

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

COLOR ADDITIVE PETITIONS

A color additive for use in or on a medical device is subject to the requirements of section 706 of the Federal Food, Drug, and Cosmetic Act if the color additive comes in direct contact with the human body for a significant period of time. Because the Medical Device Amendments of 1976 lack guidance in determining whether there is direct contact for a significant period of time, the applicant should contact the Premarket Approval Staff for assistance in determining whether the use of the color additive is subject to the requirements of section 706. FDA has determined that color additives used in tinted soft contact lenses, dyed absorbable and nonabsorbable surgical sutures, and bone cements are subject to the requirements of section 706.

The term "color additive" means a material which (1) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source and (2) when added or applied to a [medical device] or to the human body or any part thereof is capable (alone or through reaction with other substance) of imparting color thereto. The term "color additive" does not include any material which FDA determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

A color additive subject to section 706 of the act is considered unsafe (adulterated) unless the color additive is listed for the appropriate use in accordance with section 706 of the act. The listing regulation may permit unqualified use of the color additive in a generic type of device (e.g., contact lenses) or may place various limitations on its use (e.g., polypropylene nonabsorbable sutures for general but not ophthalmic surgical use). The color additive must be from a batch certified in accordance with regulations issued under section 706(c) for that use, unless the color additive has been exempted from the certification requirement. The investigational device exemption (IDE) regulations (21 CFR Parts 812 and 813) include provisions for exempting from the requirements of section 706 a color additive or any specific use of the color additive when intended solely for investigational use by qualified experts and such exemption is consistent with the public health.

If a color additive subject to section 706 is used in or on a device subject to pre-market approval and it has not previously been listed for such use, in lieu of submitting a color additive petition (CAP) under 21 CFR 71, the applicant may submit the information required under Part 71 as part of the PMA. As provided by 21 CFR 814.20(f), when submitted as part of the PMA the information must be submitted in three copies, each bound in one or more numbered volumes of reasonable size.

The applicant is cautioned that a PMA for a device that contains a color additive subject to section 706 will not be approved until the color additive is listed for use in or on the device. Regulations listing color additives for use in medical devices are codified under 21 CFR 73 (Subpart D) if exempt from certification and 21 CFR 74 (Subpart D) if subject to certification.

To assist in developing an appropriate strategy for submitting a color additive petition, the PMA applicant is advised to consider the following:

1. The review period for a color additive petition may be as long as, and may extend beyond, that for a PMA.
2. A color additive petition included in a PMA will be processed in accordance with the procedures and fee schedules in 21 CFR 71.

3. Because all color additive petitions are processed by the FDA Center for Food Safety and Applied Nutrition (CFSAN), processing of the color additive petition will be delayed if it cross references rather than includes required information in the remaining portion of the PMA reviewed by CDRH.
4. The existence of a color additive petition included in a PMA should be highlighted in the PMA cover letter to minimize delays in forwarding by CDRH of the color additive petition to CFSAN for processing.
5. A color additive petition included in a PMA is subject to the confidentiality provisions of 21 CFR 71 rather than 21 CFR 814.