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By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2017–24381 Filed 11–8–17; 8:45 am]

BILLING CODE 6750–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

Menu Labeling: Supplemental Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Menu Labeling: Supplemental Guidance for Industry.'' The draft guidance, when finalized, will address concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments. It includes expanded and new interpretations of policy, and identifies places where FDA intends to be more flexible in its approach. This draft guidance also includes many graphical depictions in order to convey our thinking on various topics and to provide examples of options for implementation. It addresses calorie disclosure signage for self-service foods, including buffets and grab-and-go foods; reasonable basis, and the criteria for considering the natural variation of foods; various methods for providing calorie disclosure information, including those for pizza; compliance and enforcement; and criteria for distinguishing between menus and other information presented to the consumer.

DATES: Submit either electronic or written comments on the draft guidance by January 8, 2018 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–F–0172 for ''Menu Labeling: Supplemental Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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 document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, HFS–800, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Ashley Rulffes, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Menu Labeling Supplemental Guidance for Industry.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA 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 alternate approach if it satisfies the requirements of the

applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments to implement the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)). The menu labeling requirements are codified at Title 21 of the Code of Federal Regulations, § 101.11 (21 CFR 101.11).

In the **Federal Register** of May 4, 2017 (82 FR 20825), we published an interim final rule (IFR) extending the compliance date to May 7, 2018. Our goals are to ensure that consumers are provided with consistent nutrition information they can use to make informed choices for themselves and their families, and to guide industry in clearly understanding the flexible ways in which the requirements can be implemented.

This draft guidance addresses concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments. The draft guidance reflects extensive further analysis by FDA in light of the comments we received to the IFR. In addition, given extensive further analysis by the Agency, we are withdrawing Questions and Answers 5.17 and 5.18 in our previous guidance entitled ''A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance With FDA's Food Labeling Regulations)'' announced in the **Federal Register** of May 5, 2016 (81 FR 27067). We address the issue of distinguishing between menus and other information presented to the consumer in this draft guidance, and once finalized, this will represent our current thinking on this topic. The draft guidance also includes many graphical depictions to further illustrate our thinking on various topics. As previously stated, although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), we do not intend to extend the comment period for the guidance, as we intend to finalize this guidance and provide clarity to the industry on these remaining questions ahead of the new compliance date of May 7, 2018.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 101.11(b)(2), (c)(3), and (d) have been approved under OMB control number 0910–0783.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24246 Filed 11–7–17; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2017–C–6238]

Colorcon, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Colorcon, Inc., proposing that the color additive regulations be amended by expanding the permitted uses of synthetic iron oxide as a color additive to include use in dietary supplement tablets and capsules.

DATES: The color additive petition was filed on October 3, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 7C0308), submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposes to amend the color additive regulations in § 73.200 (21 CFR 73.200) *Synthetic iron oxide* by expanding the permitted uses of synthetic iron oxide as a color additive to include use in dietary supplement tablets and capsules with a proposed limit of 5 milligrams, calculated as elemental iron, per day for labeled dosages.

We have determined under 21 CFR 25.32(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.

Dated: November 6, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24421 Filed 11–8–17; 8:45 am]

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