4164-01-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.

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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