Food and Drug Administration, HHS

§ 70.50 Application of the cancer clause of section 721 of the act.

(a) Color additives that may be ingested. Whenever (1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or (2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

(b) Color additives that will not be ingested. Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) Color additives for use as an ingredient of feed for animals that are raised for food production. Color additives that are an ingredient of the feed for animals raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer...