

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
130.17(c)	7	1	7	25	175
130.17(i)	4	2	8	2	16
Total					191

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 1998, through September 30, 2001, and information from firms that have submitted recent requests for temporary marketing permits.

Dated: February 26, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-5299 Filed 3-5-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs 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: Cardiovascular and Renal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on April 12, 2002, from 8:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Jaime Henriquez or La'Nise S. Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 20-386/S028, COZAAR (losartan potassium), Merck and Co., Inc., for the treatment of type II diabetic patients with nephropathy.

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 April 4, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 4, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jaime Henriquez at least 7 days in advance of the meeting.

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

Dated: February 27, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a

copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: The Persistent Effects of Treatment Studies (PETS)—(OMB No. 0930-0202, extension)—SAMHSA's Center for Substance Abuse Treatment (CSAT) will request an extension of OMB approval to allow for completion of data collection in two studies being conducted under the PETS program. CSAT has developed PETS as a family of coordinated studies that evaluates the outcomes of drug and alcohol treatment received through a wide range of publicly funded programs. Populations being studied are diverse in the nature and severity of their substance abuse and in their personal characteristics and circumstances. The conceptual underpinning of the PETS studies is a recognition that substance abuse disorders, while variable in their manifestations, are often chronic and prone to relapse. PETS focuses on the longitudinal course of substance abuse and treatment. While most previous outcome studies in the field have examined changes taking place for only several months after a particular treatment episode, PETS looks at outcomes over a longer time period of three years or more. In the context of the client's life history, careful attention has been given to the stage in his or her experience of substance abuse and treatment to what has preceded their current treatment episode, and to any

sequence of aftercare, relapse, and subsequent treatment that may follow.

The PETS Chicago study continues data collection activities initiated under a grant to local investigators as part of CSAT's Target Cities project. This study will collect two- to six-year treatment followup data on a sample of clients originally assessed for treatment services at any of 22 service delivery units on Chicago's West Side.

The PETS Longer-term Adolescent Study builds upon CSAT's adolescent substance abuse treatment outcome studies in the Adolescent Treatment Models (ATM) and Cannabis Youth Treatment (CYT) grant programs. This study includes all four CYT sites and three first-round ATM sites, and will collect followup interviews for as long as 42 months after admission to treatment.

CSAT is conducting these studies in order to develop a better understanding of the longer-term outcomes for adults and adolescents receiving substance abuse treatment and factors that influence these outcomes. The information will be used to refine treatment approaches for these populations. The tables that follow summarize the burden for the two-year period of data collection for which approval will be sought.

Adult study	Number of respondents		Responses/ respondent	Burden/ response (in hours)	Total burden (in hours)
	60-month interview	72-mo. inter- view			
Chicago	706	550	1	1.5	1,884

Adolescent Studies	Number of Respondents			Responses/ Respondent	Burden/ Response (in hours)	Total Burden (in hours)
	24-month	30-month	42-month			
7 site total	30	183	993	1	1.85	2,231

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 28, 2002.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 02-5281 Filed 3-5-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Request for Comments Regarding the Prevention, Identification, and Treatment of Co-occurring Disorders

In compliance with section 503A of the Public Health Service Act (42 U.S.C. 290aa-2a), the Substance Abuse and Mental Health Services Administration (SAMHSA) is required to provide to the United States Congress a report on the prevention, identification, and treatment of co-occurring disorders. Public comment is solicited in order to aid in the development of this report.

SUMMARY: The report, due by October 17, 2002, is mandated to include the following:

- A summary of the manner in which individuals with co-occurring disorders are receiving treatment.
- A summary of improvements necessary to ensure that individuals with co-occurring mental illnesses and substance abuse disorders receive the services they need.
- A summary of practices for preventing substance abuse among individuals who have a mental illness and are at risk of having or acquiring a substance abuse disorder.
- A summary of evidence-based practices for treating individuals with co-occurring disorders and recommendations for implementing such practices.

We understand that your time is limited and you probably will not be able to respond to every issue. Where possible, however, it would be most helpful in responding to the key issues outlined below if you could identify those issues that you consider to be either a major problem or a minor problem. Further, for those issues that you consider to be a major problem, it would be helpful if you could explain the source of your concern and your recommendations for responding to the issue. Finally, you are in no way limited to the list below. If there are additional major problems related to the prevention, identification and treatment of co-occurring disorders that should come to the attention of SAMHSA,

please describe and comment on those as well.

The issues are organized by topic area in an outline form. For example, issue A.1., "Commitment demonstrated by key decision-makers to address co-occurring disorders," is under the System-Level topic area. It would be appreciated if you would provide your responses using the alphanumeric designations in this outline (e.g., A.1., B.1., etc.). This will allow us to process your indications of major and minor problem areas and your concerns and recommendations most efficiently.

A. System-Level Issues

1. Commitment demonstrated by key decision-makers to address co-occurring disorders.
2. Presence of an interagency coordinating body.
3. Presence of a strategic plan guiding community/interagency activities.
4. Opportunities for cross-training of staff.
5. Presence of interagency agreements.
6. Uniform application and eligibility criteria.
7. Pooled or joint funding.
8. Co-occurring disorders regarded as a likely presentation, not an exception.
9. Community efforts to reduce stigma of both disorders and encourage treatment.