

practices outside public health settings despite the fact that most STD cases are seen in private health care settings. No descriptive data currently exist that allow the Centers for Disease Control and Prevention to characterize partner notification practices among the broad range of clinical practice settings where STDs are diagnosed, including acute or urgent care, emergency room, or primary and ambulatory care clinics. The existing literature contains descriptive studies of partner notification in public health clinics, but no baseline data exist as to the practices of different physician specialties across different practice settings.

The CDC proposes to fill that gap through a national sample survey of 7300 office managers and physicians who treat patients with STDs in a wide variety of clinical settings; a 70% completion rate is anticipated (n=5110 surveys). This survey will provide the baseline data necessary to characterize infection control practices, especially

partner notification practices, for syphilis, gonorrhea, HIV, and chlamydia and the contextual factors that influence those practices. Findings from the proposed national survey of office managers and physicians will assist CDC to better focus STD control and partner notification program efforts and to allocate program resources appropriately. Without this information, CDC will have little information about STD treatment, reporting, and partner management services provided by physicians practicing in the U.S. With changes underway in the manner in which medical care is delivered and the move toward managed care, clinical functions typically provided in the public health sector will now be required of private medical providers. At present, CDC does not have sufficient information to guide future STD control efforts in the private medical sector.

Data collection will involve a mail survey of practicing physicians. The questionnaire mailing will be followed

by a reminder postcard after one week, a second mailing to non-respondents at three weeks, telephone follow-up with non-respondents at five weeks, and a final certified mailing of the survey to non-respondents at eight weeks. A study specific computerized tracking and reporting system will monitor all phases of the study. Receipt of the completed questionnaire or a refusal will be logged into this computerized control system to ensure that respondents who return the survey are not contacted with reminders.

Estimated cost to respondents and government based on an average pay rate of \$25/hour, the estimated total cost burden for office managers to answer Section 1 is \$10,650. Based on an average pay rate of \$70/hour, the estimated cost burden for physicians is \$94,640. Thus the total cost burden for the data collection effort is estimated to be \$105,290.

Respondents	Sections	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Office Managers	Section 1	7300	1	.08	584
Physicians	Sections 2-4	5110	3	.03	460
Physicians	Section 5-10	5110	6	.20	6132
Total	7176

Dated: October 6, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-26983 Filed 10-9-97; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-01-98]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance

Office on (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. Prenatal HIV Prevention Survey: Knowledge, Attitudes And Practices of Health Care Providers Serving Pregnant Women Regarding HIV Counseling and Testing and the Use Of Zidovudine (ZDV) During Pregnancy—New—This is a new data collection. The purpose of this survey is to assess the knowledge, attitudes, and practices of health care providers serving pregnant women regarding HIV counseling and testing and use of ZDV during pregnancy. Data will be collected and reported to CDC to describe:

(1) providers' current practices in providing prenatal care to HIV-infected women, offering HIV counseling and

testing to pregnant women, and offering ZDV to HIV-infected pregnant women; (2) providers' knowledge of the ACTG 076 results and PHS perinatal transmission guidelines; (3) providers' attitudes regarding HIV counseling and testing of pregnant women; and, (4) providers' knowledge and experience in the use of ZDV in treating HIV-infected pregnant women.

The intended population to be studied is physicians and nurse-midwives providing prenatal care in four areas (State of Connecticut, potential population approximately 685; State of North Carolina, potential population approximately 1,500; Dade County, FL, potential population approximately 500; Brooklyn, NY, potential population approximately 260) where institutions are currently conducting a CDC-funded study related to implementation of the PHS guidelines to prevent perinatal transmission of HIV. The total annual burden hours are 685.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/response (in hrs.)
Census	2,659	1	0.05
Questionnaire (Pilot Study)	462	1	0.233
Questionnaire (Survey)	1,902	1	0.2333

2. Workshop Evaluation Component of the CDC's Prevention Marketing Initiative Local Demonstration Site Project—New—The Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention, Behavioral Intervention Research Branch is planning to conduct a series of studies as part of the evaluation of a five-city HIV prevention demonstration program. The program involves the integration of social marketing strategies and community participation in an effort to develop and implement HIV prevention activities.

Charged with developing programs for those 25 years of age and younger,

community groups in the local demonstration sites chose to segment the target audience even further, and to mount a variety of types of interventions. Decisions about segmentation and the nature of local interventions were based on formative research conducted in each community. It is hoped that this demonstration project will result in reductions in HIV risk behavior among members of the target audiences, as well as in enhanced collaboration among individuals and organizations in the participating communities.

To evaluate the effectiveness of two components of the intervention, questionnaire data will be collected

from people under 25 years old and from some parents in the demonstration communities. These data will be collected immediately before and after the Skills-Building Workshops, one month later, and six months later. In addition, questionnaire data will be collected once from individuals contacted through Outreach programs. These data will supplement a survey (announced in the **Federal Register** on 8/27/96) designed to assess the full program's coverage of the target population. Total annual burden hours are 2,798.

Respondents	Number of respondents	Number of responses/ respondents	Avg. burden/response (in hrs.)
Parental consent	1845	1	0.083
Teen consent/assent	² 3,168	1	0.0833
Pre/post questionnaire (intervention group)	³ 1,584	2	0.3333
Post questionnaire (control group)	³ 1,584	1	0.3333
Follow-up questionnaire	⁴ 2,640	1	0.3333

¹ 528 (ultimately needed per site) × 2 sites (whose target audiences are underage) plus 317 ($\frac{3}{5} \times 528$ for the one site that has not received IRB permission to waive parental consent and will train underage youth and some 18 and 19 year olds).

² $528 \times 5 \text{ sites} \times 1.2$ (to allow for 20% loss to follow-up).

³ $\frac{1}{2} \times 3,168$.

⁴ 529×5 .

3. Preventive Health and Health Services Block, Annual applications and reports—(0920–0106)—Extension—In 1994, OMB approved the collection of information provided in the grant applications and annual reports for the Preventive Health and Health Services Block Grant (0920–0106). This approval expires on September 30, 1997. CDC is requesting extension of OMB clearance for this legislatively mandated information collection.

The information collected through the applications from the official State health agencies is required from section 1905 of the Public Health Service Act. This is no change in the proposed information collection from previous years. The information collected from the annual reports is required by section 1906, specifically the requirement for uniform data sets matching the uses of funds. Minor modifications to some individual uniform data sets for chronic

diseases, as well as some other program areas, have been made to maintain consistency with performance measures developed as a result of the Government Performance and Results Act. Overall, this request reflects a 25% reduction in the collection burden to the grantees (States). The total burden hours are 5490.

Respondents	Number of respondents	Number of responses/ respondents	Avg. burden/response (in hrs.)
Annual Applications	61	1	30
Annual Reports	61	1	60

Dated: October 3, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-26984 Filed 10-9-97; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0115]

SEF, P.A.; Revocation of U.S. License No. 1166

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1166) and the product licenses issued to SEF, P.A., doing business as National Health Guard, Inc., for the manufacture of Whole Blood and Red Blood Cells (RBC's). SEF, P.A., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of the establishment license (U.S. License No. 1166) and the product licenses is effective October 10, 1997.

FOR FURTHER INFORMATION CONTACT:

Dano B. Murphy, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 1166) and product licenses issued to SEF, P.A., doing business as National Health Guard, Inc., 1885 West Commercial Blvd., suite 140, Fort Lauderdale, FL 33309, for the manufacture of Whole Blood (CPDA-1) and RBC's including frozen, deglycerolized, frozen rejuvenated, and rejuvenated deglycerolized RBC's.

On February 13, 1996, FDA attempted to inspect the SEF, P.A., facility located at 1820 North University Dr., Plantation, FL. The facility was found to be vacant. A visit that same day to the firm's previous business address, 1885 West Commercial Blvd., suite 140, Fort Lauderdale, FL, found that location to be vacant as well. On February 28, 1996, the owner of SEF, P.A., stated that all the firm's equipment was stored in a warehouse in Miami, FL. The owner also indicated that he would voluntarily surrender the firm's license because

SEF, P.A. was no longer in operation and there were no plans to resume operations. On June 17, 1996, FDA successfully contacted the owner by telephone and he indicated that he no longer desired to relinquish the license. Further attempts to contact the owner on July 2 and 29, 1996, were unsuccessful. On both occasions, messages were left with the answering party that were never replied to by the owner.

FDA sent a certified, return-receipt letter dated November 1, 1996, to the firm's owner. The letter stated that under 21 CFR 601.5(b) a license may be revoked when the Commissioner of Food and Drugs finds that: (1) Authorized FDA employees after reasonable efforts have been unable to gain access to an establishment or a location for the purposes of carrying out an inspection, or (2) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made. The letter provided the firm's owner notice of FDA's intent to revoke U.S. License No. 1166 and announced FDA's intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of April 9, 1997 (62 FR 17193), a notice of opportunity for a hearing on a proposal to revoke the licenses of SEF, P.A. In the notice, FDA explained that the proposed license revocation was based on the inability of FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation and noted that documentation in support of the license revocation had been placed on file for public examination with the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. The 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulation, may not be extended. No comments were received from any other parties.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21

CFR 5.68), the establishment license (U.S. License No. 1166) and the product licenses issued to SEF, P.A. are revoked, effective October 10, 1997.

Dated: September 25, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97-26987 Filed 10-9-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Center for Research Resources Special Emphasis Panel (SEP) meetings:

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 3, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 4, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 5, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.

Contact Person: Dr. D.G. Patel, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda 20892-7965, (301) 435-0820.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Biomedical Research Technology (Telephone Conference Call).

Date: November 7, 1997.

Time: 12:00 p.m.

Place: National Institutes of Health, 6507 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965.