

71, No. 224), make the following addition under *Additional Information*:

#### VI. ANA Administrative Policy

ANA is issuing a policy clarification statement. Currently, ANA has an administrative policy that states "An applicant can have only one active Social and Economic Development Strategies (SEDS) grant operating at any given time." In addition to the regular SEDS competition, ANA currently conducts two special initiative awards programs under Section 803(a) of the Native American Programs Act, 42 U.S.C. 2991b(a). The two additional programs funded under the SEDS Catalog of Federal Domestic Assistance number 93.612 are the SEDS-Alaska and the Improving the Well-Being of Children: Native American Health Marriage Initiative (NAHMI). By issuing this statement, ANA is reinforcing the policy that applicants may submit only one application for SEDS or one application for NAHMI, but not for both. ANA will only accept for funding competition the first application submitted. If two applications are received from the same applicant at the same time, the applicant will be notified, prior to an eligibility determination, that only one application will be accepted. ANA will continue to enforce its policy that grantees cannot receive two or more grant awards under the SEDS category.

Dated: December 9, 2006.

#### Quanah Crossland Stamps,

*Commissioner, Administration for Native Americans.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee for Reproductive Health Drugs; 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). The meeting will be open to the public.

*Name of Committee:* Advisory Committee for Reproductive Health Drugs.

*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 January 23, 2007, from 8:30 a.m. to 6 p.m. and on January 24, 2007, from 8:30 a.m. to 5:00 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Teresa Watkins, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Teresa.Watkins@fda.hhs.gov](mailto:Teresa.Watkins@fda.hhs.gov) FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On January 23 and 24, 2007, presentations and committee discussions will address current issues which influence the consideration for approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Implantable and injectable hormone products will not be discussed. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control. FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

*Procedure:* 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 on or before January 12, 2007. Oral presentations from the public will be scheduled between approximately 10 a.m. and 12 noon on January 24, 2007. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make

their presentation on or before January 5, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 8, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Teresa Watkins at least 7 days in advance of the meeting.

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

Dated: December 15, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0172]

#### Guidance for Clinical Investigators, Institutional Review Boards, and Sponsors; Process for Handling Referrals to Food and Drug Administration Under 21 CFR 50.54: Additional Safeguards for Children in Clinical Investigations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Clinical Investigators, Institutional Review Boards, and Sponsors; Process for Handling Referrals to FDA Under 21 CFR 50.54: Additional Safeguards for Children in Clinical Investigations." This guidance is intended to assist clinical investigators, Institutional Review Boards (IRBs), sponsors, and other interested parties in understanding FDA's process for handling clinical investigations that include children as subjects and that