Statement of Reimbursable Costs, Manual Instructions and Supporting Regulations in 42 CFR, 413.20 and 413.24; *Form No.*: CMS–216 (OMB# 0938–0102); *Use:* This form is required by statute and regulation for participation in the Medicare program. The information is used to determine payment for Medicare. Organ Procurement Organizations and Histocompatibility Laboratories are the users; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 108; *Total Annual Responses:* 108; *Total Annual Hours:* 4,860.

2. *Type of Information Collection Request:* New Collection: *Title of Information Collection*: Hospital Wage Index Occupational Mix Survey; *Form No.:* CMS–10079 (OMB# 0938-NEW); *Use:* In the May 4, 2001 Proposed Rule (66 FR 22674), CMS proposed to conduct a special survey to collect data from a sample of occupational categories that provide a valid measure of wage rates within a geographical area. In the August 1, 2001 Final Rule (66 FR 39860), we responded to comments from the Proposed Rule and stated that, CMS will conduct a special survey of all short-term acute-care hospitals that are required to report wage data to collect these data. Section 304 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect wage data on hospital employees by occupational category. The collection is to be completed by September 30, 2003 and to be used to adjust the wage index by October 1, 2004; *Frequency:* Other: once every three years; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 4,800; *Total Annual Responses:* 4,800; *Total Annual Hours:* 768,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 27, 2003.

Dawn Willinghan,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–8177 Filed 4–3–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–284]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Medicaid Statistical Information System (MMIS); *Form No.:* CMS–R–0284 (OMB# 0938–0345); *Use:* State data are reported by a Federally mandated process known as MSIS. These data are the basis for Medicaid actuarial forecasts for service utilization and costs; Medicaid legislative analysis and cost savings estimates; and for responding to requests for information from CMS components, the Department, Congress, and other customers. The national MSIS database will contain details that will allow constructive or predictive analysis of today's Medicaid issues (*e.g.*, pregnant women, and infants); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 53; *Total Annual Responses:* 212; *Total Annual Hours:* 7,420.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 27, 2003.

Dawn Willinghan,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–8178 Filed 4–3–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0106]

Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; and Electronic Submission Using FDA Forms 3503 and 3504

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the

Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed consolidation of four existing submissions of petitions.

DATES: Submit written or electronic comments on the collection of information by June 3, 2003.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Electronic Submission Using FDA Forms 3503 and 3504 (OMB Control Number 0910–0016)—Extension

This notice solicits comments on a proposed collection of the following four existing submissions of petitions: (1) Food Additive and Food Additive Petitions (FAPs) (OMB Control Number 0910–0016), (2) Affirmation of Generally 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 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 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 entitled ''Draft Guidance for Industry on 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Hours per Response	Total Operating & Maintenance Costs	Total Hours
CAPs						
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
GRAS Affirmation Petitions						
170.35	1	1	1	2,598		2,598
FAPs						
171.1	7	1	7	3,640		25,480
FDA Form 3503	2	1	2	1		2
Total					$5,600	31,385

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of burden for FAPs and CAPs is based on the average number of new FAPs and CAPs received in calendar years 2000 through 2002 and the total hours expended in preparing the petitions. Although the burden varies with the type of petition submitted, an average FAP or CAP, or GRAS affirmation petition, involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: March 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8265 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0057]

Determination That Albuterol Sulfate Inhalation Solution 0.5% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.