DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcements Nos. OCS–2000–01 and OCS–2001–01]

Request for Applications for the Office of Community Services' Fiscal Years 2000 and 2001 Discretionary Grants Program; Correction

AGENCY: Office of Community Services (OCS), ACF, DHHS.

ACTION: Notice; clarification and correction.

SUMMARY: This notice clarifies Program Announcement No. OCS–2000–01 published in the **Federal Register** on August 19, 1999 (64 FR 45302) and corrects Program Announcement No. OCS–2001–01, published on June 20, 2000 (65 FR 38336). This notice clarifies the Rural Community Facilities Development Program Sub-Priority Area 2.0; it explains what information should have been included in the FY 2000 announcement; and it corrects the error made requesting proposals in the FY 2001 announcement. OCS will not be accepting proposals for FY 2001 under the Rural Community Facilities Development Program—Sub-Priority Area 2.1.

FOR FURTHER INFORMATION CONTACT: Veronica Terrell, Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Phone: 202–401–5295.

For Fiscal Year (FY) 2000: Program Announcement, OCS–2000–01, issued in the **Federal Register** on August 19, 1999, the information provided on page 45304 in the last paragraph under 3. Project and Budget Periods, states ''For Priority Area 2.0, grantees will be funded for 24 month project periods and 12 month budget periods.'' OCS did not mention that the program awardees selected through the competitive process in this round would be awarded a ''Non-Competitive Continuation Grant'' for FY 2001.

For FY 2001: Program Announcement, OCS–2000–01, issued in the **Federal Register** on June 20, 2000, OCS makes the following corrections:

1. On page 38338—Under *3. Project and Budget Periods:* delete the last paragraph and replace it with the following note:

Note: There will be no new grant awards made in Fiscal Year 2001 under Sub-Priority Area 2.1. In Fiscal Year 2000, certain grantees were awarded grants for 24-month project periods and 12 month budget periods. These grantees will receive the grant funds from this category to supplement their second year of funding.

2. On page 38344—Priority Area 2.0 Rural Community Facilities Development should be corrected as follows:

FY 2001 in the first heading and the first sentence should be revised to ''FY 2000.''

The initial 1. should be removed.

The last paragraph should be removed and replaced with a new paragraph to read as follows: ''One grant of approximately $300,000 is anticipated to be made under this sub-priority area for FY 2000.

Remove section 2., Rural Community Facilities, in its entirety. OCS does not intend to compete this sub-priority area for FY 2001. The FY 2000 grantees do not have to apply competitively; their FY 2001 grants will be administered as a non-competitive continuation grant action. At an appropriate time, OCS will invite these grantees to submit requests for continuation funding for the balance of their two-year projects, subject to the availability of funds.

Dated: September 29, 2000.

Robert L. Mott,

Deputy Director, Office of Community Services.

[FR Doc. 00–25476 Filed 10–3–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nutrient Requirements of Domestic Animals and Critical Roles of Animal Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine, announces the availability of funds to support an unsolicited grant application submitted by the National Academy of Sciences (NAS). The academy has requested funds to support the activities of the National Research Council's (NRC) Committee on Animal Nutrition (CAN). The central emphasis of CAN, through its species subcommittees is the preparation and updating of a series of reports on the nutrient requirements of animals. This series addresses economically important domestic animals, including food- and fiber-producing species, as well as captive fur-bearing species, aquatic species, companion animals, service and working animals, endangered species, and animals that serve as experimental models in biomedical research. In addition CAN identifies emerging problems in the area of animal nutrition and implements appropriate mechanisms, such as deliberative studies, symposia, workshops, or roundtables to address the issues.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Peggy L. Jones, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7160. Correspondence hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–520), rm. 2129, Rockville, MD 20857.

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research, Center for Veterinary Medicine (HFV–502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8021.

SUPPLEMENTARY INFORMATION:

I. Eligible Applicants

Assistance will only be provided to the National Academy of Sciences because of the following:

1. The NAS is the only organization that submitted an unsolicited application for the purpose stated above.

2. The NAS is the only organization that has a standing Committee on Animal Nutrition for the purpose of preparing and updating reports on the nutrient requirements of animals.

3. The NRC is unique with regard to its operation and policies. The core of the NRC's work consists of studies conducted by experts selected by the NRC expressly for their expertise in the relevant scientific issues at hand.

4. CAN was formally organized in 1928 under the auspices of the NAS and NRC to provide advice to Federal agencies and the nation on the nutritional management of important domestic animals.

5. Reports produced by CAN have been widely used and accepted by Federal agencies, the biomedical community, the U.S. animal industry and abroad as a group of unbiased and comprehensive reports that form the basis of nutrient recommendations for animals in the United States and many parts of the world.

6. Reports of CAN have been translated into at least five other

languages (Spanish, Russian, Chinese, Japanese, and Turkish) and are used as a standard for animal nutrition throughout the world.

II. Funding

We anticipate that approximately $20,000 will be made available to fund this project. It is expected that the award will begin in either fiscal year (FY) 2000 or FY 2001 and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Dated: September 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25449 Filed 10–3–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1519]

Clinical Pharmacology During Pregnancy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an FDA/National Institute for Child Health and Human Development co-sponsored meeting on ''Clinical Pharmacology During Pregnancy: Addressing Clinical Needs Through Science.'' Experts from industry, academia, and the public have been invited to provide their perspectives on drug therapeutics during the second and third trimester of pregnancy. The goals of the meeting are: To summarize the state of knowledge regarding clinical pharmacology in pregnancy; to raise awareness among clinician researchers and leaders about the need for clinical research and collaboration in this area; and to garner support for such research from health advocacy groups and others.

DATES: The meeting will be held on Monday and Tuesday, December 4 and 5, 2000, from 8 a.m. to 5 p.m. The deadline for registration is November 13, 2000.

ADDRESSES: The location of the meeting is the Holiday Inn, Capitol room, 550 C St. SW., Washington, DC 20024, 202–479–4000. Transcripts of the meeting will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at http://www.fda.gov/ohrms/dockets. Register on the Internet at http://www.fda.gov/cder/audiences/women/pharmpreg2000.htm.

FOR FURTHER INFORMATION CONTACT: Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–827–2185, e-mail: kennedyd@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Most women and physicians seek to avoid the use of medications during pregnancy to protect the developing fetus from any potential adverse effects. However, medication use by pregnant women is common. A study conducted in 1994 by FDA, using several managed care data bases, found that the average number of prescriptions per patient during pregnancy (excluding prenatal vitamins, iron preparations, and medications at the time of delivery) was three. The number of prescriptions increased with maternal age. For pregnant women over the age of 35, the average number of prescriptions was five (unpublished data, FDA).

In considering the needs for clinical pharmacology data to guide drug dosing among special populations, the pregnant woman is rarely addressed. Yet, the physiology of pregnancy is dynamic and capable of influencing the pharmacokinetic profiles of many drugs. It is commonly appreciated that hormonal changes, particularly elevated estrogens and progesterone, accompany normal pregnancy, but their effects are often unappreciated.

Many women enter pregnancy with health conditions that require medications, such as neurologic and psychiatric conditions. Some health conditions tend to worsen during pregnancy, including hypertension, asthma, endocrinopathies, rheumatologic diseases, and cardiac conditions. Previously healthy women often develop illnesses during pregnancy, such as infections, diabetes, thyroid disease, thromboembolism, or cancers. Often, not using medications poses far greater risk to fetal well being and survival than the risk of a particular drug.

Most physicians seek to prescribe the lowest effective dose of any given drug to treat a pregnant woman. Their goal is to provide the best effect for the least exposure possible to the fetus. However, when deciding what the appropriate dose is for a given patient, health care practitioners usually rely on information (typically from product circulars) from studies of individuals who are not pregnant. Particularly for drugs with a narrow therapeutic window, or with marginal efficacy at the lower end of the therapeutic spectrum, this practice risks exposing the fetus to a dose of medication with little or no benefit to the mother. The result may be that the mother's condition worsens. She may require a second course of the same treatment or a switch to a second or third drug, exposing her developing infant to multiple courses of treatment over a much longer period of time.

Pregnant women are usually excluded from clinical trials and even in situations where pregnant women require therapeutics, pharmacokinetic studies are rarely done. There are many reasons for this. Pregnancy is a temporary condition and easily forgotten in ''wish lists'' for data, by subspecialists who treat pregnant women with serious medical problems. Also, interested investigators may be reluctant to pursue pharmacokinetic studies in pregnant women because of their lack of knowledge related to pregnancy or fetal development. Finally, where information does exist in the medical literature about pharmacokinetics of individual drugs in pregnancy, the data have rarely appeared in product labels, creating further disincentives for conducting such clinical research. This latter reality has its own set of probable causes, but may change as FDA enhances requirements for product safety updates based on scientific literature and human experience data. Regardless of the root causes for the current paucity of information, rational prescribing for the pregnant patient must attempt to ensure that she will have the greatest likelihood of clinical benefit from a medication in exchange for the safest or least exposure of her developing baby. This can only be achieved when adequate pharmacokinetic dosing data are available.

The agency hopes this meeting will help summarize the state of knowledge on clinical pharmacology in pregnancy, raise awareness among clinician researchers and leaders about the need for clinical research and collaboration in this area, and garner support for such research from health advocacy groups and others.