of Psychology, University of Missouri—St. Louis, engaged in scientific misconduct in clinical research supported by a National Institute of Mental Health (NIMH), National Institutes of Health (NIH) grant.

Specifically, ORI finds that Ms. Berezniak falsified scoring of taped interviews of nine subjects. The scoring was conducted to measure interviewer reliability in determining whether the subjects had post-traumatic stress disorder. The falsified data did not appear in any publications nor were they included in the study's database.

Ms. Berezniak has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed, for the two (2) year period beginning September 9, 1998:

(1) To exclude herself from serving in any advisory capacity to the Public Health Service (PHS) including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(3) That any institution that submits an application for PHS support for a research project on which her participation is proposed or uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of her research contribution. The institution also must submit a copy of the supervisory plan to ORI.

**FOR FURTHER INFORMATION CONTACT:** Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

**Chris B. Pascal,**

*Acting Director, Office of Research Integrity.*

[FR Doc. 98–26422 Filed 10–1–98; 8:45 am]

**BILLING CODE 4160–17–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of the Committee*: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on October 19, 1998, 10 a.m. to 6 p.m., and October 20, 1998, 8:30 a.m. to 5 p.m.

*Location*: Parklawn Bldg., conference rooms G and H, 5600 Fishers Lane, Rockville, MD.

*Contact Person*: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On October 19, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application for a thermal endometrial ablation system intended to treat women with abnormal uterine bleeding. On October 20, 1998, in the context of the current guidance document on thermal endometrial ablation devices entitled ''Thermal Endometrial Ablation Devices,'' the committee will discuss: (1) Initial safety studies, as well as the pivotal safety and effectiveness study, for postmenopausal patients on hormone replacement therapy, which will include inclusion/exclusion criteria, type(s) of control, and length of followup, both premarket and postmarket; and (2) proposed labeling for vacuum-assisted delivery devices. Single copies of the guidance document are available to the public by contacting the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or 301–443–6597 or by faxing your request to 301–443–8818 and requesting the document by shelf No. 547.

*Procedure*: On October 19, 1998, from 10:45 a.m. to 6 p.m. and on October 20, 1998, from 8:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 14, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. on October 19, 1998. Near the end of the committee deliberations on October 19, 1998, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. and between approximately 1:15 p.m. and 1:45 p.m. on October 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before October 14, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and address of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations*: On October 19, 1998, from 10 a.m. to 10:45 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 24, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–26502 Filed 10–1–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0713]**

### Draft Guidance for Industry on Submitting Debarment Certification Statements; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submitting Debarment Certification Statements.'' The draft guidance addresses the most commonly asked questions about debarment certification statements and information requirements under the Federal Food, Drug, and Cosmetic Act (the act) and is intended to assist in the submission of applications for human, animal, and biologic drug products, export applications for certain

unapproved products, and supplements to certain drug product applications.

**DATES:** Written comments on the draft guidance document may be submitted by December 1, 1998. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance entitled ''Submitting Debarment Certification Statements.'' Section 306(k) of the act (21. U.S.C. 335a(k)) states that drug product applications are to include a certification that the applicant did not and will not use in any capacity the services of any person who has been debarred under sections 306(a) or (b) of the act. Additionally, section 306(k) of the act requires that abbreviated new drug applications (ANDA's) and supplements to ANDA's providing for a *different or additional use* and submitted on or after June 1, 1992, contain a list of all convictions of the applicant and affiliated persons responsible for the development or submission of such application that have occurred within the last 5 years and for which a person can be debarred.

Since section 306(k) of the act became effective in 1992, FDA has received a number of requests for clarification. This draft guidance addresses the most commonly asked questions about the certification and information requirements and should be helpful to those submitting the following drug product applications to FDA: (1) New drug applications, (2) ANDA's, (3) new animal drug applications, (4) abbreviated new animal drug applications, (5) export applications for certain unapproved products, (6) biological license applications, and (7) supplements to certain drug product applications. The draft guidance was prepared by the Debarment Task Force at FDA.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on debarment certification statements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Submit written requests for single copies of the draft guidance entitled ''Submitting Debarment Certification Statements'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; or the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Requests should be identified with the docket number found in brackets in the heading of this document. Send one self-addressed adhesive label to assist the office in processing your request.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98–26424 Filed 10–1–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Research and Demonstration Projects for Indian Health

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice of single source cooperative agreement with the Center for Native American Health, College of Medicine/Arizona Prevention Center, University of Arizona.

**SUMMARY:** The Indian Health Service (IHS) announces the award of a cooperative agreement to the Center for Native American Health (CNAH), College of Medicine/Arizona Prevention Center, University of Arizona, for a demonstration project to build and expand on a unique collaborative partnership that currently exists among the CNAH, the IHS, and the Indian tribes located in the southwestern part of the country. The project is for a 2-year period, effective September 1, 1998, through August 31, 2000. Funding for the first year of the project is $243,075, plus an annual in-kind contribution by the University of $100,390.

The award is issued under the authority of the Public Health Service Act, Section 301. A general program description is contained in the *Catalog of Federal Domestic Assistance*, number 93.933.

The specific goals of the project are to increase opportunities for sub-specialty medical care at reservation health care facilities, to increase the availability of telemedicine at reservation health care facilities, to enhance community health planning and prevention activities, to facilitate counseling of high school level Indian students for entry into health careers, and to investigate the possibilities of replication of this collaborative project at other sites.

*Justification for Single Source:* The CNAH is a unique organization within the University that is guided by an Advisory Council composed of leaders from 13 Indian tribes and tribal organizations located in the southwestern part of the country and health professionals from the Arizona Department of Health, the IHS, and the University of Arizona.

*Award of a Cooperative Agreement:* The Project Director for this cooperative agreement is an IHS employee who is serving as the Director of CNAH; therefore, he will provide substantial on-going IHS programmatic involvement in the development and direction of this demonstration project. Also, the IHS has health professionals providing project guidance as members of the Advisory Council.

Contacts: For programmatic information, please contact Ms. Jan Frederick, Acting Chief, Nutrition and Dietetics, Phoenix Area IHS, Two Renaissance Square, 40 North Central Avenue, Phoenix, Arizona 85004, (602) 364–5197. For grants administration or business information, contact Ms. M. Kay Carpentier, Grants Management