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.

## II. Registration

There is no registration fee, however preregistration is required. Register early, as space is limited. The meeting room will hold approximately 250 people. Registration will begin with the publication of this notice. If you will need special accommodations due to a disability to attend the meeting, please inform the contact person listed above. You may obtain information and register on the Internet at http://www.fda.gov/cder/audiences/women/pharmpreg2000.htm.

Dated: September 25, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00–25386 Filed 10–3–00; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### Privacy Act of 1974; Report of New System

**AGENCY:** Health Care Financing, Department of Health and Human Services (HHS), Administration (HCFA).

**ACTION:** Notice of New System of Records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, ''Record of Individuals Allowed Regular and Special Parking Privileges at the HCFA Building (PRKG), HHS/HCFA/OICS, System No. 09–70–3004.'' PRKG will be used as part of our building security plan. All Federal employees will be issued parking permits by HCFA to provide regular or special parking based on specific needs.

The primary purpose of the system of records is to issue parking permits for the HCFA complex at 7500 Security Boulevard, Baltimore, Maryland. Information retrieved from this system of records will also be used to support regulatory and policy activities performed within the agency or by a contractor or consultant; support constituent requests made to a Congressional representative; and to support litigation involving the agency related to this system of records. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that HCFA provide an opportunity for interested persons to comment on the proposed routine uses, HCFA invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

**EFFECTIVE DATES:** HCFA filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 20, 2000. To ensure that all parties have adequate time in which to comment, the new system of records, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless HCFA receives comments that require alterations to this notice.

**ADDRESSES:** The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), HCFA, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kris Zaruba, Division of Facilities Management Services, Administrative Services Group, Office of Internal Customer Support, HCFA, 7500 Security Boulevard, SLL–11–08, Baltimore, Maryland 21244–1850. The telephone number is 410–786–0837.

**SUPPLEMENTARY INFORMATION:**

## I. Description of the New System of Records

*Statutory and Regulatory Basis for System of Records*

HCFA proposes a new system of records collecting data under the authority of 5 U.S.C. 301.

## II. Collection and Maintenance of Data in the System.

*A. Scope of the Data Collected*

The collected information on all HCFA employees and non-HCFA employees who require parking privileges at HCFA buildings, will contain name, social security number, parking permit number, telephone number, work location, position, title and grade, supervisor's name and telephone number and background information relating to medical or specific parking needs.

*B. Agency Policies, Procedures, and Restrictions on the Routine Use*

The Privacy Act permits disclosure of information without an individual's consent if the information is to be used for a purpose, which is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release PRKG information as provided for under ''Section III. Entities Who May Receive Disclosures Under Routine Use.''

We will only disclose the minimum personal data necessary to achieve the purpose of PRKG. HCFA has the following policies and procedures concerning disclosures of information, which will be maintained in the system. In general, disclosure of information from the system of records will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after HCFA:

(a) Determines that the use or disclosure is consistent with the reason data is being collected; e.g., implements the regulations and directives that established that Federal workers and other authorized personnel will be issued parking permits for the HCFA complex.

(b) Determines:

(1) That the purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

(2) That the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

(3) That there is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

(c) Requires the information recipient to:

(1) Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

(2) Remove or destroy at the earliest time all individually-identifiable information; and

(3) Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

(d) Determines that the data are valid and reliable.

## III. Proposed Routine Use Disclosures of Data in the System

*Entities Who May Receive Disclosures Under Routine Use*

The routine use disclosures in this system may occur only to the following