

meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

[79 FR 71253, Dec. 1, 2014]

[FR Doc. 2016-28367 Filed 11-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Food Labeling

CFR Correction

■ In Title 21 of the Code of Federal Regulations, parts 100 to 169, revised as of April 1, 2016, on pages 43 and 44, in § 101.9, paragraphs (j)(1)(i), (2) introductory text, (3) introductory text, and the first sentence of (j)(4) are revised to read as follows. And, on page 50, the effective date note at the end of § 101.9 is removed.

§ 101.9 Nutrition labeling of food.

\* \* \* \* \*

(j) \* \* \*

(1)(i) Food offered for sale by a person who makes direct sales to consumers (e.g., a retailer) who has annual gross sales made or business done in sales to consumers that is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers of not more than \$50,000, *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section, § 101.10, or § 101.11, as applicable.

\* \* \* \* \*

(2) Except as provided in § 101.11, food products that are:

\* \* \* \* \*

(3) Except as provided in § 101.11, food products that are:

\* \* \* \* \*

(4) Except as provided in § 101.11, foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section,

*Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. \* \* \*

\* \* \* \* \*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Food Labeling

CFR Correction

■ In Title 21 of the Code of Federal Regulations, parts 100 to 169, revised as of April 1, 2016, on page 50, § 101.10 is revised to read as follows:.

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the previous sentence, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. For standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient

requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

[79 FR 71253, Dec. 1, 2014]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. FDA-2016-N-0543]

RIN 0910-AH30

Food and Drug Administration Review and Action on Over-the-Counter Time and Extent Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its nonprescription (over-the-counter or OTC) drug regulations. This final rule supplements the time and extent application (TEA) process for OTC drugs by establishing timelines and performance metrics for FDA’s review of non-sunscreen TEAs, as required by the Sunscreen Innovation Act (SIA). It also amends the existing TEA process to include filing determination and withdrawal provisions to make the TEA process more efficient.

DATES: This rule is effective December 23, 2016.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this final rule, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-4246, [Kristen.Hardin@fda.hhs.gov](mailto:Kristen.Hardin@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

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