safety data, go to *productdata.aphis.usda.gov.*

* * * * *

■ 3. Section 112.5 is amended as follows:

■ a. In the introductory text, by removing the words ''paragraph (c) of this section and under the master label system provided in paragraph (d)'' and adding the words ''paragraph (d) of this section and under the master label system provided in paragraph (e)'' in their place.

■ b. In paragraph (a), by removing the words ''(*http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml*)'' and adding the words ''(*productdata.aphis.usda.gov*)'' in their place.

■ c. By redesignating paragraphs (b) through (g) as paragraphs (c) through (h).

■ d. By adding a new paragraph (b).

■ e. In newly redesignated paragraph (d)(1), by removing the citation ''§ 112.5(d)'' and adding the words ''paragraph (e) of this section'' in its place.

■ f. In newly redesignated paragraph (e)(1)(ii), by removing the citation ''§ 112.5(d)(1)(iii)'' and adding the words ''paragraph (e)(1)(iii) of this section'' in its place.

■ g. In newly redesignated paragraph (e)(1)(iii), by removing the citation ''§ 112.5(d)(1)(i)'' and adding the words ''paragraph (e)(1)(i) of this section'' in its place.

■ h. In newly redesignated paragraph (e)(1)(iv), by removing the citation ''§ 112.5(d)(1)(ii)'' and adding the words ''paragraph (e)(1)(ii) of this section'' in its place.

■ i. In newly redesignated paragraph (h), by removing the citation ''§ 112.5(c)'' and adding the words ''paragraph (d) of this section'' in its place.

The addition reads as follows:

§ 112.5 Review and approval of labeling.

* * * * *

(b) A data summary, available on the Internet at *productdata.aphis.usda.gov,* shall be used with each submission of efficacy and safety data in support of a label claim. Manufacturers will submit the efficacy and safety data information with either the efficacy and safety studies or at the time of label submission. This information will be posted at *productdata.aphis.usda.gov* to allow public disclosure of product performance.

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Done in Washington, DC, this 6th day of July 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–16898 Filed 7–9–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

RIN 0910–AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule appeared in the **Federal Register** of December 1, 2014. We are taking this action in response to requests for an extension and for further clarification of the rule's requirements.

DATES:

Effective date: This final rule is effective December 1, 2015.

Compliance date: Covered establishments must comply with the rule published December 1, 2014 (79 FR 71156) by December 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ashley Rulffes, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, email: *ashley.rulffes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule implements provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) and:

- Defines terms, including terms that describe criteria for determining whether an establishment is subject to the rule;
- establishes which foods are subject to the nutrition labeling requirements and which foods are not subject to these requirements;
- requires that calories for standard menu items be declared on menus and menu boards that list such foods for sale;
- requires that calories for standard menu items that are self-service or on display be declared on signs adjacent to such foods;
- requires that written nutrition information for standard menu items be available to consumers who ask to see it;
- requires, on menus and menu boards, a succinct statement concerning suggested daily caloric intake (succinct statement), designed to help the public understand the significance of the calorie declarations;
- requires, on menus and menu boards, a statement regarding the availability of the written nutrition information (statement of availability);
- establishes requirements for determination of nutrient content of standard menu items;
- establishes requirements for substantiation of nutrient content determined for standard menu items, including requirements for records that a covered establishment must make available to FDA within a reasonable period of time upon request; and
- establishes terms and conditions under which restaurants and similar retail food establishments not otherwise subject to the rule could elect to be subject to the requirements by registering with FDA.

In the preamble to the final rule (79 FR 71156 at 71239 through 71241), we stated that the rule would be effective on December 1, 2015, and also provided a compliance date of December 1, 2015, for covered establishments. The final rule (at 21 CFR 101.11(a)) defines ''covered establishment'' as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is voluntarily registered to be covered under 21 CFR 101.11(d).

II. Extending the Compliance Date

Since we published the final rule in the **Federal Register**, we have received numerous requests asking us to further

interpret portions of the final rule or to respond to questions asking whether specific practices would be acceptable for purposes of complying with the rule. We issued a document in the **Federal Register** (80 FR 13225, March 13, 2015) announcing the availability of a ''Small Entity Compliance Guide'' for the rule, and are considering what additional guidance might be helpful.

Since February 2015, we have received four requests asking us to extend the compliance date of the final rule based on concerns that covered establishments do not have adequate time to fully implement the requirements of the rule by the compliance date. These requests were submitted by a large retailer and trade and other associations, and they provide information regarding steps involved in implementation of the requirements. More specifically, the requests describe steps involved in developing software, information systems, and other technologies for providing nutrition information in ways that better correspond to how foods are offered for sale in covered establishments and allow for more efficient and product-specific nutrition labeling. In addition, the requests describe steps involved in training staff, implementing standard operating procedures, and developing and installing updated and consistent menu boards across all locations within a chain. Most requests sought to extend the compliance date by 1 year.

In light of these requests, we have decided to extend the compliance date for the final rule to December 1, 2016. The final rule requirements are intended to ensure that consumers are provided accurate, clear, and consistent nutrition information for foods sold in covered establishments in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. Therefore, allowing adequate time for covered establishments to fully implement the final rule's requirements, as described in the requests, helps accomplish the primary objective of the final rule and is in the public interest.

III. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a regulatory impact analysis that presents the benefits and costs of this final rule (Ref. 1). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule changes the compliance date from December 1, 2015, to December 1, 2016, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. FDA, ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date,'' 2015. Available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.*

Dated: July 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16865 Filed 7–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Venezuela Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is issuing regulations to implement the Venezuela Defense of Human Rights and Civil Society Act of 2014 (Pub. L. 113–278) and Executive Order 13692 of March 8, 2015 (''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Venezuela''). OFAC intends to supplement this part 591 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

DATES: *Effective:* July 10, 2015.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Policy, tel.: 202/622–6746, Assistant Director for Regulatory Affairs, tel.: 202/622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, OFAC, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.