## **Color Additive Petitions**

As prescribed by law, a color additive must be shown to be safe and be listed in the CFR before it may be used to color foods, drugs, cosmetics or certain medical devices. An interested person may petition the Food and Drug Administration (FDA) for the use of a proposed color additive and submit data demonstrating its safety and suitability as described in 21 CFR Part 71. The FDA will, upon written request, advise on the adequacy of experiments planned to yield these data (21 CFR 70.42(c)). If, upon evaluation of the data in the petition, additional data, and public comments, the Agency finds that the proposed color additive is safe and suitable for the intended use, then a regulation may be issued or an existing regulation altered, thereby listing the color additive for such use. The color additive will be listed in 21 CFR Part 73 if it is exempt from batch certification, or in 21 CFR Part 74 if it is subject to batch certification.

## **Petition Listings**

- Food and Color Additives: Final Rules by Year (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm047880.htm)
- Food Additive Listings (/Food/IngredientsPackagingLabeling/ucm2008017.htm)

## **Petition Guidance**

- Ingredients, Additives, GRAS & Packaging Guidance Documents & Regulatory Information
  (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/default.htm)
- <u>Guidance for Industry: Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied</u>
  <u>Nutrition for Color Additives Used in or on Contact Lenses</u>
  <u>(/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm054076.htm)</u>
- <u>Guidance for Industry: Color Additive Petitions FDA Recommendations for Submission of Chemical and Technological</u>
  <u>Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices</u>
  <u>(/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm171631.htm)</u>

More in <u>Color Additive Petitions</u> (/ForIndustry/ColorAdditives/ColorAdditivePetitions/default.htm)

Guidance Documents (/ForIndustry/ColorAdditives/ColorAdditivePetitions/ucm107295.htm)