TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
100.1(d)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions; therefore, the agency estimates that one or fewer petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the act.

Dated: February 26, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–5246 Filed 3–5–02; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0052]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Submit written or electronic comments on the collection of information by May 6, 2002.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control No. 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * *''. Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under § 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions of standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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.

[FR Doc. 02–5300 Filed 3–5–02; 8:45 am]

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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