

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.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Survey of Contract Labor in Selected Health Industries; *Form Number:* CMS-10177 (OMB#: 0938-NEW); *Use:* CMS Medicare reimbursement to hospitals and skilled nursing facilities is based, in part, on the portion of costs which are related to, are influenced by, or vary with the local labor markets. This portion is known as the labor-related share. Currently, contract labor costs for accounting and auditing services, engineering services, legal services, and management consulting services are included in the labor-related share. These costs are calculated based on data published in the Medicare cost reports and the Input-Output tables published by the Bureau of Economic Analysis (BEA). At this time, the labor-related share is not used to reimburse end-stage renal disease centers (ESRDs) for providing Medicare services. However, there is a possibility that this circumstance may change; therefore CMS will include ESRDs in the survey. It is assumed that these professional services contract labor costs are purchased in the local labor market and thus should be included in the labor-related share. A search of the literature reveals no existing work on this subject. Therefore, CMS will survey hospitals, skilled nursing facilities, and kidney dialysis centers to determine if their professional service contract labor is hired from local or national labor markets.; *Frequency:* Reporting—One-time; *Affected Public:* Not-for-profit institutions, Business or other for-profit, Federal Government, State, Local, or Tribal Government; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 4,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Lifestyle Modification Program Demonstration; *Form Number:* CMS-10044 (OMB#: 0938-0871); *Use:* The

Medicare Lifestyle Modification Program Demonstration will focus on two Medicare-sponsored, lifestyle modification programs designed to reverse, reduce, or ameliorate the progression of coronary artery disease (CAD) at risk for significant morbidity and mortality. Lifestyle modification programs are an increasingly important approach to the secondary prevention of coronary morbidity. Research has provided evidence that lifestyle changes decrease cardiovascular risk factors, resulting in lower morbidity and mortality associated with coronary artery disease (CAD). Such programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion. Consequently, lifestyle modification may also reduce the need for revascularization procedures (coronary artery bypass graft (CABG) and percutaneous coronary angioplasty (PTCA)) as well as the use of ambulatory and inpatient services for this disease. This demonstration will test the cost effectiveness and feasibility of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries.; *Frequency:* Reporting—Monthly; *Affected Public:* Individuals or Households; *Number of Respondents:* 2,240; *Total Annual Responses:* 1,680; *Total Annual Hours:* 1106.

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://www.cms.hhs.gov/regulations/pral/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on February 7, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 2, 2005.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10175]

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Center for Medicare and Medicaid Services.

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), 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because public harm will ensue from the continued denial of access from providers obtaining National Provider Identifiers (NPI) *en masse*.

Currently, providers can obtain a NPI via a paper application or over the Internet through the National Plan and Provider Enumeration System (NPPES). These applications must be submitted individually, on a per-provider basis. We are seeking OMB approval for the electronic file interchange (EFI) process.

The EFI process is designed to allow provider-designated organizations (known as electronic file interchange organizations "EFIOs") to capture multiple providers' NPI application information on a single file. (This process is also referred to as "bulk enumeration.") To ensure that the EFIO has the authority to act on behalf of each provider and complies with other Federal requirements, the EFIO must sign a certification statement and mail it to CMS. The EFI process therefore cannot commence until the certification statement receives final OMB clearance.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations (EFIOS) that Submit National Provider Identifier (NPI) Data to the National Plan and Enumeration System; *Use:* The EFI process is designed to allow organizations to submit NPI application information for large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO will electronically submit the file to NPPES for processing. As each file can contain up to approximately 100,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers; *Form Number:* CMS-10175 (OMB#: 0938-NEW); *Frequency:* Other—One-time; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 2000; *Total Annual Responses:* 1000; *Total Annual Hours:* 3000.

CMS is requesting OMB review and approval of these collections by *December 30, 2005*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by *December 23, 2005*.

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://www.cms.hhs.gov/regulations/pra/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be

mailed to the designees referenced below by *December 23, 2005*: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: William N. Parham, III and, OMB Human Resources and Housing Branch, Attention: Carrie Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 2, 2005.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005C-0482]

#### Food Ingredient Solutions, LLC; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Food Ingredient Solutions, LLC, has filed a petition proposing that the color additive regulations be amended to expand the use of sodium copper chlorophyllin to include foods generally (with the exception of meat, poultry, fish, and standardized foods) and to include fescue grass as a permitted source.

#### FOR FURTHER INFORMATION CONTACT:

Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1278.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 6C0281) has been filed by Food Ingredient Solutions, LLC, 300 Corporate Dr., suite 7, Blauvelt, NY 10913. The petition proposes to amend the color additive regulations in § 73.125 *Sodium copper chlorophyllin* (21 CFR 73.125) to expand the use to include foods generally (with the exception of meat, poultry, fish, and standardized foods) and to include fescue grass as a permitted source.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 17, 2005.

**Laura M. Tarantino,**

*Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

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

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Collection of Information:

*Title:* Effectiveness of a Community's Implementation of the NFIP Community Assistance Program CAC and CAV Reports.

*OMB Number:* 1660-0023.

*Abstract:* This collection provides basic information about floodplain management program and contact information pertaining to NFIP participating communities. The information is used by FEMA and NFIP State Coordinating Agencies to identify problems with communities' floodplain management and determine assistance. The two key methods FEMA uses in determining community assistance needs are through the CAC and CAV, which serve to provide a systematic means of monitoring community NFIP compliance. Through the CAC and CAV, FEMA can also determine to what