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

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

determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Michelle Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0374, *Michelle.Weiner@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but it must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is the subject of NDA 020711, held by GlaxoSmithKline LLC, and initially approved on May 14, 1997. ZYBAN is indicated as an aid to smoking cessation treatment.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Yichang Humanwell Pharmaceutical Co., Ltd. submitted a citizen petition dated April 18, 2022 (Docket No. FDA–2022–P–0614), under 21 CFR 10.30, requesting that the Agency determine whether ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27647 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR must be received no later than January 20, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx—New.

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (section 330H of the Public Health Service Act) and funded through HRSA, has the goal of reducing disparities in