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Name of Committee: Center for Scientific Review Special Emphasis Panel, Leprosy Immunity.

Date: August 27, 2003.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jean Hickman, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4194, MSC 7808, Bethesda, MD 20892, (301) 435-1146.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction—42 CFR part 8 (OMB No. 0930-0206; Revision)—This regulation establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as

individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA-162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA-163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA-168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions. Minor changes are being made to Form SMA-162 to account for newly approved opioid treatment drugs, to provide structures space on the form for required information and to make it more compatible with electronic submission.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondents	Hours/ response	Total hours
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	6.0	6.0
8.3(c)	Renewal of approval (SMA-163)	2	1	1.0	2.0
8.3(e)	Relinquishment notification	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTP's	1	90	0.1	9.0
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant programs.	2	2	1.0	4.0
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	1.0	20.0
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	0.5	15.0
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	0.02	9.0
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA	6	5	0.5	15.0
8.4(d)(5)	Summaries of Inspections	6	50	0.5	150.0
8.4(e)	Notifications of Complaints	6	6	0.5	18.0
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTP's	1	185	0.3	55.5
8.6(b)	Submission of 90-day Corrective plan to SAMHSA	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTP's of Probationary Status.	1	185	0.3	55.0
Total	7	376.2

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondents	Hours/ response	Total hours
8.11(b)	New programs approval (SMA-162)	75	1	1.50	112.50
8.11(b)	Renewal of approval (SMA-162)	370.00	1	1.00	370