

day notice requesting public comment

on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section and FDA Form	Annual No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	5	1	5	130	650
316.20, 316.21, and 316.26	171	2.0	342	130	44,460
316.20, 316.21, and 316.26 Form FDA 3671	40	1	40	32	1,280
316.22	30	1	30	2	60
316.27	25	1	25	4	100
316.30	500	1	500	2	1,000
316.36	1	1	1	15	15
Total					47,565

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

Dated: April 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-9467 Filed 4-29-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, Juvenile Diabetes Research Foundation Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the National Institutes of Health (NIH) and the Juvenile Diabetes Research Foundation (JDRF), is holding a public workshop focused upon the state of the art in the research and development of an artificial pancreas. The public workshop entitled “Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, and Juvenile Diabetes Research Foundation Workshop” will provide a public forum for discussing the progress and remaining challenges in the development of closed-loop systems designed to regulate glycemic control, as an aid in the management of diabetes mellitus. It is intended to provide stakeholders with information that will accelerate the development of an artificial pancreas.

DATES: The public workshop will be held on July 21, 2008, from 7:55 a.m. to 6 p.m., and on July 22, 2008, from 8 a.m. to 12:45 p.m. Registration is available until 5 p.m. on June 20, 2008 (See **REGISTRATION TO ATTEND THE PUBLIC WORKSHOP**).

ADDRESSES: The public workshop will be held at the Lister Hill Auditorium on the NIH Campus (<http://www.nih.gov/science/campus/index.html>) located at 9000 Rockville Pike, Bethesda, MD 20892.

Parking on the NIH campus is limited. Attendees are encouraged to take public transportation. There is limited parking available at the Natcher Building. See <http://www.nih.gov/about/directions.htm> for more information.

FOR FURTHER INFORMATION CONTACT: Arleen Pinkos, Center for Devices and Radiological Health (HFZ-440), 2098 Gaither Rd., Rockville, MD 20850, 240-276-0702, FAX 240-276-0651, e-mail: arleen.pinkos@fda.hhs.gov.

REGISTRATION TO ATTEND THE PUBLIC WORKSHOP: Those interested in attending the public workshop may register online at <http://www.blsmmeetings.net/artificialpancreas08/reg.cfm>. There is no registration fee to attend the meeting; however, all participants must submit a registration form. Space is limited, so please submit your registration early to reserve a space. Registration will be accepted through June 20, 2008; however, onsite registration will be permitted on a space-available basis.

Persons without Internet access may call Akia Richardson at 301-313-0244 ext. 49, by June 20, 2008, to register for onsite attendance.

If you need special accommodations due to a disability, please contact L'Tonya Frazier at 301-594-4453 at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The artificial pancreas is one of FDA's Critical Path Initiatives, a program dedicated to accelerating the availability of much needed medical products. The Interagency Artificial Pancreas Working Group, a group of multi-disciplined scientists and clinicians from FDA and NIH, was established to support this initiative. The goals of the Artificial Pancreas Initiative are twofold: to provide infrastructure for narrowing the gap between basic biomedical knowledge and clinical application of novel technologies, and to cross-fertilize and partner with stakeholders in order to identify and overcome the clinical and scientific challenges to the development of an artificial pancreas. Through collaborative efforts, such as this workshop, the group strives to develop innovative strategies to achieve their goals.

II. Agenda

World renowned experts will present information on topics that are instrumental to the development of an artificial pancreas, and each session will be followed by roundtable discussions. Session topics will include:

- State of the art design of closed-loop glycemic control systems
- Results of recently conducted clinical trials
- Clinical trial design, including how to define successes and failures of closed-loop systems

- Algorithms and in silico models
- Engineering challenges
- Patient considerations
- Metabolic monitoring
- Use of closed-loop systems in non-diabetic intensive care patients
- Paths for developing marketable closed-loop systems

The agenda for this public workshop is available on the internet at <http://www.blsmmeetings.net/artificialpancreas08/agenda.pdf>.

More information about this public workshop is available at <http://www.blsmmeetings.net/artificialpancreas08>.

Dated: April 21, 2008.

Daniel G. Schultz,
Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program Part F Dental Services Report (OMB No. 0915-0151—Extension

The Dental Reimbursement Program (DRP) and the Community-Based Dental Partnership Program under Part F of the Ryan White HIV/AIDS Program offer funding to accredited dental education programs to support the provision of oral health services for HIV-positive individuals. Institutions eligible for these programs are accredited schools of dentistry, post-doctoral dental education programs and dental hygiene programs.

The DRP Application is the Dental Services Report that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV, or to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff-111(b)). The Dental Services Report collects data in four different areas: Program information, patient demographics and services, funding, and training. It also

requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually is to verify eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of Community-Based Dental Partnership Program grant recipients. This information also allows HRSA to learn about (1) The extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive HIV/AIDS program-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the Dental Services Report is critical for HRSA, State and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The reporting burden for reviewing the Dental Services Report Instructions and completing the Report is estimated as:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Dental Services Report	80	1	80	20	1600

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: April 23, 2008.

Alexandra Huttinger,
Director, Division of Policy Review and Coordination.

[FR Doc. E8-9490 Filed 4-29-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork

Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed 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 proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be 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.