food-producing animals."	Xylazine poisoning causes hypotension, bradycardia, and respiratory depression. Ocular administration can cause sinus bradycardia, hypotension and decreased mental status. Velez LI, Shepherd G, Mills LD, Rivera W., *Systemic toxicity after an ocular exposure to xylazine hydrochloride,* J. EMERG. MED. 30(4):407-10 (2006).

Exhibit B

Inspections, Compliance, Enforcement, and Criminal Investigations

Ronald Andio, DBA Patron Farms, LLC 7/9/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

WARNING LETTER
CIN-12-312058-26

July 9, 2012

Via United Parcel Service

Mr. Ronald A. Andio, Owner
Ronald Andio, DBA Patron Farms, LLC
4445 South Turner Road
Canfield, Ohio 44406

Dear Mr. Andio:

On April 03, 05, and 30, 2012, the U.S. Food and Drug Administration (FDA) conducted an investigation of your livestock operation located at 4445 South Turner Road, Canfield, Ohio 44406. This letter notifies you of the violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the Internet through links on FDA's web page at www.fda.gov[1].

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. 360b. Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about August 20, 2011, you sold a bay thoroughbred gelding horse, identified with back tag **(b)(4)** (USDA Tag **(b)(4)**) for slaughter as food. On or about August 23, 2011, **(b)(4)** slaughtered this animal. The Canadian Food Inspection Agency (CFIA) analysis of tissue samples collected from this animal identified the presence of phenylbutazone at 0.0025 parts per million (ppm) in the muscle tissue and 0.026 ppm in the kidney tissue and clenbuterol at 0.0039 ppm in the eye (target tissue). FDA has not established a tolerance for residues of phenylbutazone and clenbuterol in the edible tissues of horses. The presence of these drugs in edible tissues from this animal in these amounts causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to inquire about the medication status of animals purchased for

slaughter. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4).

The violations listed above are not intended to an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animals. As such, you share responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. Implementing a system to determine from the source of the animals whether the animals has been medicated and with what drug(s); and

2. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

We also note that the slaughterhouse has on file an Equine Information Document (EID) certificate (or guarantee) dated August 23, 2011 from the producer stating that this animal that you sold had not been administered any drugs or vaccines or treated with any substances not permitted for use in food processing equine in the last 180 days prior to your purchase of this animal. During our inspection of your firm, you admitted that you filled out and signed the producer's name to this form and did not inquire of the producer the medication status of this animal. You provided this EID to the dealer who purchased this animal from you. Providing such a false guaranty is prohibited by section 301(h) of the FD&C Act, 21 U.S.C. 331(h). You should take appropriate actions to ensure that this violation does not recur.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Mr. Mark E. Parmon, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, please contact Compliance Officer Mark E. Parmon at (513) 679-2700, Ext. 2162, (513) 679-2773 (fax), or email: mark.parmon@fda.hhs.gov.

Sincerely yours,

/S/

Paul J. Teitell
District Director
Cincinnati District

cc: Dr. Tony Forshey, Acting Chief
Ohio Department of Agriculture
8995 East Main Street
Reynoldsburg, OH 43068-3399

Page Last Updated: 07/29/2012
Note: If you need help accessing information in different file formats, see Instructions for

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

TABLE OF CONTENTS

SUMMARY

This inspection of a horse dealer was conducted in response to an illegal drug residue in a horse. The inspection was conducted per FACTS Assignment #1397716 and Compliance Program 7301.006 "Illegal Residues in Meat, Poultry, Seafood and Other Animal Derived Foods". This inspection is a follow up to the USDA Case documented as Case No. 11-0757-OH.

On 8/23/2011, a horse with identifying tag numbers 979, 9491, and 249 was slaughtered at (b) (4) (b) (4) The horse was sampled by the Canadian Food Inspection Agency (CFIA) as sample number M8-CR-50255. The sample was collected under CFIA's National Chemical Residue Monitoring Program. The horse tissue was found to contain illegal drug residues of 0.0039ppm Clenbuterol in the eye, 0.0025ppm Phenylbutazone in the muscle, and 0.026ppm Phenylbutazone in the kidney. There is no allowable tolerance level for Clenbuterol or for Phenylbutazone.

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

This was an initial inspection of Ronald Andio, DBA Patron Farms, LLC. The current inspection found that Mr. Ronald A. Andio, Owner, and Mrs. Patricia Andio, Co-owner, operate their business as a horse dealer, buying and selling horses. Approximately (b) (4) of all horses purchased are intended for slaughter. All other horses are sold to private individuals for leisure activities or as work horses.

The current investigation found that Mr. Andio purchased the horse in question, a bay thoroughbred gelding, from (b) (6) on or around 8/19/2011. Mr. Andio stated that the horse was not treated while in his possession as it is their policy that horses intended for slaughter are not treated with any medication. Mr. Andio sold the horse to (b) (6) of (b) (4) (b) (4) on 8/20/2011 with back tag 979. The horse was then hauled from (b) (4) to (b) (4) for slaughter, with USDA tag USHA 9491.

Mr. Andio confirmed that he does not verbally ask the seller of any horses, including those intended for slaughter, whether horse had been medicated. Mr. Andio also stated that he routinely completes and signs the Equine Identification Document (EID) for the horse owners after sale. Mr. Andio stated that he completed and signed the EID for (b) (6) falsely guaranteeing that the horse purchased had not been treated by (b) (6)

Form FDA 483 (Inspectional Observations) was issued to Mr. Ronald A. Andio, Owner for not inquiring about the medication status of the animal that he purchased and delivered for sale at a slaughter plant.

Mr. Andio stated that going forward, they will be verbally inquiring the medication status of the horses prior to purchase. Mr. Andio also stated that going forward they will require the horse owner fill the EID out themselves and sign the form certifying the information on the form is true.

Documentary sample DOC 719823, consisting of a signed affidavit, sale, purchase, and shipping records for horse with identifying tag numbers 979, 9491, and 249 was collected.

The firm was created and firm data entered into the Official Establishment Inventory (OEI) on 4/4/2012 by Investigator Cochran.

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

ADMINISTRATIVE DATA

Inspected firm:	Ronald Andio, DBA Patron Farms, LLC
Location:	4445 South Turner Road Canfield, OH 44406
Phone:	330-719-5980
Mailing address:	4445 South Turner Road Canfield, OH 44406
Dates of inspection:	4/3/2012, 4/5/2012, 4/30/2012
Days in the facility:	3
Participants:	Annemarie H. Cochran, Investigator

Upon my arrival at the firm on 4/3/2012, I presented my credentials to Mr. Ronald A. Andio and Mrs. Patricia Andio; Form FDA 482 (Notice of Inspection) was issued to Ronald A. Andio, Owner. Form FDA 483 (Inspectional Observations) was issued to Mr. Ronald A. Andio, Owner, on 4/30/2012. The inspection was closed on 4/30/2012 so that I was able to perform the other inspections that were related to this horse tissue residue case.

HISTORY

Mr. Ronald Andio, Owner, stated that the name Patron Farms, LLC is mainly used for the retail sale operations of the business. The name Ronald Andio is used for the sale of horses intended for slaughter. Ronald Andio, the business, operates as a dealer of horses, buying and selling horses. Mr. Ronald Andio, Owner, stated that he has been in the horse dealing business for over 35 years.

The business is located at a private residence and does not have set hours of operation. There are no other locations. The firm is not currently registered per the 2002 Bioterrorism (BT) Act, but meets the exemptions for farms.

Official FDA correspondence should be sent to:
Ronald Andio DBA Patron Farms, LLC
ATTN: Mr. Ronald A. Andio, Owner
4445 South Turner Road
Canfield, OH 44406

INTERSTATE COMMERCE & JURISDICTION

Ronald Andio, DBA Patron Farms, LLC purchases horses within Ohio and resells them for slaughter. The horse (a bay thoroughbred gelding) bearing identifying tag numbers 979, 9491, and

249 was slaughtered and sampled by the CFIA in (b) (4) This horse was documented to have been sold by Mr. Ronald Andio of Ronald Andio, DBA Patron Farms, LLC (Canfield, OH) on 8/20/11 to (b) (6) of (b) (4) The horse was then sold to (b) (4) and slaughtered with the intent to be offered for food on 8/23/11. For FDA regulatory purposes, live animals are considered unprocessed food.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

I was accompanied during the inspection by Mr. Ronald A. Andio, Owner, and his wife Patricia Andio, Co-owner. Mr. Andio and his wife Patricia Andio together operate Ronald Andio, DBA Patron Farms, LLC, and are considered co-owners of their business. Mr. and Mrs. Andio both provided me all business related information and answered all of my questions during the inspection. Both Mr. and Mrs. Andio were able to identify and provide the paperwork and records relating to horses that are purchased and sold, including those intended for slaughter.

Mr. Ronald A. Andio, Owner, stated that he was the most responsible individual at the firm regarding horse sales. Mr. Andio explained that he handles all horse purchases, sales, and day-to-day operations. Mr. Andio is responsible for hauling horses to and from the farm, delivering horses intended for slaughter to (b) (6) maintains the sales ledger, and manages the financial aspects of the business. Mr. Ronald Andio has the duty, power and responsibility, and authority to prevent, detect, and correct violation(s).

Mrs. Patricia Andio, Co-Owner, is Mr. Ronald Andio's wife. Mrs. Andio is responsible for handling the administrative aspects of the business. Mrs. Andio is knowledgeable over all business operations and works closely with Mr. Andio on a day-to-day basis. Mrs. Andio also handles a majority of the horse resale and retail operations at the firm.

BUSINESS OPERATIONS

Horse Sales:

Ronald Andio, DBA Patron Farms, LLC is a dealer of horses. Horses are purchased from three different livestock auctions in Ohio: (b) (4) (b) (4) (b) (4) or from private sellers.

Horses that are purchased are hauled to the farm by the seller or picked-up and hauled by Mr. Andio. If the seller hauls the horse(s) to Mr. Andio's farm, the seller will drop the horse at the farm and pickup the payment check from the feed bin.

Horses are sold to individuals for leisure and work activities and to dealers. A few horses are sold at (b) (4) The remainder of horses are sold to (b) (6) of (b) (4) (b) (4) All horses that Ronald Andio sells to (b) (4) are intended for slaughter. These horses are exported to Canada for slaughter and account for approximately (b) of business at Ronald Andio, DBA Patron Farms, LLC.

Sales Documentation:

Mr. Andio stated that all payments for horse sales are made via check and are documented in a sales ledger book. This ledger lists the date, a description of the horse, purchase price, sale price, name of seller, name or number of buyer, and any profit made (see **EXHIBIT 1** for example). All sales of horses that are intended for slaughter, made to (b) (6) of (b) (4) are recorded on a sales receipt. This sales receipt lists the date, buyer's name, back tag number on horse applied by Mr. Andio's farm, a description of the horse, and the sale amount for each horse (see **EXHIBIT 3** for example).

Medication Status & Equine Identification Document (EID):

Mr. Andio stated that all horses that are purchased for slaughter must be accompanied by an Equine Information Document (EID). This is a Canadian document and is required for all horses that are exported to Canada intended for slaughter. This form asks the owner of the horse whether the horse being offered for sale was medicated while in their possession. The form requires that the owner of the horse sign the form, guaranteeing the information provided is true.

Mr. Andio stated he does not verbally ask the seller of any of the horses that he purchases whether the horse has been medicated. For horses intended for slaughter, Mr. Andio stated that some of the owners will provide a completed Equine Identification Document (EID), a Canadian required form, with a signature certifying the owner had not medicated the horse.

Mr. Andio stated that if a seller hauls and drops a horse at his farm and does not leave an EID with the horse, it is routine for him to fill out the EID for the seller with information regarding the horse. Mr. Andio stated that while he completes the EIDs from time to time for the seller, he believed that all sellers of horses that are intended for slaughter had filled out the EID themselves at one point. Mr. Andio stated that if the seller does not personally fill out the EID and sign it, they are aware that Mr. Andio fills it out and signs on their behalf and recognize that the signature certifies that they (the horse owner) have not treated the horse.

Business with (b) (6)

Mr. Andio stated that (b) (6) is one individual whom his business purchases horses from. Mr. Andio stated that he began business with (b) (6) approximately 2 years ago, and that it was his understanding that (b) (6) is involved in racehorses.

On 04/03/2012, Mr. Andio approximated that during the last two years, (b) (6) has sold his business approximately (b) horses. On 04/05/2012, Mr. Andio provided me with his business sales ledgers for the last three years. Mr. Andio provided me with these records to photograph; however, he requested that all non-essential information be redacted for privacy. Reacted photographs of these sales records are attached as **EXHIBIT 1**. Based on the sales ledgers, Mr. Andio stated that he actually began doing business with (b) (6) in 07/2009. Mr. Andio also stated that since 07/2009, (b) (6) had actually sold his business a total of (b) horses (b) mares, (b) gelding). Mr. Andio stated that all (b) horses that were sold by (b) (6) were sold to (b) (4) (b) (4) to be sent to slaughter in Canada.

Mr. Andio stated that he believed that all horses sold to him by (b) (6) were sold with (b) (b) (6) understanding that the horses may go to slaughter. Mr. Andio also stated that (b) (b) (6) does not always complete an EID for all horses sold. Mr. Andio additionally stated that he believed that (b) (6) was aware that Mr. Andio would complete the EID on (b) (b) (6) behalf, with the best information available to him.

MEDICATIONS

I asked Mr. Ronald Andio if he medicated animals prior to sending them to slaughter. Mr. Andio stated that all medications on the farm are kept in their tack room. Mr. Andio stated these medications, including antibiotics, are only given to horses intended for retail and to their personally owned horses. Mr. Andio stated that his family owns 4 horses that are located onsite. At the time of the inspection Mr. and Mrs. Andio showed me the medication storage area in the tack room. Mr. and Mrs. Andio stated that they may have Phenylbutazone or Clenbuterol onsite from time to time for use in their personal horses. There was no Phenylbutazone or Clenbuterol onsite at the time of the inspection.

Mr. Andio stated that it is his policy that horses intended for slaughter are not medicated while in their possession. Mr. Andio also stated that they do not keep treatment records because the horses medicated are not intended for slaughter.

ANIMAL IDENTIFICATION

Mr. Ronald Andio, Owner, stated that all horses that are intended for slaughter receive a back tag at his farm before being hauled to (b) (4) Horses that are sold for resale or retail do not receive identification at Mr. Andio's farm.

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

VETERINARY CLIENT PATIENT RELATIONSHIP

Ronald Andio, DBA Patron Farms, LLC uses the veterinary services of (b) (6) and (b) (6) (b) (6) of (b) (4) and (b) (6) (b) (6) of (b) (4).

One of the veterinarians from (b) (4) visits the farm on a yearly basis and as needed. During these visits, the veterinarian performs horse health checks on horses intended for retail and personally owned horses. The veterinarian will also address any other health concerns that arise. Mr. Andio stated specifically that (b) (6) is a lameness specialist. Mr. and Mrs. Andio haul lame horses intended for retail sales as well as their personal horses to (b) (4) for care.

Mr. Andio stated that none of the veterinarians from (b) (4) medicate any of the horses intended for slaughter while on the farm. Mr. Andio also stated that horses intended for slaughter are not treated by (b) (6) of (b) (4)

TISSUE RESIDUE

I visited Ronald Andio, DBA Patron Farms, LLC to follow up on a violative tissue residue in a horse. According to the official letters from the Canadian Food Inspection Agency (CFIA) and the United States Department of Agriculture – Food Safety and Inspection Service (USDA-FSIS), a horse with identifying tag numbers 979, 9491, and 249 was slaughtered at (b) (4) (b) (4) on 8/23/2011 (**ATTACHMENTS 4 & 5**). This horse was sampled under the CFIA's National Chemical Residue Monitoring Programs and was found to contain 0.0039ppm of Clenbuterol in the eye, and 0.0025ppm and 0.026ppm of Phenylbutazone in the muscle and kidney, respectively (**ATTCHMENT 4, PAGE 1**). There is no allowable tolerance for either Clenbuterol or Phenylbutazone.

Mr. Ronald Andio and Mrs. Patricia Andio provided me with the following information regarding the horse in question:

On 8/19/2011, Ronald Andio, DBA Patron Farms, LLC purchased one (1) horse from (b) (6) (b) (6) This purchase is documented in Mr. Andio's sales ledger for 8/20/2011 (**EXHIBIT 1, PAGE 22**). Mr. Andio explained that he filled in the information in the sales ledger the day after the purchase.

Please Note: The sales ledger written by Mr. Ronald Andio documents the horse seller's name to be spelled as '(b) (6) The actual spelling of the seller's name is '(b) (6) I will refer to the seller by the actual spelling of his name (b) (6) unless noted otherwise.

Mr. Andio stated that the horse he purchased from (b) (6) on 8/19/2011 was a bay thoroughbred gelding (**EXHIBIT 1, Page 22**). This horse was purchased for (b) (4) Mr. Andio provided me with a copy of his check receipt # 7809, dated 8/19/11, written to (b) (6) for (b) (4) for one (1) horse (**EXHIBIT 2**). Mr. Andio stated that he was unable to recall the way in which this horse was hauled to his farm. Mr. Andio stated that the horse may have been hauled to his farm by (b) (6) or by another individual.

Mr. Andio stated that (b) (6) did not provide a completed EID for the horse when the animal was hauled/ dropped off. Mr. Andio stated that he personally filled out the EID with information that he believed was true to the best of his knowledge. The EID identified (b) (6) (b) (6) (b) (4) as the owner of the horse from 8/10/2010 - 8/19/2011. Mr. Andio stated that he filled out the top portion of the EID, the owner's portion, for (b) (6) Mr. Andio stated that he estimated the time the horse was in (b) (6) possession, under "Owner Declaration" on the EID, to be about one year. Mr. Andio stated that then signed (b) (6) name on the document. A copy of this EID was provided to me by the CFIA on 4/04/2012 and is included in this report as **ATTACHMENT 6.**

Mr. Andio stated that on 8/20/2011, he sold a total of (b) horses to (b) (6) of (b) (4) (b) (4) This sale is documented on sales receipt # 681036, dated 8/19/2011 (**EXHIBIT 3**). Mr. Andio stated that while the sales receipt lists the date of "8/19/11", the actual date of the sale to (b) (4) was 8/20/11. The horse with back tag 979 was among the (b) horses that Mr. Andio sold to (b) (6) Mr. Andio stated that he sold horse 979 to (b) (6) on 8/20/2011 for $375.00. The load of (b) head of horses was sold to (b) (6) on 8/20/2011 for (b) (4) All (b) horses were picked up and hauled by (b) (6) from a meeting point in (b) (4) to (b) (4) on 8/20/2011.

Mr. Andio stated that the Equine Information Document (EID) was provided to (b) (4) at the time of the sale of the horse with back tag 979. Mr. Andio stated that this document was provided to (b) (6) upon delivery of the horses at (b) (4) on 8/20/2011 (**ATTACHMENT 6**).

At the time of the inspection, I asked Mr. and Mrs. Andio if they were aware that a horse that had been slaughtered in Canada, which was purchased and sold by their business, had been determined to contain violative levels of tissue residues. Mr. Andio stated that sometime after January 2012, he had received a copy of a fax that was sent to (b) (6) from (b) (4) (b) (4) The fax consisted of a copy of the EID for horse with back tag 979, USDA ("export tag") 9491, serial # 249, load 171. Mr. Andio stated that the copy of the EID that he received from (b) (6) had "residue found" written on the paper with some initials. Mr. Andio stated that this fax was the only notification he received that a horse that had originated from his farm was positive for tissue residues. Mr. Andio stated that he may have mentioned the tissue residue to (b) (6) in passing at some point, but could not remember for certain.

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

At the time of the inspection, Mr. Andio stated that he was unable to locate the copy of the fax he had received from (b) (6) I showed Mr. Andio a copy of the EID for horse with back tag 979 and USDA tag 9491 that I had received from CFIA (ATTACHMENT 6). Mr. Andio stated that the EID that I showed him appeared to be identical to the copy of the EID that he sent with the horse to Bauer Farms on 8/20/2011. Mr. Andio stated that the only difference in the documents was that the EID he had received from (b) (6) had writing on the bottom from the slaughter facility.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Failure to inquire about the medication status of the animal(s) that you purchased and delivered for sale at a slaughter plant.

Specifically, you do not ask the medication status of the animals that you purchase from independent sellers that are later sent to slaughter.

You purchased a bay thoroughbred gelding (no identifying numbers) from (b) (6) on 08/19/2011. The animal received back tag 979 at your farm and was later sold to a slaughter facility on 08/22/2011 with USDA tag USHA-9491. This animal was slaughtered at (b) (4) on 08/23/2011.

There is no documentation to show that an inquiry was made to the seller regarding the medication status of the animal.

Reference: FDCA 402(a)(4)

Supporting Evidence and Relevance:

Mr. Ronald Andio, Owner, stated that he does not ask the medication status of the horses that he purchases for his business Ronald Andio, DBA Patron Farms, LLC. The horses Mr. Andio purchases include those intended for slaughter. Mr. Andio stated that horses that are intended to go for slaughter in Canada must be accompanied by an Equine Identification Document (EID). This Canadian form requires the owner to provide their information, photos of the horse, the time the horse was in the owner's possession, and asks whether the horse was medicated in the span of time by the owner.

Mr. Andio stated that he routinely completes the EIDs for the horse owners with information that he has available. Mr. Andio also stated that he signs the owner's name on the EID in place of the owner, certifying the information on the form is true. Mr. Andio stated, however, that he does not

ask the medication status of the animals he purchases. Mr. Andio maintains no documentation to show that an inquiry was made to the seller regarding the medication status of the animal.

Discussion with Management:

I discussed with both Mr. Ronald Andio, Owner and Mrs. Patricia Andio, Co-owner, that they are required to inquire the medication status of the animals that their business purchases from sellers that are sent to slaughter. I advised Mr. and Mrs. Andio that it is their responsibility to inquire and document whether the animal they are purchasing that is intended for slaughter has been medicated. I informed both Mr. and Mrs. Andio that if an animal has been medicated and has not met the appropriate withdrawal time, it must not go to slaughter for human consumption.

I also discussed with Mr. and Mrs. Andio that they had admitted to having knowledge that (b) (6) (b) (6) deals with racehorses. For example, through our discussion, Mr. Andio stated that he had written the note "Tracker" next to (b) (6) name in his Sales Ledger for 7/20/2009 to indicate tha (b) (6) was a "track guy" and dealt with racehorses (EXHIBIT 1, PAGE 1). I discussed with (b) (6) that they had additionally mentioned that Clenbuterol and Phenylbutazone are two drugs commonly used among racehorses. I advised Mr. Andio that there is no allowable tolerance in tissues for Clenbuterol and Phenylbutazone. Therefore, horses treated with either Clenbuterol and/or Phenylbutazone must not go to slaughter. I advised both Mr. and Mrs. Andio that it is illegal to knowingly ship medicated horses intended for slaughter for human consumption.

Mr. and Mrs. Andio stated that they understood all of the above information that I discussed with them. Mr. Andio stated that going forward, they will be verbally inquiring the medication status of the horses prior to purchase. Mr. Andio also stated that going forward they will be having the horse owner fill out the EID and sign the form themselves certifying the information on the form is true.

REFUSALS

No refusals were encountered during this inspection. Mr. and Mrs. Andio were cooperative throughout the duration of the inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Ronald Andio, Owner, and Mrs. Patricia Andio, Co-owner, were both present at the close of the inspection. Form FDA 483 (Inspectional Observations) was issued to Mr. Ronald A. Andio, Owner.

I discussed with Mr. Ronald Andio, Owner and Mrs. Patricia Andio, Co-owner, that they are required to ask the owners the medication status of the animals their business purchases for slaughter. I advised Mr. and Mrs. Andio that it is their responsibility to inquire and document

whether the animal they are purchasing, that is intended for slaughter, has been medicated. I informed both Mr. and Mrs. Andio that if an animal has been medicated and not met the appropriate withdrawal time, it must not go to slaughter.

As previously noted, Mr. and Mrs. Andio admitted that they knew that (b) (6) deals with racehorses (thoroughbreds). Mr. Andio stated that for the most part, all of the thoroughbred horses that he purchases are sold for slaughter because they do not make good leisure horses. As previously noted, Mr. and Mrs. Andio also mentioned that they knew that Clenbuterol and Phenylbutazone are two drugs commonly used among racehorses. I told Mr. Andio that according to his sales ledgers, all of the horses he purchased from (b) (6) since 2009 have been thoroughbreds. I advised Mr. Andio that if he knows that the thoroughbred horses (b) (6) sells him are former racehorses and that racehorses are commonly treated with Clenbuterol and Phenylbutazone, he is knowingly sending potentially treated horses to slaughter. I highlighted again that sending treated horses to slaughter for human consumption is illegal.

I also discussed with Mr. Andio that if he does not ask the owner about the horse's medication status, then he would not have any information regarding whether or not the horse was treated to truthfully fill out the EID. I told Mr. Andio that when he signs the owner's name on the EID, he is signing a document that provides a false guarantee that the horse was not treated, and he cannot continue such practice. I advised Mr. Andio that going forward he needed to have the owner of the horse complete the EID and have the owner sign the form themselves.

Mr. and Mrs. Andio stated that they understood all of the above information that I discussed with them. Mr. Andio stated that going forward, they will be verbally inquiring the medication status of all the horses prior to purchase. Mr. Andio also stated that going forward they will be having the horse owner fill out the EID sign the form themselves certifying the information on the form is true.

ADDITIONAL INFORMATION

An affidavit was signed and collected from Ronald A. Andio, Owner on 04/03/2012; a copy of the affidavit is attached to this report. The original affidavit is attached to Documentary Sample DOC 719823.

Please Note: There is an incorrect date on the Affidavit signed by Ronald A. Andio. On page 3, the last paragraph, the date "8/20/2012" should actually read "8/20/2011"; the date written on the affidavit is incorrectly written as 2012. The horses were sold to (b) (6) on 8/20/2011.

Establishment Inspection Report	FEI:	3009486627
Ronald Andio, DBA Patron Farms, LLC	EI Start:	04/03/2012
Canfield, OH 44406	EI End:	04/30/2012

SAMPLES COLLECTED

Documentary sample DOC 719823, consisting of affidavits, sale, purchase, and shipping records for the animal (horse) with identifying tags: 979, 9491, 279, was collected.

EXHIBITS COLLECTED

1.	Sales Ledger, Redacted to Show (b) (6) Horse Sales Only	22 Pages
2.	Ronald Andio Check # 7809, Dated 8/19/11	1 Page
3.	Ron Andio Sales Receipt # 681036, Dated 8/19/11	1 Page
4.	CD-R Containing Original Copies of Photographs	1 Page

ATTACHMENTS

1. FDA 482 (Notice of Inspection)
2. FDA 483 (Inspectional Observations)
3. FDA 463a (Affidavit) signed by Ronald A. Andio, Owner, Dated 04/03/2012
4. CFIA Letter to USDA and Report of Analysis, Dated 10/17/2011
5. USDA – FSIS Letter and Residue Information, Dated 10/17/2011
6. Equine Identification Document (EID)

Annemarie H. Cochran

Annemarie H. Cochran, Investigator

Exhibit C

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Christ S. King 4/11/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER
12-PHI-14

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 11, 2012

Mr. Christ S. King, Owner
54 7 Lenover Road
Parkesburg, Pennsylvania 19365

Dear Mr. King:

On March 7, 9, and 22, 2012, the U.S. Food and Drug Administration (FDA) conducted an investigation of your dairy operation located at 547 Lenover Road, Parkesburg, Pennsylvania 19365. This letter notifies you of the violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the Internet through links on FDA's web page at www.fda.gov [1].

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. § 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. § 360b.

Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about October 25, 2011, you sold a bob veal calf, identified with sales/back tag **(b)(4)** for slaughter as food. On or about October 26, 2011, **(b)(4),** slaughtered this animal. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from this animal on October 26, 2011, identified the presence of 89.980 parts per million (ppm) of sulfamethazine residue in the liver and 72.928 ppm in the muscle tissues. FDA has established a tolerance of 0.1 ppm for residues of sulfamethazine in the uncooked edible tissues of cattle as codified in Title 21, Code of Federal Regulations (C.F.R.), Section 556.670 (21 C.F.R. 556.670). However, FDA has not established a tolerance for the use of Sustain III Calf Bolus (Sulfamethazine sustained-release boluses, NADA #120-615, 8.02-gram) in the edible tissue of calves under one month of age or in calves being fed an all milk diet as codified in 21 C.F.R. 520.2260b. The presence of this drug in edible tissue from this animal in these amounts causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain treatment records. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4).

We also found that you adulterated the new animal drug Sustain III Calf Bolus (sulfamethazine sustained-release boluses, NADA #120-615, 8.02-gram). Specifically, our investigation revealed that you did not use Sustain III Calf Bolus as directed by its approved labeling. Use of this drug in this manner is an extralabel use. See 21 C.F.R. 530.3(a).

The extralabel use of approved animal or human drugs in animals is allowed under the FD&C Act only if the extralabel use complies with sections 512(a)(4) and (5) of the FD&C Act, 21 U.S.C. § 360b(a)(4) and (5), and 21 C.F.R. Part 530, including that the use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship.

Our investigation found that you administered Sustain III Calf Bolus (sulfamethazine sustained-release boluse NADA #20-615, 8.02-gram) to your bob veal calf identified with sales/back tag **(b)(4)** without following the animal class as stated on the approved labeling. Your extralabel use of Sustain III Calf Bolus was not under the supervision of a licensed veterinarian, in violation of 21 C.F.R. § 530.11 (a) and your extralabel use of Sustain III Calf Bolus resulted in an illegal drug residue, in violation of 21 C.F.R. § 530.11 (c). Because your use of this drug was not in conformance with its approved labeling and did not comply with 21 C.F.R. Part 530, you caused the drug to be unsafe under section 512(a) of the FD&C Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of section 501(a)(5) of the FD&C Act, 21 U.S.C. § 351(a)(5).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law. You should take prompt action to correct the violations

described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Robin M. Rivers, Compliance Officer, U.S. Food and Drug Administration, Room 900 U.S. Customhouse, 200 Chestnut Street, Philadelphia, Pennsylvania 19106. If you have any questions about this letter, please contact Ms. Rivers at (215) 717-3076 or E-mail at robin.rivers.@fda.hhs.gov .

Sincerely,

/S/

Kirk D. Sooter
District Director
Philadelphia District

Links on this page:

1. http://www.fda.gov

Links on this page:

1. http://www.fda.gov

Exhibit D

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Brouillette Farm, Inc. 6/11/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
Phone: (781) 587-7500

WARNING LETTER
CMS # 312860

VIA UPS Next Day Air

June 11, 2012

Ms. Waibel
Co-Owner
Brouillette Farm, Inc.
2443 Marvin Road
Richford, VT 05476-9562

Dear Ms. Waibel:

On April 17, 23 and May 17, 2012, the U.S. Food and Drug Administration (FDA) conducted an investigation of your dairy operation located at 2443 Marvin Road, Richford, VT, 05476. This letter notifies you of the violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the Internet through links on FDA's web page at www.fda.gov [1].

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. 360b. Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about January 23, 2012, you sold a cow, identified with state back tag **(b)(4)** for slaughter as food. On or about January 24, 2012 **(b)(4)** slaughtered this animal. United Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from this animal identified the presence of 3.34 parts per million (ppm) of flunixin in the liver tissue, and 0.0369 ppm in muscle. FDA has established a tolerance of 0.125 ppm for residues of flunixin in the liver tissues and 0.025 ppm in the muscle of cattle as codified in Title 21, Code of Federal Regulations, Section 556.286(b) (21 C.F.R. 556.286 (b). The presence of this drug in edible tissue from this animal in these amounts cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain drug treatment and drug inventory records. In addition, you lack an adequate system for assuring that expired drugs are discarded and not used. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction. You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter.

Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Karen Archdeacon, Compliance Officer, U.S. Food and Drug Administration, One Montvale A venue, Stoneham, MA 02180. If you have any questions about this letter, please contact Compliance Officer Karen Archdeacon at (781) 587-7491 or Email at karen.archdeacon@fda.hhs.gov.

Sincerely,

/s/

Mutahar S. Shamsi
District Director
New England District

cc:
Mr. Waibel
Co-Owner
Brouillette Farm, Inc.
2443 Marvin Road
Richford, VT 05476-9562

Vermont Agency of Agriculture
116 State Street
Montpelier, VT 05620

USDA/FSIS District Office
District 65
230 Washington Ave.
Albany, NY 12203

Links on this page:

1. http://www.fda.gov/

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1. http://www.fda.gov/

Exhibit E

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

John Malcore Livestock LLC 6/27/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

June 27, 2012

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 12 - 37

John J. Malcore
Owner
John Malcore Livestock, LLC
234 Rocky Road
Luxemburg, Wisconsin 54217-9501

Dear Mr. Malcore:

On February 28, March 17, and April 9, 2012, the Food and Drug Administration (FDA) conducted an investigation of your cattle operation located at 234 Rocky Road, Luxemburg, Wisconsin. This letter notifies you of violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the Internet through links on FDA's web page at www.fda.gov.

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. § 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. § 360b. Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about December 27, 2011, you sold a steer, identified with back tag **(b)(4)**, for slaughter as food. On or about December 27, 2011, **(b)(4)**, slaughtered this animal. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from this animal identified the presence of flunixin at 1.03 parts per million (ppm) in the liver. A tolerance of 0.125 ppm in the liver has been established for residues of flunixin in the edible tissues of cattle as codified in Title 21, **Code of Federal Regulations** (21 CFR), section 556.286 (21 CFR 556.286). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain complete treatment records. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4).

We also found that you adulterated the new animal drug **(b)(4)** (flunixin meglumine) Injectable Solution, ANADA **(b)(4)**. Specifically, our investigation revealed that you did not use the drug as directed by its approved labeling. Use of this drug in this manner is an extralabel use. See 21 CFR 530.3(a).

The extralabel use of approved animal or human drugs in animals is allowed under the FD&C Act only if the extralabel use complies with sections 512(a)(4) and (5) of the FD&C Act, 21 U.S.C. § 360b(a)(4) and (5), and 21 CFR Part 530, including that the use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship.

Our investigation found that you had illegally obtained and used several by-prescription-only animal drugs from **(b)(4)**. Having illegally obtained

these by-prescription-only animal drugs from an unlicensed layperson, your subsequent use of these products was without benefit of a valid prescription from a licensed veterinarian. One of the by-prescription-only animal drugs found on your farm was **(b)(4)** (flunixin meglumine) Injectable Solution, ANADA **(b)(4)**. Our investigation found that you administered the drug to a steer, identified with back tag **(b)(4)**, without following the route of administration as stated in the approved labeling. Your extralabel use of **(b)(4)** (flunixin meglumine) Injectable Solution, ANADA **(b)(4)**, was not under the supervision of a licensed veterinarian in violation of 21 CFR 530.11(a), and your extralable use resulted in an illegal drug residue, in violation of 21 CFR 530.11(d). Because your use of this drug was not in conformance with its approved labeling and did not comply with 21 CFR Part 530, you caused the drug to be unsafe under section 512(a) of the FD&C Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of section 501(a)(5) of the FD&C Act, 21 U.S.C. § 351(a)(5).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within 15 working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Timothy G. Philips, Compliance Officer, at the address on this letterhead. If you have any questions about this letter, please contact Mr. Philips at (612) 758-7133.

Sincerely,
/S/
Michael Dutcher, D.V.M.
Director
Minneapolis District

cc: Robert Ehlenfeldt, D.V.M.
State Veterinarian
WDA Division of Animal Health
P.O. Box 8911
Madison, WI 53708-8911

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U.S Department of **Health & Human Services**

Links on this page:

Exhibit F

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

McGovern Farm, Inc 6/28/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

WARNING LETTER
CMS # 318279

VIA UPS Next Day Air

June 28, 2012

Mr. Hugh E. McGovern
Owner
McGovern Farm, Inc.
383 Main Street
Dunstable, MA 01827-1804

Dear Mr. McGovern:

An investigation of your operation located in Dunstable, MA, by a Food and Drug Administration investigator on April 23 – June 08, 2012 confirmed a cow purchased and sold by you on or about July 26, 2011, for slaughter for human food to **(b)(4)**, was in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. 360b.

Specifically, our investigation revealed that on or about July 26, 2011, you sold a cow, identified with state back tag **(b)(4)** for slaughter as food. On or about July 27, 2011, **(b)(4)**, slaughtered this animal. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from this animal identified the presence of 0.47 parts per million (ppm) of Desfuoylceftiofur in the kidney tissue, and the presence of 0.153 ppm of Sulfadimethoxine in the liver tissue and 0.15 ppm in the muscle. FDA has established a tolerance of 0.4 ppm for residues of Desfuoylceftiofur in the kidney tissues of cattle as codified in Title 21, Code of Federal Regulations, Section 556.113(b) [21 C.F.R. 556.113(b)]. FDA has established a tolerance of 0.1 ppm of Sulfadimethoxine in the liver tissue and muscle of cattle as codified in Title 21, Code of Federal Regulations, Section 556.640(b) [21 C.F.R. 556.640(b)]. The presence of these drugs in edible tissue from this animal in these amounts cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii).

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction. The violations listed above are not intended to be an all-inclusive list. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. Implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
2. Implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and
3. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offer animals for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Karen Archdeacon, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180. If you have any questions about this letter, please contact Compliance Officer Karen Archdeacon at (781) 587-7491 or Email at karen.archdeacon@fda.hhs.gov.

Sincerely,

/S/

Mutahar S. Shamsi
District Director
New England District

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- Site Map
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10903 New Hampshire Avenue
Silver Spring, MD 20993
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U.S Department of **Health & Human Services**

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