

§ 130.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(a) The Food and Drug Administration recognizes that before petitions to amend food standards can be submitted, appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of experimental packs of food varying from applicable definitions and standards of identity prescribed under section 401 of the act.

(b) It is the purpose of the Food and Drug Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards, that the tests are necessary to the completion or conclusiveness of an otherwise adequate investigation, and that the interests of consumers are adequately safeguarded; permits for such tests shall normally be for a period not to exceed 15 months. The Food and Drug Administration, or good cause shown by the applicant, may provide for a longer test market period. The Food and Drug Administration will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Food and Drug Administration providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity. The test period will begin on the date the person holding an effective permit from the Food and Drug Administration introduces or causes the introduction of the food covered by the permit into interstate commerce but not later than 3 months after notice of the issuance of the permit is published in the FEDERAL REGISTER. The Food and Drug Administration shall be notified in writing of the date on which the test period begins as soon as it is determined.

(c) Any person desiring a permit may file with the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-822), 5100 Paint Branch Pkwy., College Park, MD 20740, a written application in triplicate containing as part thereof the following:

(1) Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and nondeleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers. The statement shall include the reasons why the applicant does not consider the data obtained in any prior investigations which may have been conducted sufficient to support a petition to amend the standard.

(9) The proposed label (or an accurate draft) to be used on the food to be marketed. The label shall conform in all respects to the general requirements of the act and shall provide a means whereby the consumer can distinguish between the food being tested and such food complying with the standard.

(10) The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the

need for such period. If a period longer than 15 months is requested, a detailed explanation of why a 15-month period is inadequate shall be provided.

(11) The probable amount of such food that will be distributed. The amount distributed should be limited to the smallest number of units reasonably required for a bona fide market test. Justification for the amount requested shall be included.

(12) The areas of distribution.

(13) The address at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Food and Drug Administration may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Food and Drug Administration concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403(g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Food and Drug Administration may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Food and Drug Administration or upon application of the permittee during the effective period of the permit.

(g) The Food and Drug Administration may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Food and Drug Administration concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the FEDERAL REGISTER stating that fact. The notice will include an invitation to all interested persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the FEDERAL REGISTER granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market test shall notify the Food and Drug Administration in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the FEDERAL REGISTER.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related

records are available for public disclosure when the notice of a permit or extension thereof is published in the FEDERAL REGISTER. Such disclosure shall be in accordance with the rules established in part 20 of this chapter.

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 46 FR 37500, July 21, 1981; 54 FR 24892, June 12, 1989; 59 FR 15051, Mar. 31, 1994; 66 FR 17359, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001]

Subpart B—Food Additives in Standardized Foods

§ 130.20 Food additives proposed for use in foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in part 171 of this chapter shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in part 171 of this chapter.

PART 131—MILK AND CREAM

Subpart A—General Provisions

Sec.

131.3 Definitions.

131.25 Whipped cream products containing flavoring or sweetening.

Subpart B—Requirements for Specific Standardized Milk and Cream

- 131.110 Milk.
- 131.111 Acidified milk.
- 131.112 Cultured milk.
- 131.115 Concentrated milk.
- 131.120 Sweetened condensed milk.
- 131.125 Nonfat dry milk.
- 131.127 Nonfat dry milk fortified with vitamins A and D.
- 131.130 Evaporated milk.
- 131.147 Dry whole milk.
- 131.149 Dry cream.
- 131.150 Heavy cream.
- 131.155 Light cream.
- 131.157 Light whipping cream.
- 131.160 Sour cream.
- 131.162 Acidified sour cream.
- 131.170 Eggnog.
- 131.180 Half-and-half.
- 131.200 Yogurt.
- 131.203 Lowfat yogurt.
- 131.206 Nonfat yogurt.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14360, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 131 appear at 63 FR 14035, Mar. 24, 1998.

Subpart A—General Provisions

§ 131.3 Definitions.

(a) *Cream* means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) *Pasteurized* when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):