

recognized as safe (GRAS) status (OMB control number 0910-0132), (3) labeling requirements for color additives (other than hair dyes) and petitions (CAPs) (OMB control number 0910-0185), and (4) electronic submission of food and color additive petitions (OMB control number 0910-0480).

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the act is effective. FAPs are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175 through 178, and 180 (21 CFR parts 172, 173, 175 through 178, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. CAPs are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR part 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR part 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Under authority of sections 201, 402, 409, and 701 of the act (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS that are submitted on a voluntary basis by the food industry and other interested parties. Specifically under section 201(s) of the act, a substance is 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. The act has historically been interpreted to permit food manufacturers to make their

own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under 21 CFR 170.35(c)(1).

In the **Federal Register** of July 31, 2001 (66 FR 39517), FDA announced the availability of a draft guidance for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions." This guidance describes the procedures for electronic submission of FAPs and CAPs using FDA Form No. 3503, entitled "Food Additive Petition Submission Application," and FDA Form No. 3504, entitled "Color Additive Petition Submission Application."

FDA scientific personnel review food and color additive and GRAS affirmation petitions to ensure the safety of the intended use of the substance in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food (or for color additives, its use in food, drugs, cosmetics, or medical devices). Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of April 4, 2003 (68 FR 16517) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the reporting burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
<b>CAPS</b>						
70.25	0	1	0	0	0	0
71.1	2	1	2	1,652	\$5,600	3,304
FDA Form 3504	1	1	1	1	0	1
<b>GRAS Affirmation Petitions</b>						
170.35	1	1	1	2,598		2,598
<b>FAPs</b>						
171.1	7	1	7	3,640		25,480
FDA Form 3503	2	1	2	1		2
<b>Total</b>					<b>\$5,600</b>	<b>31,385</b>

<sup>1</sup> There are no capital costs associated with this collection of information.