

Dated: December 16, 2022.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Child Care and Development Fund (CCDF) Consumer Education Website and Reports of Serious Injuries and Death

AGENCY: Office of Child Care, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Office of Child Care (OCC), Administration for Children and

Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a 3-year extension of the CCDF Consumer Education website and Reports of Serious Incidents and Death (Office of Management and Budget (OMB) #: 0970-0473, expiration date: April 30, 2023). There are no changes requested to the reporting requirements.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The existing Consumer Education website reporting requirement will not be modified and requires states and territories to include

information about state or territory policies (related to licensing, monitoring, and background checks) and provider-specific information, including results of monitoring and inspection reports and, if available, information about quality. The existing Reporting of Serious Injuries and Death reporting requirement will not be modified. CCDF Lead Agencies must establish procedures that require child care providers that care for children receiving CCDF subsidies to report to a designated state, territorial, or tribal entity any serious injuries or deaths of children occurring in child care. There are no standard federal forms associated with these reporting requirements.

Respondents: The Consumer Education website information collection requirement applies to the 50 states, the District of Columbia, and 5 territories that receive CCDF grants. Reporting of Serious Injuries and Death is a requirement for child care providers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Consumer Education Website	56	1	300	50,400	16,800
Reporting of Serious Injuries and Death	10,000	1	1	30,000	10,000

Estimated Total Annual Burden Hours: 26,800.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Pub. L. 113-186; 42 U.S.C. 9858 *et seq.*

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-P-1189]

Canned Tuna Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is amending StarKist Co.'s temporary permit to market test canned tuna. The temporary permit is amended to add one additional manufacturing location. This amendment will allow the applicant to continue to test market and collect data on consumer acceptance of the test product.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 2014 (79 FR 35362), we issued a notice announcing that we had issued a temporary permit to StarKist Co., 225 North Shore Dr., Pittsburgh, PA 15212, to market test products identified as canned tuna products. The permit allowed for the test product to be manufactured at Galapesca S.A., Km. 12.5 Via A Duale, Guayaquil, Ecuador, and StarKist Samoa Co., 368 Atu'u Rd., Pago Pago, American Samoa 96799. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned tuna in 21 CFR 161.190, which was issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of March 7, 2016 (81 FR 11813), we issued a notice announcing that we were extending the temporary market permit issued to StarKist Co., among other parties. The extension allows the applicants to continue to measure consumer acceptance of the products and assess the commercial feasibility of the products, in support of a petition to

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.

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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