DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the cumulative list of orphan drug and biological designations as of December 31, 1999. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Melvin Lessing or Stephanie Donahoe, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act which requires public notification of designations, FDA maintains a cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 1999, and, therefore, brings the February 26, 1999 (64 FR 9515), publication up to date. This list is available upon request from the Dockets Management Branch (address above). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this notice. In addition, the list is updated monthly and is available upon request from OPD or the FDA's Dockets Management Branch. The current list is also available on the Internet at http://www.fda.gov/orphan.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (address above).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: February 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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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: Evaluation of the Addiction Technology Transfer Center Program (New)

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to conduct an evaluation of its Addiction Technology Transfer Centers (ATTCs). The goal underlying the training and education opportunities provided through the ATTCs is to enhance the competencies of professionals in a variety of disciplines to address the clinical needs of individuals with substance abuse problems using research-based curricula and training materials through both traditional and non-traditional technologies.

The ATTCs disseminate current health services research from the National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Mental Health (NIMH), Agency for Health Care Policy and Research (ACHPR), National Institute of Justice (NIJ), and other sources and applied knowledge development activities from SAMHSA using innovative technologies by developing and updating state-of-the-art research-based curricula and developing faculty and trainers. Participants in ATTC trainings are self-identified and participate in either academic courses or continuing education/professional development trainings. Academic courses are offered at all levels. Continuing education/professional development trainings are designed to meet identified needs of counselors and other professionals who work with individuals with substance abuse problems.

Both a process and an outcome evaluation will be conducted. The process evaluation will describe the

training and education needs of pre-service and currently practicing professionals, the types of training events that students/trainees receive through the ATTCs, and student/trainee satifaction with services. The outcome evaluation will focus on specific changes in clinical practice made by trainees as a result of knowledge received.

Analysis of this information will assist CSAT in documenting the numbers and types of participants in ATTC education/training offerings, describing the extent to which participants improve in their clinical competency, and which method is most effective in disseminating knowledge to the various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The evaluation design for students and trainees will be a description of each course/training event, and a pre-post design that collects identical information at initiation of ATTC courses/trainings, at the completion to the course/training, and again after 3 months. This time frame is necessary to allow students/trainees the opportunity to implement changes in clinical practice. In addition, the evaluation will collect satisfaction measures after each course/training event. A formal comparison group is not available.

The 13 ATTCs anticipate providing courses/trainings for 12,000 students/trainees per year over the next 2 years. Data collection burden will be borne primarily by the ATTC faculty for course descriptions (15 minutes) and students/trainees for pre and post and follow-up (30 minutes for each). ATTC staff will conduct follow-up mailings and/or interviews. The chart below summarizes the annualized burden for this project over a two-year period.

Respondent type	Number of respondents	Average responses/ respondent	Average time/ response (hours)	Annual burden (hours)
Students/trainees	12,000	3	.50	18,000
Faculty/trainers	195	1	.25	49
ATTC summary reports	13	4	8	416
Total	12,208			18,465

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 23, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2000 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP) announces the availability of FY 2000 funds for grants for the following activity. This activity is discussed in more detail under Section 4 of this notice. This notice is not a complete description of the activity; potential applicants must obtain a copy of Parts I and II of the Guidance for Applicants (GFA) before preparing an application. Part I is entitled National Youth Substance Abuse Prevention Initiative (State Incentive Cooperative Agreements for Community-Based Action) (short title: State Incentive Grants). Part II is entitled General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements.

Activity	Application deadline	Estimated funds available, FY 2000	Estimated Number of awards	Project period
State Incentive Grants	5/10/00	$12 million	4 awards	3 years.

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 2000 funds for the activity discussed in this announcement were appropriated by the Congress under Public Law No. 106–113. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The SAMHSA Centers' substance abuse and mental health services activities address issues related to Healthy People 2000 objectives of Mental Health and Mental Disorders; Alcohol and Other Drugs; Clinical Preventive Services; HIV Infection; and Surveillance and Data Systems. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone: 202–512–1800).

SAMHSA has published additional notices of available funding opportunities for FY 2000 in past issues of the **Federal Register**.

General Instructions: Applicants must use application form PHS 5161–1 (Rev. 6/99; OMB No. 0920–0428). The application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161–1 which includes Standard Form 424 (Face