A person or business wishing to request FDA approval to use a new food or color additive or GRAS ingredient, or a new use of a regulated food or color additive or GRAS ingredient, must comply with §§ 409(a), 201(s) and 721 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. §§ 348, 321(s), and379e(a)). Without FDA review and approval of food additive, color additive, and GRAS affirmation petitions as required by law, it would not be possible to protect the nation's food supply.

Food Additive Petitions and Labeling Requirements

Section 409(a) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. § 348) provides that a food additive shall be deemed to be unsafe unless: 1) it and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; 2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or 3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under subsection (h) is effective. With the exception of notifications for food additives that are food contact substances, food additive petitions provide the only method for premarket safety review and approval of food additives permitted by law. Section 409(b) of the act specifies the information that must be submitted by a petitioner to establish the conditions under which a food additive may be safely used.

FDA's regulations in Title 21 of the Code of Federal Regulations, part 171 (21 CFR part 171) specify the information that must be submitted in a food additive petition to meet the statutory requirements. The regulations also provide a standard format to expedite processing of the petition.

Labeling requirements for food additives intended for human consumption, addressing information needed by a manufacturer to use the additive safely, are set forth in various regulations contained in 21 CFR parts 172, 173 and 180. Labeling requirements for indirect food additives are set forth in several individual regulations contained in 21 CFR parts 175 through 178. The labeling regulations are considered by FDA to be cross referenced to § 171.1.

Generally Recognized as Safe Affirmation Petitions

Section 201(s) of the act (21 U.S.C. § 321(s)) defines a generally recognized as safe (GRAS) substance as an exception from the legal definition of a food additive. This section defines a substance as GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food under the conditions of its intended use. Section 201(s) of the act does not define what is meant by "scientific procedures" or "common use in food," nor does it specify how the substance is to be evaluated as GRAS. To implement the GRAS provisions of § 201(s), FDA has issued procedural regulations in 21 CFR part 170. The procedural regulations at 21 CFR 170.30 are designed to

delineate and specify, with particularity, eligibility for classification as GRAS, and to set forth the information that must be submitted to FDA to gain agency concurrence that a substance is GRAS. The regulations add no substantive requirements to the law, but attempt to explain the requirements for classification as GRAS. More specifically, the procedural regulations in 21 CFR 170.35(c)(1) provide a standard format for submission of GRAS affirmation petitions.

In the Federal Register of April 17, 1997 (62 FR 18938) FDA proposed to replace the current GRAS affirmation process with a notification procedure whereby any person may notify FDA of their determination that a particular use of a substance is GRAS. The format for a GRAS notice is spelled out in the 1997 proposed rule. The notifier would receive only a letter from FDA. FDA has been accepting GRAS notices under this proposed rule. Since there have been no GRAS affirmation petitions received since the 1997 proposed rule, FDA is assigning minimal burden to the information collection requirements in 21 CFR 170.35.

Color Additive Petitions and Labeling Requirements

Section 721(a) of the act (21 U.S.C. § 379e(a)) provides that a color additive shall be deemed to be unsafe: 1) unless the additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements, or 2) unless the additive and its use conform to the terms of an exemption for investigational use. Section 721(b) of the act (21 U.S.C. § 379e(b)) specifies the information that must be submitted by a petitioner in order to establish that a color additive is safe and suitable for its proposed use. FDA's regulations in 21 CFR part 71 specify the information that must be submitted in a color additive petition to meet the statutory requirements. The regulations also provide a standard format to expedite processing of the petition.

The labeling requirements for color additives intended for foods, drugs, devices, or cosmetics are set forth in FDA's regulations in 21 CFR parts 73 and 74. These labeling requirements cross reference to 21 CFR 70.25, which requires that color additives to be used in foods, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.