DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1189]

Canned Tuna Deviating From Identity Standard: Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the extension of temporary permits issued to Bumble Bee Foods, LLC; Chicken of the Sea International; and StarKist Seafood Company (the applicants) to market test products (designated as ''canned tuna'') that deviate from the U.S. standard of identity for canned tuna. 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. We also invite other interested parties to participate in the market test.

DATES: 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.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17, we issued temporary permits to Bumble Bee Foods, LLC, 9655 Granite Ridge Dr., San Diego, CA 92123; Chicken of the Sea International, 9330 Scranton Rd. Suite 500, San Diego, CA 92121; and StarKist Seafood Company, 225 North Shore Dr., Pittsburgh, PA 15212, to market test products identified as ''canned tuna'' that deviate from the requirements of the standard of identity for canned tuna in 21 CFR 161.190 (79 FR 35362, June 20, 2014). We issued the permits to facilitate market testing of products that deviate from the requirements of the standard of identity for canned tuna issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate marketing tests of products identified as ''canned tuna.'' These test products deviate from the U.S. standard of identity for canned tuna (§ 161.190) in that they are labeled without the statement ''Below Standard in Fill'' as required in § 161.190(c)(4) and § 130.14(b). The test products meet all the requirements of the standard with the exception of this deviation.

On September 3, 2015, the applicants asked us to extend the temporary permit so they could have more time to market test the canned tuna products and gain additional consumer acceptance in support of the petition to amend the standard for canned tuna. We find that it is in the interest of consumers to extend the permit for the market testing of canned tuna to gain additional information on consumer expectations and acceptance. Therefore, under § 130.17(i), we are extending the temporary permits granted to Bumble Bee Foods, LLC (141,000,000 pounds (lbs) (63,800,905 kilograms (kgs))); Chicken of the Sea International (77,500,000 lbs (35,067,873 kgs)); and StarKist Seafood Company (182,500,000 lbs (82,579,185 kgs)) to provide continued market testing of the specified amounts of product for each applicant on an annual basis. The test products will bear the name ''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. All other conditions and terms of this permit remain the same.

In addition, we invite interested persons to participate in the market test under the conditions of the permit, except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Supervisor, Product Evaluation Labeling Team, Food Labeling and Standards Staff, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must describe the test products and the area of distribution, specify and justify the amount requested, and include the labeling that will be used for the test product (*i.e.,* a draft label for each size of container and each brand of product to be market tested) (see § 130.17(c)). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by 21 CFR part 101.

Dated: March 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0544 (formerly 2004D–0487)]

A Dietary Supplement Labeling Guide: Chapter II. Identity Statement; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised guidance for industry entitled ''A Dietary Supplement Labeling Guide: Chapter II. Identity Statement.'' This guidance is part of a longer guidance entitled ''A Dietary Supplement Labeling Guide,'' which covers the most frequently raised questions about the labeling of dietary supplements using a question and answer format and is intended to help ensure that the dietary supplements sold in the United States are properly labeled. We are revising the guidance to correct an inaccurate statement.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*