

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1728-94 and CMS-10091]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & 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 & Medicaid Services (CMS) 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.

**1. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Home Health Agency Cost Report; **Use:** Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The CMS-1728-94 cost report is needed to determine the amount of reimbursable cost, based upon the cost limits, that is due these providers furnishing medical services to Medicare beneficiaries. **Form Number:** CMS-1728-94 (OMB#: 0938-0022); **Frequency:** Reporting: Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 5069; **Total Annual Responses:** 5069; **Total Annual Hours:** 892,144.

**2. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Accepting New Patients Indicator UPIN (Unique Physician Identification Number) Participating Physicians Directory; **Use:**

CMS is expanding the Participating Physician Directory to provide additional information about physicians who participate in Medicare. The new data element "accepting new Medicare patients" will provide beneficiaries and other users with much needed information about the physicians who participate in the Medicare program. It will also provide a service to physicians who are either seeking new Medicare patients or who wish to reduce the burden of responding to callers when they are no longer accepting new Medicare patients. **Form Number:** CMS-10091 (OMB#: 0938-0905); **Frequency:** Reporting: Daily, Weekly and Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 109,800; **Total Annual Responses:** 10,980; **Total Annual Hours:** 915.

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/PaperworkReductionActof1995>, 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 March 20, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 10, 2007.

**Michelle Shortt,**

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

[FR Doc. E7-604 Filed 1-18-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10176]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & 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 & Medicaid Services (CMS) 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.

**1. Type of Information Collection Request:** New Collection; **Title of Information Collection:** Governmental Status of Health Care Provider Form; **Use:** The questions presented on the "Governmental Status of Health Care Provider" form are required for CMS to be able to determine the permissibility of State funding sources associated with selected reimbursement-related State Plan Amendments. Without the information gathered on this form, CMS will not be able to determine the State's compliance with Section 1902(a)(30)(A) or Section 1903(w) of the Social Security Act. If CMS cannot determine compliance, CMS cannot approve the State Plan Amendments, resulting in potential harm to Medicaid beneficiaries. The respondents of this information request will be the State's State Medicaid Agency. **Form Number:** CMS-10176 (OMB#: 0938-NEW); **Frequency:** Reporting: Once and on occasion; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 50; **Total Annual Responses:** 4,000; **Total Annual Hours:** 4,000.

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/PaperworkReductionActof1995>, 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 March 20, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Dated: January 12, 2007.

**Michelle Shortt,**

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

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BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0014]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Electronic Submission Using Food and Drug Administration 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 the information collection provisions of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations, and electronic submission using FDA Forms 3503 and 3504. This notice also notifies the public of, and solicits comments on, FDA's proposal to transfer the collection of information and burden associated with petitions submitted to amend the indirect food additive regulations from the subject collection of information Office of Management and Budget (OMB) control number 0910-0016 to the collection of information for the Food Contact Substances Notification System (OMB control number 0910-0495).

**DATES:** Submit written or electronic comments on the collection of information by March 20, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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:**

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from 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 these topics: (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—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180 (OMB Control Number 0910-0016)—Extension**

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. Food additive petitions (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, 179, and 180 (21 CFR parts 172, 173, 179, 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. Color additive petitions (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 71.1) specifies the information that a petitioner must submit 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 section 201(s) of the act (21 U.S.C. 321(s)), a substance is GRAS if it is generally recognized among experts