

FDA Issues Final Rule Regarding "Listing of Color Additives Exempt From Certification; Bismuth Citrate"

March 29, 2010

On March 26, 2010, the Food & Drug Administration (FDA), issued a final rule titled, "[Listing of Color Additives Exempt From Certification; Bismuth Citrate](#)," amending the color additive regulations to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

This regulation follows the [initial notice](#) published by FDA on February 25, 2008, which announced that a color additive petition (CAP 8c0286) had been filed by Combe, Inc. to amend the color additive regulations at 21 CFR 73.2110 for bismuth citrate to increase the maximum permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp from 0.5 percent (weight per volume (w/v)) to 2.0 percent (w/v). Bismuth citrate is commonly used as an active ingredient in hair dyes used to darken hair on the scalp.

After reviewing the data in the petition and other materials related to the safety of the use of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp, FDA concluded that use of bismuth citrate at levels up to 2.0 percent (w/v) "is safe and...will achieve its intended technical effect." The rule will go into effect on April 27, 2010, "except as to any provisions that may be stayed by the filing of proper objections."

More information about the regulation, including information on submitting objections or requests for hearings, is available [here](#).