DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Postpartum Hemorrhage Among Women with an Undiagnosed Bleeding Disorder, Potential Extramural Projects (PEP) 2008–R–28

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 1 p.m.–2 p.m., May 16, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''Postpartum Hemorrhage Among Women with an Undiagnosed Bleeding Disorder, PEP 2008–R–28.''

Contact Person for More Information: Linda Shelton, Program Specialist, Coordinating Center for Health and Information Service, Office of the Director, CDC, 1600 Clifton Road, NE., Mailstop E21, Atlanta, GA 30333, Telephone (404) 498–1194.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 10, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–8407 Filed 4–17–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Evaluation of Breastfeeding Promotion and Support Programs for African-American Women, Potential Extramural Project (PEP) 2008–R–25

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 1 p.m.–2:30 p.m., May 22, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''Evaluation of Breastfeeding Promotion and Support Programs for African-American Women, PEP 2008–R–25.''

Contact Person for More Information: Linda Shelton, Program Specialist, Coordinating Center for Health and Information Service, Office of the Director, CDC, 1600 Clifton Road, NE., Mailstop E21, Atlanta, GA 30333, Telephone (404) 498–1194.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 10, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–8438 Filed 4–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10260]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Advantage (MA) Disclosure Requirements; *Use:* The information collection requirements are mandated by 42 CFR 422.111 and 422.80. MA organizations will be required to notify plan members of the coming year's changes using a combined standardized document. MA organizations and potential MA organizations (applicants) will use the information to comply with the eligibility requirements and the MA contract requirements. CMS will use this information to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees. *Form Number:* CMS–10260 (OMB# 0938–New); *Frequency:* Yearly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 670; *Total Annual Responses:* 670; *Total Annual Hours:* 8040.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 17, 2008:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 9, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–8229 Filed 4–17–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0321] (formerly Docket No. 2007N–0485)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 19, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0111 and Application for Food and Drug Administration Approval to Market a New Drug. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for Food and Drug Administration Approval to Market a New Drug—(OMB Control Number 0910–0001—Extension)

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination whether the product is safe and effective for use.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314), who apply for approval of a new drug application (NDA) or abbreviated new drug application (ANDA) in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application. (The burden hours for § 314.50(h) are already approved by OMB under OMB control number 0910–0513 and are not included in the burden estimates in table 1 of this document.)

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug, drug product, or method of use.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend its application at the time notice is provided to include a statement certifying that the required notice has been provided. A 505(b)(2) applicant also is required to amend its application to document receipt of the required notice.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act. (The information collection burden estimate for 505(b)(2) applications is included in table 1 of this document under the estimates for § 314.50 (a), (b), (c), (d), (e), (f), and (k)).

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (The burden hours for §§ 314.80(c)(1) and (c)(2) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (The burden hours for § 314.80(i) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)