

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.

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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