

other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by November 10, 2015.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

**CMS-855S Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers**

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. The term “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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Revision of a currently approved collection;

*Title of Information Collection:* Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers; *Use:* The primary function of the CMS 855S Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier enrollment application is to gather information from a supplier that tells us who it is, whether it meets certain qualifications to be a health care supplier, where it renders its services or supplies, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payment.

The goal of this revision of the CMS 855S is to simplify and clarify the current data collection and to remove obsolete and/or redundant questions. Grammar and spelling errors were corrected. Limited informational text has been added within the application form and instructions in conjunction with links to Web sites when greater detail is needed by the supplier. To clarify current data collection differentiations and to be in sync with accreditation coding, Section 3D (“Products and Services Furnished by This Supplier”) has been updated. This revision does not offer any new material data collection. *Form Number:* CMS-855S (OMB Control Number: 0938-1056); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 31,915; *Total Annual Responses:* 31,915; *Total Annual Hours:* 36,842. (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374.)

Dated: September 8, 2015.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015-22944 Filed 9-10-15; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-3156]

**Drug Interactions With Hormonal Contraceptives: Public Health and Drug Development Implications; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled “Drug Interactions with Hormonal Contraceptives: Public Health and Drug Development Implications” and an opportunity for public comment on the topic of drug interactions with hormonal contraceptives (HCs). The goal of this public meeting is to provide an opportunity for FDA to seek input from experts on the public health concerns associated with use of HCs and interacting drugs that might affect efficacy and safety, pharmacokinetic (PK)/pharmacodynamic (PD) considerations in designing drug interaction studies with HCs during drug development, and approaches to translating the results of drug interaction information into informative labeling and communication. The input received may be used to refine FDA’s thinking on HC drug interaction study design and interpretation, and labeling communication on drug interaction risk.

**DATES:** The public meeting will be held on November 9, 2015, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the meeting in person or via Web cast must register by October 9, 2015. Please submit either electronic or written comments by December 15, 2015, to receive consideration. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting and submit electronic or written comments.

**ADDRESSES:** The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public

meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments 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.

FDA will post the agenda approximately 5 days before the meeting at: <http://www.fda.gov/Drugs/NewsEvents/ucm459342.htm>.

**FOR FURTHER INFORMATION CONTACT:** Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3196, Silver Spring, MD 20993, 301-796-2398, email: [Christine.Le@fda.hhs.gov](mailto:Christine.Le@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In general, HCs are highly effective in preventing pregnancy when used correctly. However, concomitant use of other drugs may affect the safety and/or efficacy of HCs due to drug interactions affecting either blood levels (PK) and/or physiologic effects (PD) of HC components (e.g., estrogen and progestins). Understanding drug interaction potential of HCs and other drugs is important when investigating HC-related issues, and in the design and conduct of clinical trials. Evolving knowledge on drug interaction mechanisms has led to new insights and increased interest in the clinical investigation of drug interactions with HCs.

Historically, most drug interaction studies conducted during drug development with HCs have not had a clearly stated rationale for the choice of HCs being studied. Questions remain as to whether the study results of specific contraceptive steroids can be extrapolated to other progestins or estrogens or other dose strengths. The choice of HC is important because different progestins may have different metabolic and/or transporter pathways and safety profiles. Without a mechanistic understanding of the underlying drug-drug interaction (DDI) mechanism, it is difficult to interpret and extrapolate study results from one HC to another.

**II. Discussion Topics for the Meeting and for Public Comments**

The public meeting on November 9, 2015, will include a discussion of the following topics on which FDA is also seeking public comment:

- Public health concerns associated with use of HCs and interacting drugs that might affect efficacy and safety.
- PK and PD considerations in designing drug interaction studies with HCs during drug development. Key elements in designing a study include a mechanistic understanding of potential DDI mechanisms, the choice of contraceptive products and their dose, study population/duration, and proper selection of a PK alone or PK-PD-based drug interaction study approach.
- Drug interaction study result interpretation and its potential impact on guidance of HC use in women of childbearing potential who are enrolled in clinical trials for other therapeutic agents during drug development.
- The current approach of translating the results from drug interaction studies into labeling recommendations and opportunities to improve the communication to healthcare providers.
- Research opportunities and tools for investigating the safe use of HCs in the presence of other drugs.

The input received may be used to refine FDA's thinking on the drug interaction study design with HCs and labeling communication of drug interaction risks with HCs.

**III. Meeting Attendance and Participation**

If you wish to attend these meetings, register online at <https://www.surveymonkey.com/r/HC-DDIMeeting>. Please register by October 9, 2015. Those who are unable to attend the meetings in person can register to view a live Web cast of the meetings. You will be asked to indicate in your registration whether you plan to attend in person or via the Web cast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meetings will be based on space availability. If you need special accommodations because of disability, please contact Christine Le (see **FOR**

**FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

FDA will hold an open public comment period during the November 9, 2015, public meeting to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting on a first-come, first-served basis.

**IV. Comments**

Regardless of whether you attend this meeting, you can submit electronic or written comments, including responses to the public docket (see **ADDRESS** above), by December 15, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

**V. Transcripts**

Transcripts for the November 9, 2015, meeting will be posted, when available, at <http://www.fda.gov/Drugs/NewsEvents/ucm459342.htm>.

Dated: September 4, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (the Advisory Council) is scheduled for September 29, 2015, from 9:00 a.m. to 5:00 p.m. ET. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should email [CARB@hhs.gov](mailto:CARB@hhs.gov). Registration information is available on the Web site <http://www.hhs.gov/ash/>