

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This draft guidance addresses concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments. The draft guidance reflects extensive further analysis by FDA in light of the comments we received to the IFR.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 We address the issue of distinguishing between menus and other information presented to the consumer in this draft guidance, and once finalized, this will represent our current thinking on this topic. The draft guidance also includes many graphical depictions to further illustrate our thinking on various topics.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.

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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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