NEWS RELEASE
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Color Spectrum Expands as FDA Approves Colorcon's Iron Oxide Petition

Meeting the demand for more stable pigments from dietary supplement manufacturers.

Harleysville, Pennsylvania, USA, 1st November 2018. Colorcon, Inc. today announced the FDA's approval of the Color Additive Petition (21 CFR 73.200) submitted by Colorcon for the use of iron oxide as a color additive for use in dietary supplement tablets and capsules. This approval will allow the use of iron oxide in dietary supplement tablets and capsules (with a limit of 5 mg, the same as for US regulations for drugs), calculated as elemental iron, per day for labeled dosages, marketed in the United States. Colorcon is a world leader in the pharma excipient sector, currently offering a wide palette of colors with thousands of film coating formulation options; this now extends use into dietary supplements and supports the increasing drive for clean labeling.

Colorcon developed this petition in response to ever-increasing requests from dietary supplement manufacturers for more stable pigment options, as they strive to meet consumer demand for more label friendly ingredients in their products. Iron oxides are widely used in the pharmaceutical and food industries around the world, and are extremely stable to light and chemical interactions, improving color stability for the end product. Extending the use of iron oxides into the USA nutritional arena enables an ever wider choice of color for dietary supplements, providing distinct shades and hues to improve branding and product recognition.

Steve French, of the Natural Marketing Institute (NMI) explains "As natural products across many product categories continue to gain momentum, it is clearly evident that this global trend is here to stay. This clean label phenomenon has permeated many consumer packaged goods, including dietary supplements and the use of ingredients such as iron oxide, among others, should benefit many manufacturers looking to meet increased consumer demand in the USA."

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The FDA, after their review of Colorcon's requested amendment, agreed to expand the range of product categories in which iron oxide can be used to include dietary supplement tablets and capsules in the United States.

"We are proud to be instrumental in expanding the use of iron oxides, especially for use in the dietary supplement industry, said Kelly Boyer, Colorcon's Film Coating General Manager. "These highly stable colorants provide high opacity and good coverage when used for film coating of tablets. They provide a broader color palette, widening the options available for branding and differentiation when used in combination with other pigments. With our globally recognized color expertise, Colorcon will successfully utilize iron oxides as colorants across a broad range of dietary supplement applications, bringing an expanded spectrum of colors, with improved stability, to our customers."

Information related to the approval is referenced in the Federal Register, USA, Docket Number FDA-2017-C-6238

Company Information

Colorcon is a world leader in the development, supply and technical support of formulated film coating systems, modified release technologies, and functional excipients for the pharmaceutical and dietary supplement industries. Our best-in-class products and technologies are complemented by our extensive application data and value-added services to support all phases of oral dose design, development, and manufacture. Our focus on market issues and technology development has earned Colorcon an international reputation as a pharmaceutical and nutritional supplier of choice. That reputation is based on superior product quality, unparalleled technical support, extensive regulatory assistance and reliable supply from multiple locations. Colorcon has 21 technical service laboratories globally and more than 1200 employees exclusively dedicated to its customer base.

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