Dated: November 19, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–30919 Filed 11–24–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0456]

Agency Information Collection Activities: Proposed Collection

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 reinstatement 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 and recordkeeping requirements relating to the use of narcotic drugs in treating drug addiction.

DATES: Submit written comments on the collection of information by January 26, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 reinstatement 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 listed below.

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.

Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction Reporting and Recordkeeping Requirements (21 CFR 291.505) (OMB Control Number 0910–0140—Reinstatement)

Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) provides for a separate controlled substances registration for practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment. This separate registration is conditioned on the Secretary of Health and Human Services (the Secretary) determining that the applicant is a practitioner who is qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought. Section 303(g) requires that the Secretary (and, by delegation, FDA and the National Institute of Drug Abuse): (1) Establish standards for practitioners who dispense narcotic drugs to persons for maintenance and/or detoxification treatment; (2) determine whether practitioners who wish to conduct such treatment are qualified under the standards; and (3) determine whether such practitioners will comply with the standards regarding the quantities of narcotic drugs that may be provided for unsupervised use by persons in such treatment.

Regulations found at 21 CFR 291.505 were issued under this authority. These regulations establish reporting requirements that include an application for approval of use of narcotic drugs in a narcotic addiction treatment program that must be submitted to, and approved by, FDA before the treatment program (which may be an individual or an organization) may receive shipments of narcotic drugs. Additional submissions are required when significant changes are implemented by treatment programs; for some kinds of changes, the regulations require FDA preapproval of the change before it is implemented. Additional submissions and FDA preapproval are also required if a treatment program seeks an exemption from certain requirements. The regulations contain no periodic reporting requirements.

The regulations governing the use of narcotic drugs for treatment of addiction also contain recordkeeping requirements that codify usual and customary practices within the medical and rehabilitative communities. Because the records required by the regulations would be kept even without a regulatory requirement, the time and financial resources necessary to comply with the recordkeeping requirements have not been included in the burden estimate below (see 5 CFR 1320.3(b)(2)).

FDA is requesting approval of the following FDA forms:

Form FDA–2632—''Application for Approval for Use of Narcotic Drugs in a Narcotic Addiction Treatment Program''. Organizations or individuals who wish to receive shipments of narcotic drugs for the treatment of narcotic addiction are required to submit this form in duplicate to FDA and to the appropriate State regulatory authority. All information and attachments to the application are required by the regulation. The application must include a list of personnel active in the program, such as physicians, nurses, and counselors; the names of hospitals, institutions, and analytical laboratories; and all other facilities used to provide necessary services required by the regulations. Form FDA–2632 is also used to report to FDA that a program will relocate, change the sponsor, or dispense Levo-Alpha-Acetyl-Methadol (LAAM).

Form FDA–2633—''Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program''. Each licensed physician authorized to administer or

dispense narcotic drugs for the treatment of narcotic addiction must complete this form and submit it to FDA and to the appropriate State regulatory authority.

Form FDA–2635—''Consent to Treatment with an Approved Narcotic Drug''. This form is to be completed by the practitioner and signed by the patient when the practitioner explains the treatment program to each new patient. The completed form becomes part of the patient's records and is not transmitted to FDA. Having a patient execute an informed consent form before undertaking a course of medical therapy, such as maintenance or detoxification, is usual and customary medical practice.

Form FDA–2636—''Hospital Request for Methadone Detoxification Treatment''. Before a hospital may receive shipments of methadone for detoxification treatment, a responsible official of the hospital must submit this form to FDA and to the appropriate State regulatory authority, and must have received a notice of approval from FDA. Form FDA–2636 is also used to inform FDA of changes in responsible hospital administrators.

Respondents to this information collection are sponsors and physicians, for treatment programs, and hospital officials, for hospital detoxification programs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Time per Response	Total Hours
Form FDA–2632, Application for Approval for Use of Narcotic Drugs in a Narcotic Addiction Treatment Program (New Programs)	291.505(b)(1)(ii), (b)(2)(i), (b)(2)(vi), (b)(3)(i), (c)(3), (c)(4), (d)(2)(i), and (d)(4)(i)(D)	55	1	55	105 min	96.25
Form FDA–2632, Application for Approval for Use of Narcotic Drugs in a Narcotic Addiction Treatment Program (Relocation)	291.505(b)(1)(ii), (c)(4)	35	1	35	70 min	40.83
Form FDA–2632, Application for Approval for Use of Narcotic Drugs in a Narcotic Addiction Treatment Program (Sponsor Change)	291.505(c)(2)(ii),(c)(4)	60	1	60	20 min	20
Form FDA–2632, Application for Approval for Use of Narcotic Drugs in a Narcotic Addiction Treatment Program (Levo-Alpha-Acetyl-Methadol(LAAM)Use)	291.505(b)(2)(iv), (c)(4)	75	1	75	15 min	18.75
Form FDA–2633, Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program	291.505(c)(4)	275	1	275	15 min	68.75
Form FDA–2636, Hospital Request for Methadone Detoxification Treatment (New Applicant)	291.505(f)(2)	20	1	20	10 min	3.33
Form FDA–2636, Hospital Request for Methadone Detoxification Treatment (Administrator Change)	291.505(f)(2)	5	1	5	10 min	0.83
Notifications of deletion of facility in which medication is administered	291.505(b)(2)(i)	45	1	45	15 min	11.25
Requests to change testing laboratory	291.505(d)(2)(i)	25	1	25	40 min	16.66
Reports of addition, modification, or deletion of any program services	291.505(d)(4)(i)(D)	32	1	32	15 min	8
Requests to allow patients to take home daily doses greater than 100 milligrams	291.505(d)(6)(v)(D)	600	1	600	15 min	150
Requests for exemptions from specific program standards	291.505(d)(11)	800	3	2,100	30 min	1,050
Requests for approval of a hospital as a temporary treatment program	291.505(f)(2)(i)	3	1	3	15 min	.75
Requests for alternative methods of distribution	291.505(j)(1)	5	1	5	30 min	2.5
TOTALS		2,035		3,335		1,487.9

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

These estimates are based on conversations with treatment and detoxification programs, on the number of responses received in past years, and on examination of received responses.

Dated: November 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30911 Filed 11–24–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0376]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The purpose of the proposed collection of information, a two-part telephone survey of tobacco retailers, is to assess the effectiveness of an advertising campaign aimed at increasing retailers' awareness of, and motivating retailers to comply with, new regulations that prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age and require retailers to verify, by means of photographic identification containing the bearer's date of birth, the age of every purchaser who is younger than 27 years old. The first phase of the survey must be completed by December 31, 1997.

DATES: Submit written comments on the collection of information by December 5, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–18, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: 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.

Tobacco Retailer Tracking Survey

On February 28, 1997, new Federal regulations at 21 CFR part 897 went into effect that prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and require retailers to verify, by means of photographic identification, the age of purchasers younger than 27 years old. FDA is planning to conduct a pilot advertising will campaign, in one State, aimed at raising retailers' awareness of the new regulations, and motivating retailers to comply. The campaign will target persons who sell cigarettes or smokeless tobacco to consumers for their personal use, including clerks and cashiers in grocery and convenience stores, pharmacies and drug stores, gas stations, liquor stores, taverns and bars, and tobacco stores. As part of the pilot, FDA is proposing to conduct a two-part telephone survey of tobacco retailers to measure their awareness of, and self-reported compliance with, the new regulations before and after exposure to the advertising campaign in the test State. FDA also would study levels of awareness and self-reported compliance among tobacco retailers in a control State matched demographically with the test State. Retailers in the control State would not be exposed to the media campaign, and FDA would not be actively conducting compliance checks before awareness and self-reported levels of compliance are measured.

A random sample of 1,350 tobacco retailers in the test State (675 for each phase) and 300 tobacco retailers in the control State would be selected for a telephone interview. All interviewing would be conducted by a single market research firm that would employ computer-aided telephone interviewing technology to expedite the fieldwork and ensure accuracy. FDA plans to use the results of the survey in designing a nationwide advertising campaign that would help to reduce youth access to cigarettes and smokeless tobacco. Under 21 U.S.C. 393(b)(2)(C), FDA is authorized to conduct surveys and other research relating to its responsibilities under the Federal Food, Drug, and Cosmetic Act.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,650 survey	1	1,650	.2	330
Total		1,650		330

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

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. This information is needed by December 31, 1997, and is essential to the agency's mission. The use of normal PRA clearance procedures would be likely to result in the prevention or disruption of this collection of information.

Dated: November 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30912 Filed 11–24–97; 8:45 am]

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