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State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

May 9, 2018

REGULATORY ALERT 2018-02

NOTICE OF PROPOSED CHANGES TO THE CALIFORNIA WIC PROGRAM

Purpose

For the California Department of Public Health (CDPH) to inform stakeholders of the California Special Supplemental Nutrition Program for Women, Infants, and Children (WIC Program) of CDPH's plan to amend California WIC Authorized Food List WIC Bulletin Regulations section 82600, pursuant to Health and Safety Code Section 123322.

Stakeholder Workgroup Information

In accordance with Health and Safety Code section 123322, CDPH will meet with stakeholders by webinar on May 22, 2018 to receive input on the amendments to the WIC Authorized Food List Infant Formula regulations. If you are interested in participating in this stakeholder workgroup, please send an e-mail by close of business on May 15, 2018 with the subject line reading "Infant Formula Amendments Stakeholder RSVP" to WICRegulations@cdph.ca.gov, with the following information included in the body of the e-mail:

Name:

Company Name (if applicable):

Address:

E-mail Address:

Stakeholder Group Represented: (Stakeholders can include, but are not limited to: currently authorized WIC vendors, owners or representatives of a non-WIC authorized store, manufacturers, WIC Local agency representatives, WIC participants, advocates, and consumer groups)

CDPH will contact you by May 17, 2018 with details on how and when to attend a webinar workgroup meeting. Stakeholders participating in a meeting will be assigned to the first available meeting.

Comment Period

CDPH will accept written comments from stakeholders regarding the adoption of the proposed action. The comment period will be open for 20 calendar days, from May 10, 2018 through May



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30, 2018. Send your comments electronically to the following e-mail address:

WICRegulations@cdph.ca.gov.

If this proposed action is not withdrawn, CDPH will publish its final action, including responses to the comments received, on its website no later than 120 days after the end of the comment period.

Proposed Regulation

The California Department of Public Health, which administers the California WIC Program, proposes to amend the following rules in California regulation via regulatory bulletin.

Article 5. WIC Authorized Food List

82600 WIC Authorized Food List: Infant Formula

(a) Infant Formula Category

- (1) Authorized infant formula shall be selected and prescribed for a participant by a competent professional authority. Participants may only purchase the brand, type (physical form), size, and number of prescribed cans printed on their food instrument(s).
- (2) Contract Formula
 - (A) Authorized contract infant formula must meet the requirements in 7 Code of Federal Regulations part 246.10(e)(12), table 4 (2015), and is selected through a competitive bidding process. The list of the current contract formulas can be found at:
http://www.cdph.ca.gov/programs/wicworks/Documents/WICFoods/Formula_Flyer_English.pdf
<https://www.cdph.ca.gov/Programs/CFH/DWICSN/CDPH%20Document%20Library/WICFoods/FormulaFlyerEn.pdf>.
- (3) Non-Contract Formula
 - (A) Non-contract brand infant formula is all infant formula that is not covered by an infant formula cost containment contract awarded by the State agency. Non-contract brand formula may only be issued in food package III for participants with qualifying conditions with medical documentation pursuant to 7 Code of Federal Regulations part 246.10(d)(1)(i) (2015).
- (4) The following types of infant formula are never authorized for purchase as part of the Infant Formula Category:
 - (A) Low iron or no iron formula.

Nature of the Regulation

CDPH proposes amendment of the WIC Authorized Food List Bulletin Regulations for Infant Formula as set forth in Attachment 1 of this notice. This proposed regulation would amend the existing Infant Formula regulations to update the web address of the list of current contract formulas.

Reason for the Regulation

The reasons for this amendment are included in Attachment 1 of this notice.

Authority

Federal:

The Child Nutrition Act of 1966, title 42 of the United States Code, section 1786 (Public law 89-645, Section 17), as amended, establishes the federal authority under which states may administer the Special Supplemental Nutrition Program for Women, Infants, and Children through local agencies. The WIC Program was established as a result of a Congressional finding that substantial numbers of pregnant, postpartum and breastfeeding women, infants and young children up to the age of 5 from families with eligible income are at special risk with respect to their physical and mental health by reason of inadequate nutrition or health care, or both. The purpose of the WIC Program is to provide supplemental foods and nutrition education. In fulfilling this objective, the WIC Program is funded and administered by the United States Department of Agriculture (USDA), Food and Nutrition Service, pursuant 7 Code of Federal Regulations, part 246.

The WIC Program is also subject to federal memoranda and directives from USDA.

State:

The WIC Program was established under the authority of Health and Safety Code section 123275 et seq. The regulations for CDPH's administration of the WIC Program are contained in the California Code of Regulations, title 22, sections 40601 through 40815, and in the WIC Regulatory Bulletins posted at:

<https://www.cdph.ca.gov/Programs/CFH/DWICSN/Pages/LawsandRegulations.aspx>.

Questions and Additional Information:

If you have any questions, please contact CDPH at WICRegulations@cdph.ca.gov.



Catherine Lopez, M.Ed.
Policy and Planning Branch Chief
Women, Infants and Children Division
California Department of Public Health

Attachment 1

WIC Authorized Food List Infant Formula Amendments and Statement of Reasons

California Special Supplemental Nutrition Program for Women, Infants, and Children

May 9, 2018

Health & Safety Code § 123322 authorizes the California Department of Public Health to establish regulations regarding the authorized foods for the California Special Supplemental Nutrition Program for Women, Infants, and Children using a regulatory bulletin process. The Department is utilizing this process to adopt these regulations. This document is intended to provide reasons why the Department proposes to amend WIC Authorized Food List Bulletin Regulations for Infant Formula as specified in Regulatory Alert 2018-02.

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82600 WIC Authorized Food List: Infant Formula

PROPOSED REGULATION

- (a) Infant Formula Category
 - (1) Authorized infant formula shall be selected and prescribed for a participant by a competent professional authority. Participants may only purchase the brand, type (physical form), size, and number of prescribed cans printed on their food instrument(s).
 - (2) Contract Formula
 - (A) Authorized contract infant formula must meet the requirements in 7 Code of Federal Regulations part 246.10(e)(12), table 4 (2015), and is selected through a competitive bidding process. The list of the current contract formulas can be found at:
http://www.cdph.ca.gov/programs/wicworks/Documents/WICFoods/Formula_Flyer_English.pdf
<https://www.cdph.ca.gov/Programs/CFH/DWICSN/CDPH%20Document%20Library/WICFoods/FormulaFlyerEn.pdf>
 - (3) Non-Contract Formula
 - (A) Non-contract brand infant formula is all infant formula that is not covered by an infant formula cost containment contract awarded by the State agency. Non-contract brand formula may only be issued in food package III for participants with qualifying conditions with medical documentation pursuant to 7 Code of Federal Regulations part 246.10(d)(1)(i) (2015).
 - (4) The following types of infant formula are never authorized for purchase as part of the Infant Formula Category:
 - (A) Low iron or no iron formula.

AUTHORITY

Federal:

7 Code of Federal Regulations part 246.10(b)(1)(i) (2018): *State agency responsibilities*: State agencies may: Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section for the supplemental foods in their States . . . These State agency criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal.

7 Code of Federal Regulations part 246.10(b)(2)(i) (2018): *State agency responsibilities*: State agencies must identify the brands of foods and package sizes that are acceptable for use in their States in accordance with the requirements of this section.

7 Code of Federal Regulations part 246.10(e)(12), table 4 (2018): *Minimum requirements and specifications for supplemental foods*: The minimum requirements and specifications for infant formula in all applicable food packages are as follows:

Infant formula . . .

All authorized infant formulas must:

- (1) Meet the definition for an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107;
- (2) Be designed for enteral digestion via an oral or tube feeding;
- (3) Provide at least 10 mg iron per liter (at least 1.5 mg iron/100 kilocalories) at standard dilution;
- (4) Provide at least 67 kilocalories per 100 milliliters (approximately 20 kilocalories per fluid ounce) at standard dilution.
- (5) Not require the addition of any ingredients other than water prior to being served in a liquid state.

Exempt infant formula . . .

All authorized exempt infant formula must:

- (1) Meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 350a(h)) and the regulations at 21 CFR parts 106 and 107; and
- (2) Be designed for enteral digestion via an oral or tube feeding.

State:

Health and Safety Code section 123290: The Department . . . shall . . . designate specific supplemental foods to meet the minimum nutritional requirements for recipients.

Health and Safety Code section 123322, subdivisions (a)(3) and (b): (a) In order to effectively manage and administer the federal and state requirements for the vendors in the WIC Program, and remain in compliance with the conditions of federal funding, the department shall establish requirements for all of the following: . . . (3) The WIC Program authorized foods. (b) Notwithstanding any other provisions of law, including the requirement in Section 123315 for enacting regulations to implement that section and Section 123310, the department may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement, interpret, or make specific this section by means of an action by bulletin or similar instruction.

California Code of Regulations, title 22, section 40715, subdivision (c)(1)-(4): The specific foods authorized shall be determined by the department based upon federal minimum nutrient requirements specified for the particular food group, programmatic needs, financial constraints, and space limitations on the face of the food instruments . . . The following criteria shall be used by the Department to designate the specific foods authorized:

- (1) Cost of the foods;
- (2) Appropriateness of foods to the participant's category;
- (3) Statewide availability of the foods for a period of at least one year; and

- (4) Nutrient content of the food, its relationship to the nutritional needs of participants, and its consistency with the nutrition education goals of the Program.

STATEMENT OF REASONS

82600 WIC Authorized Food List: Infant Formula

(a)(2)(A) The Department transitioned to a new website in 2017. The Department is proposing to update the web address for the flyer listing contract infant formulas to its new location on the CDPH website.