The Veterinarian-Client-Patient Relationship (VCPR), Federal Prescribing & License/Liability Considerations

Kent D. McClure, DVM, JD

Associate Executive Vice President &
Chief Advocacy Officer

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Veterinary-Client-Patient Relationship

VCPR

- Operates in a very distinct manner from a physician-patient relationship
- Defined at both the Federal and State Level
  - Federal definitions supersede in a conflict
  - Veterinarians must comply with the federal VCPR definitions where they apply

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VCPR – Colorado

Colo. Rev. Stat. Ann. § 12-315-104

"Veterinarian-client-patient relationship" means that relationship established when:

(a) The veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the owner or other caretaker has agreed to follow the instruction of the veterinarian;

(b) There is sufficient knowledge of an animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal, which means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept; and

(c) The practicing veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.

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VCPR - Federal

- Federal Food Drug and Cosmetic Act / Regulations
- Federal Virus-Serum-Toxin Act / Regulations
- Horseracing Integrity and Safety Act / Regulations

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VCPR – FDA

21 CFR 530.3(i)

(1) Veterinarian has assumed the responsibility for making medical judgments and the client has agreed to follow the instructions of the veterinarian;

(2) Veterinarian has sufficient knowledge to make a general or preliminary diagnosis of the medical condition of the animal; and

(3) The practicing veterinarian is readily available for followup.

"Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of examination of the animal, and/or by medically appropriate and timely visits to the premises where the animals are kept."

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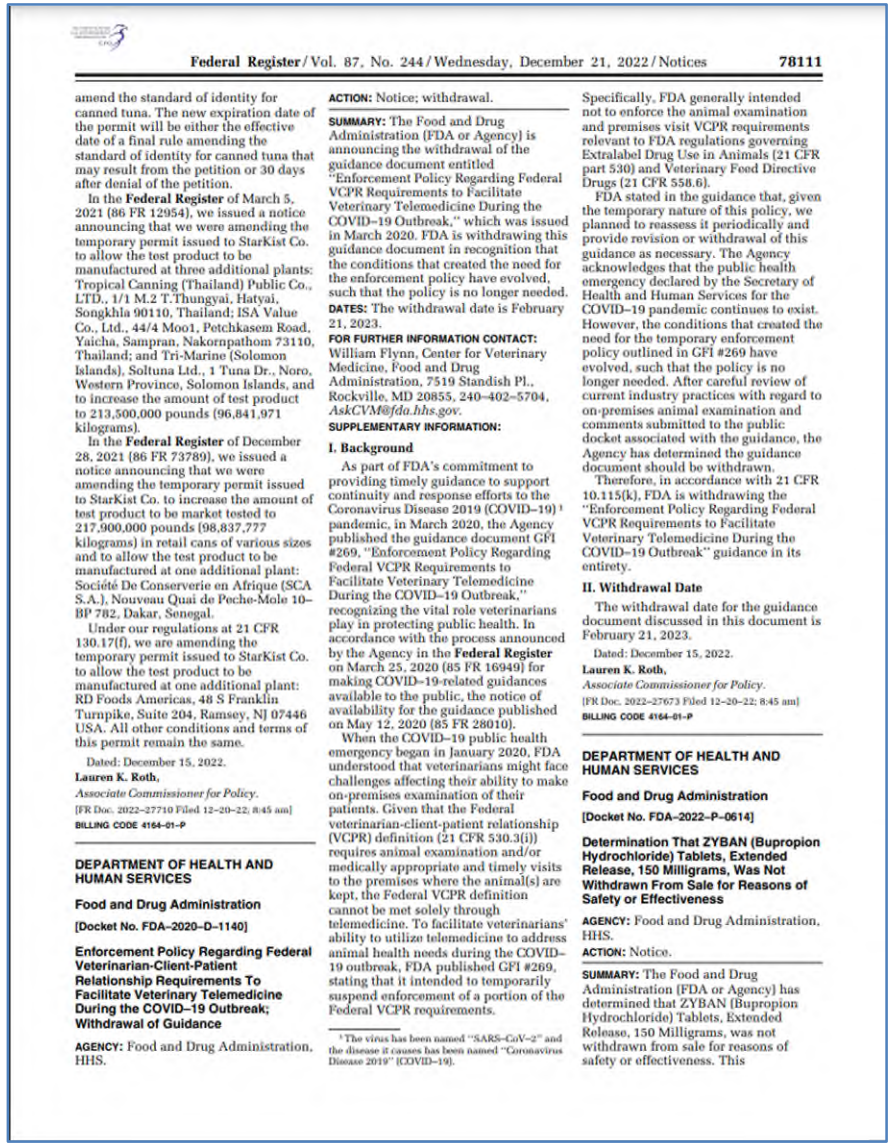
FDA – VCPR

87 Fed. Reg. 78111 (Dec. 21, 2022)

- "Given that the Federal veterinarian-client-patient relationship (VCPR) definition (21 CFR 530.3(i)) requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine."



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amend the standard of identity for canned tuna. The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for canned tuna that may result from the petition or 30 days after denial of the petition.

In the **Federal Register** of March 5, 2021 (86 FR 12954), we issued a notice announcing that we were amending the temporary permit issued to StarKist Co. to allow the test product to be manufactured at three additional plants: Tropical Canning (Thailand) Public Co., LTD., 1/1 M.2 T.Thungyai, Hatyai, Songkhla 90110, Thailand; ISA Value Co., Ltd., 44/4 Moo1, Petchkasem Road, Yaicha, Sampran, Nakornpathom 73110, Thailand; and Tri-Marine (Solomon Islands), Soltuna Ltd., 1 Tuna Dr., Noro, Western Province, Solomon Islands, and to increase the amount of test product to 213,500,000 pounds (96,841,971 kilograms).

In the **Federal Register** of December 28, 2021 (86 FR 73789), we issued a notice announcing that we were amending the temporary permit issued to StarKist Co. to increase the amount of test product to be market tested to 217,900,000 pounds (98,837,777 kilograms) in retail cans of various sizes and to allow the test product to be manufactured at one additional plant: Société De Conserverie en Afrique (SCA S.A.), Nouveau Quai de Peche-Mole 10–BP 782, Dakar, Senegal.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to StarKist Co. to allow the test product to be manufactured at one additional plant: RD Foods Americas, 48 S Franklin Turnpike, Suite 204, Ramsey, NJ 07446 USA. All other conditions and terms of this permit remain the same.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27710 Filed 12–20–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1140]

Enforcement Policy Regarding Federal Veterinarian-Client-Patient Relationship Requirements To Facilitate Veterinary Telemedicine During the COVID–19 Outbreak; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled "Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak," which was issued in March 2020. FDA is withdrawing this guidance document in recognition that the conditions that created the need for the enforcement policy have evolved, such that the policy is no longer needed.

DATES: The withdrawal date is February 21, 2023.

FOR FURTHER INFORMATION CONTACT: William Flynn, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5704, *AskCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, in March 2020, the Agency published the guidance document GFI #269, "Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak," recognizing the vital role veterinarians play in protecting public health. In accordance with the process announced by the Agency in the **Federal Register** on March 25, 2020 (85 FR 16949) for making COVID–19-related guidances available to the public, the notice of availability for the guidance published on May 12, 2020 (85 FR 28010).

When the COVID–19 public health emergency began in January 2020, FDA understood that veterinarians might face challenges affecting their ability to make on-premises examination of their patients. Given that the Federal veterinarian-client-patient relationship (VCPR) definition (21 CFR 530.3(i)) requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine. To facilitate veterinarians' ability to utilize telemedicine to address animal health needs during the COVID–19 outbreak, FDA published GFI #269, stating that it intended to temporarily suspend enforcement of a portion of the Federal VCPR requirements.

[1] The virus has been named "SARS-CoV–2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID–19).

Specifically, FDA generally intended not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals (21 CFR part 530) and Veterinary Feed Directive Drugs (21 CFR 558.6).

FDA stated in the guidance that, given the temporary nature of this policy, we planned to reassess it periodically and provide revision or withdrawal of this guidance as necessary. The Agency acknowledges that the public health emergency declared by the Secretary of Health and Human Services for the COVID–19 pandemic continues to exist. However, the conditions that created the need for the temporary enforcement policy outlined in GFI #269 have evolved, such that the policy is no longer needed. After careful review of current industry practices with regard to on-premises animal examination and comments submitted to the public docket associated with the guidance, the Agency has determined the guidance document should be withdrawn.

Therefore, in accordance with 21 CFR 10.115(k), FDA is withdrawing the "Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak" guidance in its entirety.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is February 21, 2023.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27673 Filed 12–20–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0614]

Determination That ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn from sale for reasons of safety or effectiveness. This

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Where does the FDA VCPR Apply?

ELDU (“Off-Label”)

- Any use of an FDA-approved human drug in animals, including over-the-counter (OTC) human drugs. 21 USC 360b(a)(5)
- Any use of an FDA-approved animal drug in any manner that differs from its approved labeling. 21 USC 360b(a)(4)
  - Includes: a different frequency of administration, different dose, different medical indication for use, different route of administration, or use in a different species.

Where does the FDA VCPR Apply?

VFDs & Compounded Drugs

Veterinary Feed Directives

- Authorization of a Veterinary Feed Directive. 21 USC 354; 21 CFR 558.6

Drugs Compounded from Bulk

- Use of drugs compounded from bulk active ingredients by veterinarians. FDA GFI# 256

These (ELDU, VFDs, Compounding) are very common occurrences in the day-to-day practice of veterinary medicine.

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Federal Food Drug & Cosmetic Act

Consequences of disregarding

Any particular use or intended use of an FDA-approved drug for animals that does not comply with the approved labeling or that does not follow the FDA VCPR requirements for ELDU or VFDs causes the **use** of the drug to be deemed unsafe and the drug adulterated by the Federal Food, Drug & Cosmetic Act. If the drug is in animal food/feed, then the feed is deemed unsafe and adulterated as well.

- Can be enforced by FDA
- Can be used in private civil litigation
- Can be used by state licensing boards for discipline

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Prescribing Requirements

Veterinary Medicine

21 USC 353(f)

- Veterinary prescription drugs are limited to use "under the professional supervision of a licensed veterinarian"
- "shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice."
- Dispensing in violation causes the drug to be deemed misbranded.

Human Healthcare

21 USC 353(b)

- Human prescription drugs are limited to use "under the supervision of a practitioner licensed by law to administer such drug."
- shall be dispensed only upon a written or oral prescription (or refill) of a "practitioner licensed by law to administer such ."
- Dispensing in violation causes the drug to be deemed misbranded

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Prescribing Implications

On-Label Use of an Animal Drug

- Must be under the professional supervision of a licensed veterinarian
- May only be dispensed by or on the order of a licensed veterinarian in the course of their professional practice

Off-Label Human or Animal Drug

- Requires physical examination by a licensed veterinarian or medically appropriate & timely visits to the premises where the animals are kept

Consequences

- Sale of misbranded drugs
- Sale of unsafe and adulterated drugs and animal feed
- Civil & Criminal penalties under the FDCA
- Civil Litigation & Disciplinary action by licensing boards

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Insurance & Liability

- Claims involving telemedicine / electronic interactions

- Unresolved Insurance concerns - MLP
  - Employee vs. Supervision
  - Would a MLP be assisting the veterinarian in the delivery of professional care or would the veterinarian be supervising someone else delivering care
  - Strict liability on the part of the supervising veterinarian

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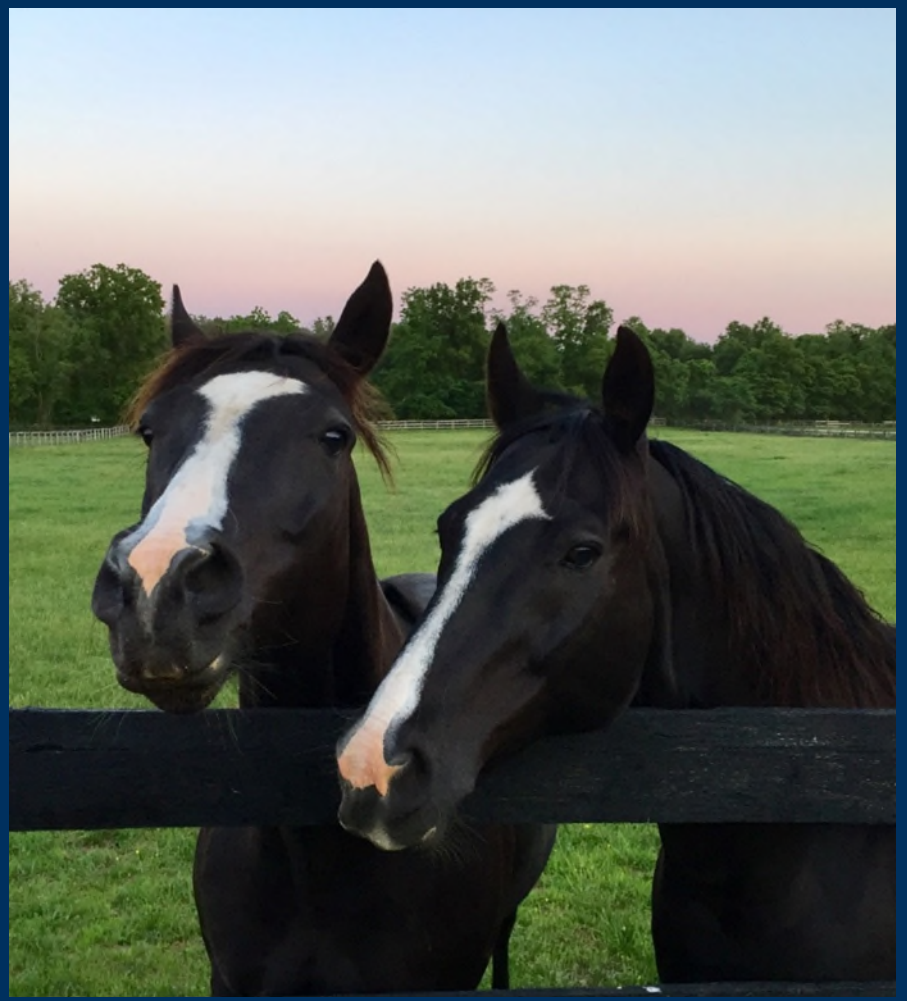
Questions?



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