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Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity: Guidance for Industry

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For questions regarding this document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

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Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to clarify, for the food industry, aspects of the application process for temporary marketing permits (TMPs). This guidance also describes a change that simplifies the label review process. It will streamline and improve the efficiency of the TMP application process. This guidance is intended to help the industry better understand and utilize the TMP application process.

This guidance is a part of FDA's efforts to support innovation in the food marketplace to help ensure consumers have access to healthier food choices. One way FDA is working to support this goal is by updating standards of identity (SOIs) and identifying new ways to streamline SOI-related processes, such as the TMP application process, to provide additional clarity and flexibility to encourage industry to innovate and produce healthier foods.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling, Division of Food Labeling and Standards in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

The Federal Food, Drug, and Cosmetic Act gives FDA the authority to establish definitions and standards for foods with respect to identity, quantity, and fill of container.[2] We establish definitions and standards by regulation under a food's common or usual name. We may, among other things, establish SOIs. We have established more than 280 SOIs.[3] They typically set forth permitted ingredients, both mandatory and optional, and sometimes describe the amount or proportion of each ingredient. Many SOIs also prescribe a method of production or formulation. SOIs are intended to protect consumers against economic adulteration, maintain the integrity of food, and reflect consumers' expectations about the food.

Foods for which FDA has established an SOI must conform to the applicable standard.[4] We permit manufacturers to market test products that deviate from the applicable SOI so they may conduct research and obtain data to support a petition to amend food standards. FDA recognizes that, before industry submits a petition to amend a food standard, appropriate investigations of potential advances in food technology may require product testing in interstate markets.[5] Manufacturers who want to obtain a permit to market test food products that deviate from the established SOIs may apply for a TMP (e.g., TMPs were granted to market test a new cacao product[6] and to market test a preservative in certain cheese products[7]). This product testing may help to determine consumer acceptance of foods varying from applicable SOIs.

The TMP application requirements are outlined in 21 CFR 130.17(c). The initial TMP is effective for 15 months. However, FDA may provide for a longer test period.[8] To request a longer test period, applicants must provide a detailed explanation of why a 15-month period is inadequate.[9]

III. Discussion

FDA is modernizing existing food SOIs. Our goals are to promote industry innovation and provide flexibility to manufacturers, in part to produce more healthful foods, while protecting consumers against economic adulteration, maintaining the basic nature, essential characteristics, and nutritional integrity of food.

[2] 21 U.S.C. 341.
[3] See 21 CFR Chapter I, Subchapter B for specific food standards.
[4] 21 U.S.C. 343(g) and 21 CFR 130.8.
[5] 21 CFR 130.17(a).
[6] 84 FR 64541 (November 22, 2019).
[7] 85 FR 80118 (December 11, 2020).
[8] 21 CFR 130.17(b).
[9] 21 CFR 130.17(c)(10).

In September 2019, we hosted a public meeting titled "Horizontal Approaches to Food Standards of Identity Modernization."[10] We also reopened for comment a 2005 proposed rule on "Food Standards; General Principles and Food Standards Modernization."[11] These activities were intended to give stakeholders an opportunity to discuss our effort to modernize food SOIs and provide information about changes we could make to existing standards, to facilitate innovation and provide flexibility for the development of healthier foods. In both forums, the comments asserted that the current TMP application process is inefficient. They suggested that the SOI process disincentivizes the use of technology and innovative ingredients. The comments suggested ways FDA could increase flexibility and promote innovation through the TMP process. We considered the comments and developed this guidance to clarify and improve efficiency of the TMP application process.

IV. Questions and Answers

Temporary Marketing Permit (TMP) Application Process

1. Can a TMP apply to more than one standardized food?

Yes. FDA permits multiple standardized foods to be included on a single TMP application. So, multiple SOIs can be listed on the application.

For example, FDA issued a TMP to allow market tests of cheese products that deviated from multiple SOIs for specific standardized cheese and related products.

2. Can multiple companies jointly submit an initial TMP application? Can a trade association, law firm or other representative submit a TMP application on behalf of multiple companies?

Yes. Multiple companies may jointly submit a TMP application, provided the requested deviation(s) are the same. Similarly, a trade association, law firm or other representative can apply on behalf of multiple companies for the same initial TMP. We will issue the TMP response letter to each company individually, rather than to the trade association, law firm, or other representative.

For example, FDA issued a TMP to the companies that jointly submitted an initial TMP application for canned tuna. A law firm submitted the initial TMP application on behalf of the companies. The TMP was issued to each individual company.

TMP Test Period

3. Can the test period for an initial TMP be longer than 15 months?

Yes. Our regulation specifies that the test period is normally 15 months.[12] The regulation also states that FDA may provide for a longer test market period if the applicant shows good

[10] 84 FR 45497 (August 29, 2019).
[11] 85 FR 10107 (February 21, 2020).
[12] 21 CFR 130.17(b).

cause.[13] Additionally, § 130.17(c)(10) requires an applicant to include a detailed explanation of why a 15-month period is inadequate, if they request a test period of longer than 15-months. An applicant may request a different market test period, in their initial TMP application, for a variety of reasons (e.g., to test seasonal products, to gather more data, and to accommodate lengthy manufacturing or distribution processes that impact availability of test products).

After a TMP is granted, an applicant may apply for an extension of the permit, if they determine a longer test period is necessary.[14]

Label Review

4. Can a TMP application include a single representative label instead of a label for every stock keeping unit (SKU) contemplated under the TMP?

Yes. An applicant can submit one proposed label for the food to be market tested.

Our regulation at 21 CFR 130.17(c)(9) requires an applicant to submit the proposed label or an accurate draft for the food to be market tested. Some applicants interpret this to include labels for all affected SKUs. Currently, an applicant submits copies of the proposed labels in triplicate to FDA.

We are clarifying that an applicant can submit one proposed label for the food to be market tested. For example, if the applicant has several individual labels for a food sold in different product sizes (bulk, multipack, family size, etc.), one proposed label can be submitted for FDA review with the TMP application. If there are multiple standardized foods listed on the TMP application, one proposed label should be submitted for each food to be market tested. Applicants are responsible for ensuring that all labels of foods to be market tested comply with our food labeling regulations at 21 CFR part 101 and provide a means for the consumer to distinguish between the food being tested and the standardized food.[15]

V. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 130.17 have been approved under OMB control no. 0910-0133.

[13] Id.
[14] 21 CFR 130.17(i).
[15] 21 CFR 130.17(c)(9).