



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2017-C-6238]

Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 4, 2018, for the final rule that appeared in the *Federal Register* of November 1, 2018, and that amended the color additive regulations to provide for the expanded safe use of synthetic iron oxides as color additives to include use in dietary supplement tablets and capsules.

DATES: Effective date of final rule published in the *Federal Register* of November 1, 2018 (83 FR 54869) confirmed: December 4, 2018.

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 final rule 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: In the *Federal Register* of November 1, 2018 (83 FR 54869), we amended the color additive regulations in § 73.200, “Synthetic iron oxide” (21 CFR 73.200), to provide for the expanded safe use of synthetic iron oxides as color additives in dietary supplement tablets and capsules, including coatings and printing inks, such that the total amount of elemental iron per day for labeled dosages does not exceed 5 milligrams.

We gave interested persons until December 3, 2018, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the *Federal Register* of November 1, 2018, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the November 1, 2018, final rule. Accordingly, the amendments issued in the final rule became effective December 4, 2018.

Dated: April 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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