

Commission from taking action should it determine that respondents are not in full compliance with any final order. Furthermore, the Commission continues to adhere to its Policy Statement Concerning Errors and Omissions Clauses in Consent Decrees, 59 F.R. 34440 (July 5, 1994). We consider it highly unlikely that other facts would present themselves—in the administrative or federal court context—that would warrant application of the same or a similar rebuttable presumption.

Statement of Commissioner Mozelle W. Thompson

I am writing to express my concurrence with the Statement of Chairman Robert Pitofsky and Commissioner Sheila F. Anthony on the proposed consent agreement that the Commission accepted today for public comment in *Civic Development Group, Inc.* I have voted to support this proposed agreement in recognition of the allegation of serious harm caused by respondents through their fraudulent telemarketing fundraising and the need to place such respondents under order. However, one provision of the order raises issues addressed by my two aforementioned colleagues and that I wish also to address through this Statement.

Part V of the Order in *Civic Development Group* states that in any Commission action to enforce the order, "there shall be a rebuttable presumption that the respondents have exercised good faith in complying with [substantive provisions of the order] if the respondents show, by a preponderance of the evidence, that they have established and maintained the education and compliance program mandated in Paragraph IV of the order * * *."

I question the propriety of accepting a consent agreement that results in shifting the burden of proof to benefit a party that the Commission is claiming engaged in unlawful conduct. There are serious risks in permitting any party or adjudicative body to interfere with the Commission's well-supported prosecutorial discretion, and it could be argued that the limited rebuttable presumption in Part V allows respondent's compliance with the procedural requirements to detract from the Commission's ability to pursue substantive violations.

For purposes of this case only, I accept the order's burden-shifting provision and concur with the Chairman, Commissioner Anthony, and staff that this order is acceptable based on the unique and specialized aspects of

this case. Accordingly, in my view, the order presented here should not be regarded as having precedential value.

I trust that staff will continue to work closely with the company to monitor its compliance with the stringent requirements of Part IV as well as all other requirements of the order.

[FR Doc. 98-7700 Filed 3-24-98; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthy People 2010 Planning Process; Amendment

A notice published in the **Federal Register** on February 17, 1998 [63 FR 7810]. The notice is amended as follows:

On page 7810, third column, under the heading **SUPPLEMENTARY INFORMATION** on line 27, website is incorrect. It should read at <http://www.cdc.gov/nceh/programs/hp2010/>

All other information and requirements of the February 17, 1998, notice remain the same.

Dated: March 19, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-7691 Filed 3-24-98; 8:45 am]

BILLING CODE 4163-18-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0456]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by April 24, 1998.

ADDRESSES: Submit written comments on the collection of information to

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.

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

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 the Department 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:

(1) 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);

(2) 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;

(3) 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; and

(4) 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 BURDEN¹

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Form	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Time per Response	Total Hours
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.

Dated: March 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-7665 Filed 3-24-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4349-N-09]

Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval by March 27, 1998, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: The due date for comments is: March 27, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone

(202) 708-0050. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to a proposed "Request for Proposals—Contract Administrators for Project-Based Section 8 Housing Assistance Payments Contracts." This emergency processing is essential to provide for the immediate, ongoing, responsible administration of over 20,000 Section 8 contracts. These contracts represent a substantial investment to support the physical and financial well-being of affordable housing on a nation-wide basis. It is necessary for the Department to obtain the contract administration capability sought in the Request as soon as possible to ensure that the recent restructuring of the Department does not adversely affect this national investment, but instead, through Departmental oversight of successful bidders rather than direct, hands-on administration, results in improvements in the quality and affordability of the nation's housing stock.

The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 USC Chapter 35):

(1) Title of the information collection proposal:

"Request for Proposals—Contract Administrators for Project-Based Section 8 Housing Assistance Payments Contracts" (Request)

(2) Summary of the collection of information:

Each party seeking to become a contract administrator under the Request would be required to submit current information, as listed below:

1. Name.
2. Address.
3. Geographic service area in which the applicant proposes to serve as contract administrator.
4. Documented evidence that, within the last two years immediately prior to the date of the proposal, the proposer has performed duties substantially similar to those provided for in the Request.
5. Description of the applicant's experience in conducting mortgage foreclosures or in related activities which would qualify the applicant to serve as a foreclosure commissioner.
6. Description of how the proposer has provided similar services in the past, and a detailed description of experience with oversight of multifamily residential portfolios.
7. The proposal must describe methods used to manage and control prior contracts or portfolios.
8. The proposal must provide the names, addresses and telephone numbers of all references.
9. The proposal must demonstrate a thorough understanding of HUD's requirements and ability and capacity to perform all of the duties and tasks required.