Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—(OMB Control Number 0523)—Extension

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of the following products: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products, and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These burden estimates are based on the number of applications FDA received over the past 2 fiscal years.

Dated: August 18, 2009.

David Horowitz,

Assistant Commissioner for Policy

[FR Doc. E9–20409 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Recruitment and Retention of Pregnant Women into an Asthma Pregnancy Registry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Mental Models Study of Recruitment and Retention of Pregnant Women into an Asthma Pregnancy Registry. Pregnancy registries are a common source of safety information about medications used during pregnancy. Together with other information being collected, FDA will use the results from this study to better understand how pregnant women and their health care providers make decisions about participation in pregnancy exposure registries. FDA will use this new knowledge to develop and recommend effective ways to support the involvement of health care providers and pregnant women in pregnancy registries. Ultimately, greater involvement of health care providers and pregnant women in pregnancy registries will improve the quality of safety information gathered through the registries. Better safety information will support informed treatment decisions by health care providers and women who need prescription medications while pregnant.

DATES: Submit written or electronic comments on the collection of information by October 26, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, *Elizabeth.Berbakos@fda.hhs.gov*, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60–day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Mental Models Study of Recruitment and Retention into an Asthma Pregnancy Registry

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The proposed information collection will help FDA advance public health by identifying priorities, perceptions and communication needs about how pregnant women and their health care providers make decisions about participation in a pregnancy registry. Understanding these priorities, perceptions and communication needs will foster more effective approaches to recruitment of pregnant women into pregnancy registries and full retention of those women until the end of the registry study period. Ultimately, early enrollment and complete follow up of women in pregnancy registries will strengthen the quality of safety data about use of needed medications during pregnancy.

Before a medication is approved by FDA for sale in the United States, pregnant women are rarely included in experimental research studies of the medication because of concerns that the experimental treatment may harm the developing fetus and/or the pregnant woman. As a result, when a medication is approved for marketing in the United States, little systematically collected human data are available to define the chance of serious side effects in pregnant women and/or their developing fetuses from use of the medication during pregnancy.

A pregnancy registry is a research study conducted after a medication has been approved, during which pregnant women being treated with the medication are observed to identify possible harms to the woman and/or to her developing fetus. Pregnant women voluntarily enroll in a pregnancy registry; data about the pregnancy, labor, delivery and newborn are collected and analyzed to identify any serious adverse outcomes and consider whether use of the medication may be linked to any observed harm. The quality of pregnancy registry data is enhanced by enrollment of women early in their pregnancy and by complete follow up of all enrolled pregnancies to the end of the registry study period.

Ultimately, high quality human pregnancy data gathered through a pregnancy registry and incorporated into medical product labeling will provide patients and their health care provider's useful information so they may make informed medical treatment decisions during pregnancy. Data collected from this mental models study will be incorporated into recommendations for improvement of the quality of pregnancy registries, ultimately improving medical treatment decisions, and potentially improving pregnancy outcomes.

FDA engages in various regulatory and communication activities to support, and at times, require collection of safety data through establishment of a pregnancy registry. Pregnancy exposure registries are a major source of human pregnancy data for product labeling; therefore, FDA is committed to fostering ongoing improvements in the design and conduct of pregnancy registries. In 2002 FDA issued Guidance for Industry entitled ''Establishing Pregnancy Exposure Registries'' (see *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071639.pdf*). This guidance provides an overview of pregnancy exposure registries, describing when and how to conduct a pregnancy registry about treatment of a disease in pregnancy or use of a specific medication or group of medications during pregnancy. The FDA Office of Women's Health maintains a list of current pregnancy registries on its Web site, see *http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134844.htm*. FDA regulations (21 CFR 201.57) describe the content of required product labeling for prescription drugs. On May 28, 2008, FDA proposed major revisions to required product labeling to provide better information about the effects of medicines used during pregnancy. Enactment of the Food, Drug and Cosmetics Amendments Act of 2007 gave FDA new legal authority to require post-approval studies to assess certain safety concerns, including, in certain situations, establishment of a pregnancy registry. Through this data collection and analysis, FDA will identify and address the perceptions and communication needs of pregnant women and health care providers to support their participation in pregnancy registries.

The project will use ''mental modeling,'' a qualitative research method that compares a model of the priorities, perceptions, communication needs, and decision-making processes of a group or groups to a model of the same priorities, perceptions, communication needs, and decision-making processes developed from expert knowledge and experience. In this study, the decision models of women who are current or potential participants in a pregnancy registry and of health care providers who have participated or might participate in a pregnancy registry will be derived through qualitative structured interviews. The project focuses on an asthma disease-based pregnancy registry; the three cohorts to be interviewed are described in detail in the following paragraphs.

Using information gathered from the interviews, the decision model about pregnancy registry involvement for pregnant women and health care providers will be developed and then compared to decision models about pregnancy registry involvement that were derived from experts in the fields of obstetrical and asthma treatment during pregnancy, design and conduct of pregnancy registries, FDA medication regulation, and biomedical ethics. FDA will use telephone interviews with the three cohorts to determine the priorities, perceptions, communication needs and other factors that influence decisions about participation in a pregnancy registry by pregnant women and health care providers. A comparison between an expert model and models based on the information collected directly from women and health care providers may identify consequential perception, priority and communication gaps that can be redressed through strategic efforts to foster involvement in pregnancy registries designed by FDA or others.

Using a protocol derived from the research that resulted in the ''expert model,'' trained interviewers will conduct one-on-one telephone discussions with a total of 60 individuals (20 individuals per cohort) from the three cohorts described here:

(1) Potential Pregnancy Registry Participants: women older than 18 years who are currently being treated for asthma and are pregnant or have been pregnant within the past 18 months, and who may or may not currently be participating in a pregnancy registry;

(2) Current Pregnancy Registry Participants: pregnant women older

than 18 years who are current participants in any pregnancy registry for a chronic condition; and

(3) Health Care Providers: to include a mix of health care providers (including specialists, obstetrician-gynecologists, and primary care providers) some who have participated in a pregnancy registry and some who have not participated in a pregnancy registry.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60	1	1	1.0	60.0
Total				60.0

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The study will involve about 60 respondents and take approximately 1 hour each to complete. These estimates are based on the Contractor's extensive experience with mental models research.

Dated: August 18, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20407 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Peripheral and Central Nervous System Drugs 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). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs 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 14, 2009, from 8 a.m. to 5 p.m.

Location: The Inn and Conference Center, University of Maryland University College (UMUC), Marriott Conference Centers, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7300.

Contact Person: Diem-Kieu Ngo, 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: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22–250, with the proposed trade name AMAYA (fampridine) 10 milligram (mg) tablets, manufactured by Acorda Therapeutics, Inc. The proposed indication for this new drug product is to improve walking ability in individuals with multiple sclerosis (MS). MS is a neurological disease that may cause a wide variety of possible symptoms, including in some patients difficulty in walking.

FDA intends to make background material available to the public no later than 2 business days 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/AdvisoryCommittees/Calendar/default.htm*. 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 September 29, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 September 21, 2009. 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 September 22, 2009.

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 Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: August 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20380 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Oncologic Drugs 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). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.