Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner will establish a color additive advisory committee under the following circumstances:

(a) The Commissioner concludes, as a matter of discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations about the safety of a color additive on which important issues are pending before FDA and for interested persons to present information and views at an oral public hearing before a color additive advisory committee.

(b) There is an issue arising under section 721(b)(5)(B) of the FD&C Act concerning the safety of a color additive, including its potential or actual carcinogenicity, that requires the exercise of scientific judgment and a person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that the matter, or the Commissioner as a matter of discretion determines that the matter should, be referred to a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person is conditioned upon receipt of the application fee specified in § 14.155.

(4) Any person adversely affected may request referral of the matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee reviews all available information relating to the matter referred to it, including all information contained in any pertinent color additive petition and in FDA files. All information reviewed is placed on public display and is available for review at the office of the Division of Dockets Management.

(b) The Commissioner specifies to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, is designated as the beginning of the period allowed for consideration of the matter by the committee. Within 60 days after the first meeting, unless the time is extended as provided in paragraph (d) of this section, the Chairperson of the committee shall certify to the Commissioner the report containing the recommendations of the committee, including any minority report. The report states the recommendations of the committee and the reasons or basis for them. The report includes copies of all material.