

Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Tamar S. Nordenberg, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Mr. Andrew Morris, a former employee at Quad Pharmaceuticals, Inc. (Quad), first as a bench chemist and later as a manager in Quad's research and development department, pled guilty and was sentenced on May 13, 1994, for making a false statement to a U.S. Government agency, a Federal felony under 18 U.S.C. 1001, and for obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

*A. False Statement to a Federal Agency*

Mr. Morris, while working as a bench chemist at Quad, made a false representation in a certificate of analysis regarding the potency of a particular lot of the drug azathioprine sodium, which was submitted to FDA in support of an abbreviated new drug application (ANDA) for the drug.

*B. Obstruction of an Agency Proceeding*

During an FDA audit of Quad's research and development department, Mr. Morris gathered and destroyed certain nonsterile samples of colistimethate sodium. These samples had previously been represented to FDA as sterile in batch production records. These records were prepared under Mr. Morris' supervision and were included in the ANDA for the drug product.

Mr. Morris is subject to debarment based on a finding, under section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)), that he was convicted of felonies under Federal law for conduct relating to the development, approval, and regulation of a drug product. Mr. Morris' false statements in documents used to support the ANDA's for the two Quad drug products relate to the development or approval of a drug product because FDA relies on the safety and efficacy data and information in the ANDA's in making its decisions whether to approve drug products. Mr. Morris' false statements and destruction of drug samples relate to the regulation of drug products because FDA's regulatory decisions about Quad drug

products may have been affected by the conduct.

In a letter received by FDA on May 16, 1994, Mr. Morris notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Mr. Morris waived his opportunity for a hearing and any contentions concerning his debarment.

**II. Findings and Order**

Therefore, the Interim Deputy Commissioner for Operations, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.20), finds that Mr. Andrew Morris has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product (21 U.S.C. 335a(a)(2)(A)); and relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings and based on his notification of acquiescence, Mr. Andrew Morris is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective May 16, 1994, the date of notification of acquiescence (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(ee)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Morris, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Morris, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any ANDA's submitted by or with the assistance of Mr. Morris during his period of debarment.

Any application by Mr. Morris for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0285 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 4, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*  
[FR Doc. 95-695 Filed 1-10-95; 8:45 am]

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**National Institute on Deafness and Other Communication Disorders; National Institutes of Health**

**Notice of Meetings of the National Deafness and Other Communication Disorders Advisory Council and its Planning Subcommittee**

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the National Deafness and Other Communication Disorders Advisory Council and its Planning Subcommittee on January 25-27, 1995, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting of the full Council will be held in Conference Room 10, Building 31C, and the meeting of the subcommittee will be in Conference Room 7, Building 31C.

The meeting of the Planning Subcommittee will be open to the public on January 25 from 2 pm until 3 pm for the discussion of policy issues. The meeting of the full Council will be open to the public on January 26 from 8:30 am until recess for a report from the Institute Director and discussion of extramural policies and procedures at the National Institutes of Health and the National Institute on Deafness and Other Communication Disorders and on January 27 from 8:30 am to approximately 9:30 am for a report on extramural programs of the Division of Human Communication. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) or Public Law 92-463, the meeting of the Planning Subcommittee on January 25 will be closed to the public from 3 pm to adjournment. The meeting of the full Council will be closed to the public on January 27 from approximately 9:30 am until adjournment. The closed portions of the meetings will be for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council and Subcommittee meetings

may be obtained from Dr. Earleen F. Elkins, Executive Secretary, National Deafness and Other Communication Disorders Advisory Council, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Executive Plaza South, Room 400C, Bethesda, Maryland 20892, 301-496-8693. A summary of the meetings and rosters of the members may also be obtained from her office. For individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, please contact Dr. Elkins at least two weeks prior to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: January 3, 1995.

**Susan K. Feldman,**

*Committee Management Officer, NIH.*

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## Office of Community Services

[Program Announcement No. OCS 95-04]

### Family Violence Prevention and Services Program

**AGENCY:** Office of Community Services, Administration for Children and Families, (ACF), Department of Health and Human Services.

**ACTION:** Notice of the availability of funding to States and Native American Tribes and Tribal organizations for family violence prevention and services.

**SUMMARY:** This announcement governs the proposed award of fiscal year (FY) 1995 formula grants under the Family Violence Prevention and Services Act to States (including Territories and Insular Areas) and Native American Tribes and Tribal organizations. The purpose of these grants is to assist in establishing, maintaining, and expanding programs and projects to prevent family violence and to provide immediate shelter and related assistance for victims of family violence and their dependents.

This announcement also specifies a new expenditure period for these funds and sets forth the application process and requirements for grants to be awarded for FY 1996 through FY 2000.

**CLOSING DATES FOR APPLICATIONS:** Applications for FY 1995 family violence grant awards meeting the criteria specified in this announcement must be received at the address specified below by March 13, 1995.

Grant applications for FY 1996 through FY 2000 should be received at the address specified below by November 15 of each following fiscal year.

**ADDRESSES:** Applications should be sent to: Office of Community Services, Administration for Children and Families, Attn: William D. Riley, 5th Floor, West Wing, 370 L'Enfant Promenade, SW., Washington, DC 20447.

**FOR FURTHER INFORMATION CONTACT:** William D. Riley (202) 401-5529 or Al M. Britt (202) 401-5453.

#### SUPPLEMENTARY INFORMATION:

##### Introduction

This notice for family violence prevention and services grants to States and Indian tribes serves two purposes. The first is to confirm a Federal commitment to reducing family and intimate violence and to urge States, localities, cities, and the private sector to become involved in State and local planning efforts leading to the development of a more comprehensive and integrated service delivery approach (Part I). The second purpose is to provide information on application requirements for FY 1995 grants to States and Indian tribes. These funds will support prevention activities, shelters, and related services for battered women and their children (Part II).

#### Part I. Reducing Family and Intimate Violence Through Coordinated Prevention and Services Strategies

##### A. The Importance of Coordination of Services

A person facing family or intimate violence may need more than immediate medical care and shelter. Assured protection and effective support are essential to end ongoing abuse.

The effects of domestic violence may manifest themselves in varying forms, including: substance abuse, hopelessness, arrest, felony charges, mental health concerns, injuries, lost time at work, child abuse, and welfare dependence. When programs that seek to address these issues operate independently of each other, a fragmented, and consequently less effective, service delivery and prevention system may be the result. Coordination and collaboration among the police, prosecutors, the courts, victim services providers, child welfare and family preservation services, and medical and mental health service providers is needed to provide more responsive and effective services to victims of domestic violence and their

families. It is essential that all interested parties are involved in the design and improvement of protection and services activities.

To help bring about a more effective response to the problem of intimate violence, the Department of Health and Human Services (HHS) urges State agencies and Indian tribes receiving funds under this grant announcement to coordinate activities funded under this grant with other new and existing resources for family and intimate violence and related issues.

#### B. Coordination of Efforts

##### 1. Federal Coordination

In the fall of 1993, a Federal Interdepartmental Work Group (including the Departments of Health and Human Services, Justice, Education, Housing and Urban Development, Labor, and Agriculture) began working together to study cross-cutting issues related to violence, and to make recommendations for action in areas such as youth development, schools, juvenile justice, family violence, sexual assault, firearms, and the media. The recommendations formed a framework for ongoing policy development and coordination within and among the agencies involved.

The interdepartmental working group also initiated a "Cities Project" (now known as PACT, Pulling America's Communities Together) to help coordinate Federal assistance to four geographic areas (Denver; Atlanta; Washington, DC; and the State of Nebraska) as they develop comprehensive plans for violence prevention and control.

Based on these coordination efforts, a new interdepartmental strategy was developed for implementing the programs and activities recently enacted in the Violent Crime Control and Law Enforcement Act of 1994 (Crime Bill). A Steering Committee on Violence Against Women is coordinating activities among family violence-related programs and across agencies and departments.

##### 2. Opportunities for Coordination at the State and Local Level

The major domestic violence prevention activities funded by the Federal government focus on law enforcement and justice system strategies; victim protection and assistance services; and prevention activities, including public awareness and education. Federal programs also serve related needs, such as housing, family preservation and child welfare services, substance abuse treatment, and job training.