K. Distribution Records

Sections 212.20(c) and 212.90(a) require that written procedures regarding distribution of PET drug products be established and maintained. We estimate that it will take approximately 1 hour annually to establish and maintain records of these procedures for each PET production facility. Section 212.90(b) requires that distribution records be maintained. We estimate that it will take approximately 15 minutes to create an actual distribution record for each batch of PET drug products, with a total burden of approximately 16,157 hours for all PET producers.

L. Complaints

Sections 212.20(c) and 212.100 require that PET drug producers establish written procedures for dealing with complaints, as well as document how each complaint is handled. We estimate that establishing and maintaining written procedures for complaints will take approximately 1 hour annually for each PET production facility and that each facility will receive approximately one complaint a year and will spend approximately 30 minutes recording how the complaint was dealt with.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
212.20(c) and (e); 212.50(a) and (b)	129	1.71	221	20	4,420
212.20(d) and (e); 212.50(c); 212.80(c)	129	501	64,629	.5 (30 min.)	32,315
212.20(c); 212.30(b); 212.50(d), 212.60(f)	129	15	1,935	1	1,935
212.30(b); 212.50(d); 212.60(f)	129	3,758	484,782	.08 (5 min.)	40,237
212.20(c); 212.40(a) and (b)	129	2	258	1	258
212.40(e)	129	36	4,644	.166 (10 min.)	771
212.20(c); 212.60(a) and (b); 212.61(a); 212.70(a), (b), and (d).	129	25	3,225	1	3,225
212.60(g); 212.61(b); 212.70(d)(2) and (d)(3)	129	501	64,629	.16 (10 min.)	10,728
212.70(f)	129	1	129	1	129
212.20(c); 212.71(a)	129	36	4,644	1	4,644
212.71(b)	129	1	129	1	129
212.20(c); 212.71(d)	129	1	129	1	129
212.20(c); 212.90(a)	129	1	129	1	129
212.90(b)	129	501	64,629	.25 (15 min.)	16,157
212.20(c); 212.100(a)	129	1	129	1	129
212.100(b) and (c)	129	1	129	.5 (30 min.)	65
Total					115,400

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours
212.70(e)	129	.25	32	1	32

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

Dated: March 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06351 Filed 3–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: 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 (OMB) 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, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (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.

Information Collection Request Title: HRSA AIDS Education and Training Centers Evaluation Activities: (OMB No. 0915–0281)—Revision

Abstract: The AIDS Education and Training Centers (AETC) Program, under the Ryan White HIV/AIDS Program established by Title XXVI of the Public Health Service (PHS) Act, as amended, supports a network of regional and national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects information on AETC training events, and is required to report aggregate data on their activities to HRSA's HIV/AIDS Bureau (HAB). The data provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by AETC trainees, and the increase in capacity achieved through training events. Collection of this information allows HRSA's HAB to provide information on training activities and types of education and training provided to Ryan White HIV/AIDS Program Grantees, resource allocation, and capacity expansion. Trainees are asked to complete the Participant Information Form (PIF) for each activity they complete, and trainers are asked to complete the Event Record (ER).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PIF	116,624	1	116,624	0.167	19,476.2
ER	18,070	1	18,070	0.2	3,614.0
Total	134,694		134,694		23,090.2

The estimated annual burden to AETCs is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Aggregate Data Set	16	2	32	32	1024.0

The total burden hours are 24,114.2.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail to the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: March 12, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–06382 Filed 3–19–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, ''Limited Competition: Collaborative Partnership to Advance Global Biomedical Research Programs (U01).''

Date: April 12, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Andrea L Wurster, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room