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