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.

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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