



NEWS RELEASE

FOR IMMEDIATE RELEASE

COLORCON COMMUNICATIONS CONTACT:

Deborah J. Taylor

Director - Global Market Communications

dtaylor@colorcon.com

Colorcon's Petition Finalized to Expand Uses for Calcium Carbonate in Dietary Supplements

Harleysville, Pennsylvania, USA, 23rd November 2022 Colorcon, a world leader in the development and supply of film coating systems and excipients for the pharmaceutical and nutritional industries, announces that it has successfully petitioned for expansion of the use of calcium carbonate (CaCO₃) as color in dietary supplement tablets and capsules.

The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of calcium carbonate in dietary supplement tablets and capsules, including coatings and printing inks, in amounts consistent with good manufacturing practice (GMP). This amendment means the material can be used as an alternative color additive in place of titanium dioxide (TiO₂), which is banned for food use in the European Union. The color additive petition (CAP) for CaCO₃ submitted by Colorcon, Inc has been granted and is effective from 28th Oct 2022.

Alexa Smith, Director - of Global Quality & Regulatory Services, explains, "Colorcon submitted the petition to facilitate the expanded use of CaCO₃ as a color additive to support companies who want to formulate film coatings for dietary supplement tablets without the use of TiO₂. Formulating without TiO₂ is a particular issue in Europe, where legislation banning TiO₂ (E171) use in foods is now in place; using CaCO₃ as an alternative opacifier is now a viable option. In the USA, TiO₂ is not banned in foods; however, some consumers would rather use products without, and this successful petition enables this."

Annabel Bordmann, General Manager of Film Coatings, adds, "Colorcon leads the evolution in coating products for dietary supplements through Nutrafinish[®], Dietary Supplement Coatings and the expanded use of CaCO₃ widens the choices for this market. Nutrafinish coatings are formulated to meet regulatory needs and appeal to consumers".



Through the extensive portfolio of fully formulated coatings, Colorcon provides the scope for dietary supplement manufacturers to reduce complexity and time-to-market by delivering high-quality products with ingredients carefully selected from commonly used food ingredients and support label-friendly. This is backed by our superior, dedicated technical support and regulatory expertise.

Company Information

Colorcon is a world leader in the development, supply, and technical support of specialty ingredients, formulated film coating systems, modified release technologies, and functional excipients for the pharmaceutical, animal health and nutritional industries. Our best-in-class products and technologies are complemented by our extensive application data and value-added services to support all phases of solid oral dose design, development, and manufacture. Our focus on market issues and technology development has earned Colorcon an international reputation as a pharmaceutical design and development partner. That reputation is based on superior product quality, unparalleled technical support, extensive regulatory assistance, and reliable supply from multiple locations. Colorcon has 11 manufacturing facilities, 25 technical service laboratories globally and more than 1300 employees exclusively dedicated to its customer base.

For more information, visit www.colorcon.com