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.

[FR Doc. 06–9834 Filed 12–21–06; 8:45 am]

BILLING CODE 4184–01–M

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*or 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.

[FR Doc. E6–21949 Filed 12–21–06; 8:45 am]

BILLING CODE 4160–01–S

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

have been referred to FDA for review under FDA regulations on additional safeguards for children in clinical investigations. The guidance describes the procedures FDA generally intends to follow in handling clinical investigations referred for review under § 50.54 (21 CFR 50.54) and in reaching final determinations in accordance with these regulations. The guidance announced in this notice finalizes the draft guidance of the same title dated May 2006.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

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.'' FDA issued 21 CFR part 50, subpart D, ''Additional Safeguards for Children in Clinical Investigations,'' (subpart D) as an interim final rule on April 24, 2001 (66 FR 20598). Under these regulations, an IRB must review clinical investigations involving children as subjects and covered by subpart D and approve only those clinical investigations that satisfy the criteria described in §§ 50.51, 50.52, or 50.53, as well as the conditions of all other applicable sections in subpart D.

Under § 50.54, if an IRB does not believe that a clinical investigation within the scope described in §§ 50.1 and 56.101 (21 CFR 56.101) and involving children as subjects meets the requirements of §§ 50.51, 50.52, or 50.53, the clinical investigation may proceed only if:

- (1) The IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (2) The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determines either of the following:
- That the clinical investigation in fact satisfies the conditions of § 50.51, 50.52, or 50.53, as applicable, or
- That the following conditions are met:
- The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- The clinical investigation will be conducted in accordance with sound ethical principles; and
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in § 50.55.

The guidance describes the procedures FDA generally will follow in handling clinical investigations referred for review under § 50.54 and in reaching final determinations under that regulation. The guidance is based in part on FDA's experience to date with such referrals. The Department of Health and Human Services (HHS) has human subject protection regulations that also govern research involving children as subjects and supported or conducted by HHS. (See 45 CFR part 46, subpart D.) The guidance also addresses situations in which a clinical investigation is subject to both 21 CFR 50.54 and 45 CFR 46.407.

In the **Federal Register** of May 10, 2006 (71 FR 27264), FDA announced the availability of the draft guidance of the same title dated May 2006. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the process for handling referrals to FDA under§ 50.54. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information required under § 50.54 is a recordkeeping requirement. IRB recordkeeping requirements are set forth in FDA regulations on IRBs (21 CFR part 56) at § 56.115. The collection of information in § 56.115 has been approved under OMB Control No. 0910–0130. Although FDA had included an analysis of the estimated annual reporting burden in the notice of availability for the draft guidance (71 FR 27264), that analysis made clear that, based on the agency's experience to date with the regulation addressed in the guidance, FDA only expects approximately five respondents per year to submit information to the agency under the guidance. Accordingly, FDA has concluded that, under 5 CFR 1320.3(c), there is no collection of information associated with this guidance.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm* or*http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21950 Filed 12–21–06; 8:45 am]

BILLING CODE 4160–01–S