

attorney to reiterate the agency's initiative to remove from its pending petition inventory those petitions that are no longer being pursued by the petitioner. In that letter, the agency stated that if Dairy Crest Foods, Ltd., wished to pursue the petition, the agency would continue to work on it. However, if Dairy Crest Food, Ltd., did not wish to pursue the petition, the agency requested that Dairy Crest Food, Ltd., withdraw the petition without prejudice to a future filing. FDA asked that the petitioner inform the agency of its decision within 30 days of the date of the letter; the agency added that failure to respond within that time would be considered approval to withdraw the petition. As of this date, Dairy Crest Food, Ltd., has not responded to FDA in any way. Therefore, the agency is announcing that it considers this petition to be withdrawn by the firm, without prejudice to a future filing (21 CFR 171.7).

Dated: April 27, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-12055 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on June 5, 1998, 9 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, or

FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396, or the World Wide Web (WWW) at <http://www.fda.gov>. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an excimer laser for the correction of myopia using laser in-situ keratomileusis. FDA staff will present to the committee the clinical requirements section of the proposed International Standards Organization standard for ophthalmic viscosurgical devices.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 29, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and between approximately 1 p.m. and 1:30 p.m. An additional 30-minute time period will be given for public comment at the end of the panel discussion on the PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 29, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 30, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-12170 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-2567-A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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: Extension of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction and Supporting Regulations in 42 CFR 486.301-.325; *Form No.:* HCFA-2567-A (OMB# 0938-0391); *Use:* This Paperwork package provides information regarding deficiencies for Organ Procurement Organizations (OPO) as well as deficiencies noted during periodic facility and laboratory certification surveys. This information is used to make decisions concerning OPO redesignation, certification/recertification of health care facilities participating in the Medicare/Medicaid Programs, and laboratories regulated by the Clinical Laboratory Improvement Amendments; *Frequency:* Biennially and Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 49,200; *Total Annual Responses:* 98,400; *Total Annual Hours:* 196,800.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2-26-17, 7500 Security

Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 28, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98-12092 Filed 5-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-116, HCFA-R-148, and HCFA-R-231]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations in 42 CFR 493.1-2001; *Form No.:* HCFA-116 (OMB# 0938-0581); *Use:* These certification requirements have been established for any entity that performs testing on human beings for diagnostic or treatment purposes. If a laboratory conducts relatively simple tests that are categorized as waived or provider performed microscopy test procedures (PPMP), it must obtain a certificate of waiver or certificate of PPMP. If the laboratory conducts any tests outside of these two categories, it must apply for

a certificate of compliance or certificate of accreditation and initially obtain a registration certificate. These certificates ensure that laboratories are in compliance with CLIA.; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 20,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Limitation on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals; Medicaid and Supporting Regulations in 42 CFR 433.68, 433.74, 447.74 and 447.272; *Form No.:* HCFA-R-148 (OMB# 0938-0618); *Use:* These information collection requirements specify limitations on the amount of Federal financial participation available for medical assistance expenditures in a fiscal year. States receive donated funds from providers and revenues are generated by health care related taxes. These donations and revenues are used to fund medical assistance programs.; *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 3,892.

3. *Type of Information Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare+Choice (M+C) Providers Sponsored Organization (PSO) Waiver Request Form and Supporting Regulations in 42 CFR 422.374; *Form Number:* HCFA-R-231; *Use:* The PSO waiver request form is for use by PSO's that do not have a State risk-bearing entity license and that wish to enter into a M+C contract with HCFA to provide prepaid health care services to eligible Medicare beneficiaries. HCFA will use the information requested on this form to determine whether the applicant is eligible for a waiver of the state licensure requirement for M+C organizations as allowed under section 1855(a)(2) of the Social Security Act.; *Frequency:* One-time.; *Affected Public:* Business or other for-profit, not-for-profit institutions, and Federal Government.; *Annual Number of Respondents:* 30.; *Total Annual Responses:* 30.; *Total Annual Hours Requested:* 300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/>

[regs/prdact95.htm](http://www.hcfa.gov/regs/prdact95.htm), or E-mail your request, including your address, phone number, OMB number, and HCFA 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 24, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98-12094 Filed 5-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-235]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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 the 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: New Collection; *Title of Information Collection:* Data Use Agreement Information Collection Requirements, model agreement, and Supporting regulations; *Form No.:*