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For biologics issues contact: Edward Tabor, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3518.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107-250, was signed into law. Among other things, MDUFMA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding several new provisions concerning devices intended for pediatric use. MDUFMA requires FDA, within 270 days of enactment, to issue guidance on the safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products.

On February 4, 2003, FDA published a **Federal Register** document entitled, "Medical Device User Fee and Modernization Act of 2003, Establishment of a Public Docket" (68 FR 5643) (hereinafter referred to as the MDUFMA Docket). In this **Federal Register** document, the agency identified several statutory provisions for which FDA was particularly interested in receiving stakeholder input, and this pediatric provision was one of them. No comments were submitted to the MDUFMA Docket on this topic. In the **Federal Register** of July 24, 2003 (68 FR 43729), FDA announced the availability of a draft of this guidance document and invited interested persons to comment by October 22, 2003. Three comments were submitted in response to the draft guidance, and the agency considered the comments while finalizing the document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on premarket assessment of pediatric medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Premarket Assessment of Pediatric Medical Devices" by fax, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1220) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910-0120) and premarket approval applications (21 CFR part 814, OMB control number 0910-0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-11028 Filed 5-13-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Collection: Comment Request

In compliance with the requirement for opportunity for public comment on data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the data collection methods and instruments, call the HRSA Reports Clearance Officer on (301) 443-1891.

Comments are invited on: (a) Whether the continued collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Evaluation of the Health Care for the Homeless Respite Pilot Initiative (OMB No. 0915-0269)—Extension

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration, is conducting an extension of an evaluation of the Health Care for the Homeless (HCH) Respite Pilot Initiative. Data are being collected from the ten HCH grantees participating in the Pilot Initiative. The National Health Care for the Homeless Council is conducting the evaluation through a cooperative agreement with the BPHC. The evaluation focuses on assessing the effect of respite services on the health of homeless people as well as examining any differences in outcomes based on client or program characteristics. The evaluation is being conducted

throughout the project period of Pilot Initiative.

The estimated response burden is as follows:

Type of respondents	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
HCH Grantees	10	200	2000	0.25	500
Program data	10	1	10	.5	5
Total	10	2010	505

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 10, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-10979 Filed 5-13-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2004 Geriatric Academic Career Awards (GACA)—CFDA 93.250

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of deadline date; correction.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** of April 27, 2004, containing an incorrect announcement number for the extension of a due date.

In FR Doc. 04-9472, in the **Federal Register** of April 27, 2004, on page 22849, in the second column, line 12 the language “HRSA-03-019 Fiscal Year 2004” is corrected to read: “HRSA-04-024 Fiscal Year 2004.”

Dated: May 10, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-10978 Filed 5-13-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given that the following committee will convene its forty-seventh meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 6, 2004, 2 p.m.–4:30 p.m.; June 7, 2004, 8:30 a.m.–4:30 p.m.; June 8, 2004, 8:30 a.m.–10:30 a.m.

Place: Arbor Day Farm Lied Lodge and Conference Center, 2700 Sylvan Road, Nebraska City, NE 68410, Phone: 402-873-8733, Fax: 402-873-4999.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, June 6, 2004, at 2 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. The first session will open with a discussion of the Committee business and updates by Federal staff. This will be followed by an overview of Nebraska by Committee Member Keith Mueller and a discussion of Health Care in Nebraska by Sandy Johnson, Executive Director of the State Medical Association. The final two sessions of the day will consist of a panel discussion on obstetrics and obesity in Nebraska and a dialogue on human services in Nebraska. The Sunday meeting will close at 4:30 p.m.

Monday morning, June 7, 2004, at 8:30 a.m. the Committee will break into Subcommittees and conduct site visits to local health and human services facilities. Transportation to these facilities will not be provided to the public. The Integrated Programs Subcommittee will visit Crete, NE; the Temporary Assistance for Needy Families Subcommittee will visit Beatrice, NE; the Obesity Subcommittee will visit Syracuse, NE; and the Obstetrics Subcommittee will visit Tecumseh, NE. The Committee will

conduct a joint site visit in Fairbury, NE. The Committee will reconvene at 2:15 p.m. in Nebraska City, NE, for an overview of the site visits. The Committee will break into Subcommittees to work on the 2005 report. The Monday meeting will adjourn at 4:30 p.m.

The final session will be convened Tuesday morning, June 8, 2004, at 8:30 a.m. The Committee will summarize the Subcommittees discussions and draft an outline for the annual report. The meeting will conclude with a discussion of the letter to the Secretary. The meeting will be adjourned at 10:30 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, HRSA’s Office of Rural Health Policy (ORHP), telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP’s Web site <http://www.ruralhealth.hrsa.gov>.

Dated: May 7, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-10977 Filed 5-13-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: April 2004

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of April 2004, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or